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ISBN 978-1-83862-071-4

Printed in Great Britain by Encompass Print Solutions, Derbyshire Tel: 0844 2480 112

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ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

ANAND AND ANAND
ANDERSON MÔRI & TOMOTSUNE
BOULT WADE TENNANT LLP
BRISTOWS LLP
CLIFFORD CHANCE
DEEP & FAR ATTORNEYS-AT-LAW
DERIŞ
GATTAI, MINOLI, AGOSTINELLI & PARTNERS
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SMART & BIGGAR
TAYLOR WESSING NV
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Although patent litigators should always be mindful that patent litigation has, with some justification, been called the ‘pathology of the patent system’, not so much as a criticism, but more in recognition of how remarkably little patent litigation there is, in fact, when seen in relation to the ever increasing number of patents in force at any one time, patent litigation is also the anvil on which patent law is forged. This is because the ‘black letter’ law of patents tends to be terse by comparison to most other areas of law, and it is only with experience of how courts and tribunals interpret such law and apply it that one can start to appreciate its true scope and effect. This, in part, explains how such similarly expressed statutory provisions as one finds in different patent laws can sometimes result in such different outcomes in different jurisdictions – disparities that are all the more evident when they concern the same product or process, and patents that, though in different jurisdictions, are all members of the same family, and are all intended to protect the same invention. As it becomes increasingly common for patent disputes to proceed in multiple jurisdictions these differences in outcome become ever more apparent.

Such disparities are not only a consequence of differing substantive laws, or differences in interpretation of similarly expressed laws. They can also be a consequence of the considerable procedural differences between jurisdictions, the nature of which is outlined in this Review. However, the Review does not only summarise patent litigation procedures. The respective contributors to it, as leading practitioners in each of their jurisdictions, also focus on recent developments in substantive patent law as demonstrated by the most important recent court decisions in their respective jurisdictions, meaning that this Review also provides insight into the current controversies that affect patent law generally.

On a global basis courts in multiple jurisdictions continue to be involved in controversies over standard-essential patents, one emerging aspect of which is the potential challenge that these present to the territorial nature of patents, as exemplified by the appeal, to be heard by the UK Supreme Court this autumn, against the imposition by the English courts of a global licence, on terms that they assess, as the price for exploiting standard-essential patents in the UK. Meanwhile, three appeals concerning standard-essential patents are pending before the German Federal Supreme Court, providing it with its first opportunity for a decade (since its Orange Book Standard decision) to revisit this area of the law. In the United States the most prominent controversy remains the question of excluded subject matter, which for want of clear judicial guidance has now attracted the interest of the legislature. In Europe, one apparent trend is towards greater flexibility as to injunctive relief, particularly in medicine – by for example, in the UK, tailored injunctions, or, in Germany, expedients such as compulsory licences, although in Germany there is also talk of legislation to address the issue. Again in Europe, the past year has seen no progress towards the entry into force of the
long-heralded Unified Patent Court Agreement. Although the pending challenge before the Federal German Constitutional Court to the consistency of the Agreement with the German Constitution is the only formal impediment to its entry into force, the imminent withdrawal of the UK from the EU as from 31 October 2019 presents a further problem, because the Agreement as drafted does not envisage participation by non-EU Member States. This raises the prospect, even if the German challenge is rejected, of having to amend the Agreement before it can enter into force to take account of such withdrawal; either to exclude the UK from its scope or, as the UK government has urged, expressly to provide for its inclusion, a course that, however, it is not at all clear would be compatible with the case law of the European Court of Justice, irrespective of any treaty language.

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This chapter discusses the European Patent Office’s streamlined opposition procedure and the general trend of the Boards of Appeal towards restricting the appeal process to being a review of the decision at issue rather than an opportunity to present a fresh case, which has now been codified in the updated Rules of Procedure of the Boards of Appeal.

The European Patent Office provides an opportunity to file a central opposition against the grant of a European patent within an opposition period of nine months. Opposition proceedings are predominantly written proceedings, but typically will conclude with oral proceedings before an Opposition Division of three members in either Munich, The Hague or, occasionally, Berlin. Decisions of the Opposition Divisions may be appealed to the Boards of Appeal. The Boards of Appeal of the European Patent Office is an autonomous body, consisting of 28 boards that each deal with different subject-matter areas. The Boards of Appeal can exercise any power within the competence of the Opposition Division, or remit the case to the Opposition Division for further prosecution.

The opposition procedure at the European Patent Office is extensively used. According to statistics published by the European Patent Office, in 2017, 4 per cent of granted patents were opposed, with 31 per cent of decisions revoking the opposed patent in its entirety and 42 per cent leading to an amendment. With such a large number of oppositions being filed, there has been a growing backlog of pending cases. Typically, an average length of time for a straightforward case is in the region of 26 months. Although it is likely to be a more expensive procedure, the advent of the Unified Patent Court, discussed elsewhere in this Law Review, could potentially offer a faster route to revocation of a European patent.

However, in July 2016, the European Patent Office streamlined the procedure for oppositions, along with a commitment to reduce the duration of the procedure from the expiry of the opposition period until the issuance of a decision by the Opposition Division. The new procedure is intended to reduce the duration of a straightforward case to a maximum of 15 months. The streamlining of the opposition procedure may, therefore, help to avoid the proposed Unified Patent Court negatively impacting the number of oppositions filed, and will reduce the likelihood of revocation proceedings being run in parallel at both the European Patent Office and the Unified Patent Court.

Recently, there have been changes not only to the opposition procedure, but also to the appeals process. In an effort to enhance the independence of the Boards of Appeal, in June 2016, the Implementing Regulations of the European Patent Convention were amended to allow the Boards of Appeal to be organised as a separate unit within the European Patent Office.
Office with its own president who is answerable only to the Administrative Council, the body that oversees the work of the European Patent Office. This has been accompanied by the relocation of the Boards of Appeal to Haar in October 2017. The first president of the Boards of Appeal, Carl Josefsson, assumed the role in March 2017. It is possible that the change in structure of the Boards of Appeal could lead to significant changes to the way the Boards operate. In the first annual report of the Boards of Appeal following this organisational change, the new President has indicated his intention to increase the productivity of the Boards such that within five years 90 per cent of cases will be settled within 30 months. In 2017, the average length of appeal proceedings was 38 months and so this target will be quite a challenge. As with prosecution and opposition cases before the Examining and Opposition Divisions of the European Patent Office, the Boards of Appeal have a significant and growing backlog of cases, with the number of appeals pending for more than two years increasing from 3,979 in 2016 to 4,178 in 2017. The two mechanisms intended to implement the increase in productivity are, first, an increase in resources and, second, ‘efficiency measures’. The increase in resources is reported to only be for a limited period of time. An intention to increase manpower has been planned, with the 2019 budget including an additional 23 technical board members and a further 16 technical board members in the 2020 budget. One of the efficiency measures is the revision of the Rules of Procedure of the Boards of Appeal, discussed below.

The Rules of Procedure of the Boards of Appeal define the appeal process. For an opposition case, this typically involves two rounds of written correspondence followed by oral proceedings in Munich. In the first written round, each appealing party files its grounds of appeal: a statement indicating the reasons for setting aside the appealed decision along with any facts and evidence to be relied upon. A patentee may accompany its grounds of appeal with one or more requests, each request including an alternative set of claims for consideration in the proceedings. In the second written round, each party files a reply to the other side’s grounds of appeal. The grounds of appeal, together with the reply, are intended to form each party’s complete case on appeal. However, it is often the case that further submissions will be made. This may be the case where one party’s reply raises a new issue, or when further evidence or prior art becomes available at a later stage. Any such further submissions may be considered an amendment to the party’s case.

The provisions of the Rules of Procedure of the Boards of Appeal that mainly influence practice are those that determine admissibility. First, the Boards can hold inadmissible facts, evidence or requests that could have been presented or were not admitted in the opposition proceedings. Second, any amendment to a party’s case after it has filed its grounds of appeal or reply may be admitted, or not, at the Board’s discretion.

These two powers give the Boards great flexibility in deciding how to deal with each case. The case law has developed numerous threads that explore the various issues that may be considered by the Board when exercising its discretion. These include:

- the *prima facie* relevance of the new evidence or request;
- whether the admission will raise issues not previously considered;
- the age of the patent;
- the reasons why the new evidence or request was not filed earlier; and
- in the case of new prior art, whether it is more relevant than earlier filed art.

Because the Board’s powers are entirely discretionary and the issues relating to discretion are numerous, the Boards of Appeal have been quite varied in how discretion is exercised.
However, there has been a notable and significant recent trend across most Boards towards an application of the discretionary powers in a more restrictive manner so as to limit the ability to which the parties may develop their case on appeal.

For instance, it has become increasingly likely that parties will be punished for treating the appeal process as a continuation of the opposition proceedings, rather than a review of the decision of the Opposition Division. While it is correct that the purpose of an appeal was always intended to be a review of the reasons for the decision, for many years the practice followed by the parties and by the Boards was more flexible. As a result of the increasingly strict application of discretion in respect of admissibility, the outcome of an increasing number of cases is being decided on procedural grounds rather than for substantive reasons.

One recent case, T1903/13, is illustrative of how far the Boards might take that principal. The respondent (patentee) filed a number of auxiliary requests on appeal that the Boards accepted were essentially already filed during opposition proceedings. However, the requests were not considered by the Opposition Division because a higher-ranking request was allowed. These requests were not convergent with the claims allowed by the Opposition Division, meaning that they were not sequentially narrowed versions of the allowed claims. The Boards, therefore, refused to take the requests into account, because to consider those requests would be to consider inventive concepts that were not the subject of the appeal.

In the past, parties have often used the written opinion of the Boards, where issued, to guide the filing of further requests or to replace requests. However, it is now very clear that parties should not allow a point to be unanswered with the intention of awaiting any written opinion before dealing with the issue. In T1459/11, the Boards stressed that the written opinion is intended to prepare the case for oral proceedings rather than to be an invitation for the parties to make further submissions.

In decision T875/14, the respondent (patentee) filed a request in reply to the Boards’ views on novelty and inventive step expressed in the written opinion. The Boards noted that the objections were not raised ex officio, but had already been presented in the appellant’s (opponent’s) grounds for appeal. Thus, the Boards did not accept that the request filed by the respondent (patentee) was in response to an unexpected development, and so the request was not admitted.

In the event that a new request is responsive to an unexpected development, it is necessary for the request to deal with all outstanding issues (Case Law of the Boards of Appeal, 8th Edition, IV, E, 4.4.1). In T416/12, the Boards indicated that it should be possible to establish this with little or no investigative effort on its part.

The restriction of the scope of appeals is not only applicable to patentees. The Boards apply similar approaches to the admission of documents filed late by opponents as for requests filed late by patentees. For example, in T2384/13, the appellant (opponent) was prevented from filing a new prior art document on appeal when it was apparent during opposition proceedings that the objections were not considered convincing such that the appellant should have filed the document earlier. In T340/12, the Boards considered that if a prior art document is clearly very relevant, then this should take precedence over the procedural aspects of its late filing. However, this is not always the case. In T2471/13, the Boards refused to admit a prior art document, irrespective of its relevance, owing to the decision of the appellant (opponent) to withhold it during opposition proceedings.

It is also becoming more difficult to raise new attacks, even when the documents used are already in proceedings. In T875/14, the appellant (opponent) attempted to raise a new objection during the oral proceedings that, for the first time, considered inventive
step when starting from a prior art document different from that used as the closest prior art in earlier filed attacks. Although that document was already present in the proceedings, and was considered to deprive the granted claims of novelty, the argument itself constituted an amendment of the appellant’s case. The argument was not admitted because the request it was raised against was formed of a subset of the granted claims. Despite there being a large number of independent claims in the granted patent, the Boards concluded that the argument should have been raised earlier. On the other hand, in T1830/11, new evidence was admitted when filed with the appellant’s (opponent’s) grounds of appeal for use against a request formed by incorporating the subject matter of a dependent claim into claim 1. The Boards, in that instance, considered that there was no requirement for an opponent to provide evidence against every possible fallback position in the granted claims. In case T55/11, a new inventive step objection was raised that combined two documents used in an existing argument. However, the roles of the two documents were switched in the new argument such that the closest prior art document in the new objection was the combination document in the earlier objection. Because the Boards had indicated in their written opinion that the combination of the two documents was to be considered, the patentee could have foreseen the new objection and so the argument was admitted.

Not only should the opponent’s intended arguments in respect of the prior art be elaborated at the earliest opportunity, but also the patentee’s reasons for filing each of the requests. While it may in some cases be immediately evident that the auxiliary requests overcome all outstanding objections, where this is not the case the Boards have argued that requests should only be considered filed on the dates on which they are substantiated. In T1784/14, a number of the respondent’s (patentee’s) auxiliary requests were considered inadmissible despite being filed before the Opposition Division and mentioned in the respondent’s (patentee’s) reply to the grounds for appeal. Since it was not apparent how those requests dealt with the objections against the earlier requests, they were not considered validly filed.

On 1 January 2020, a revised version of the Rules of Procedure of the Boards of Appeal will come into force, with the aim of improving the efficiency of the Boards so as to reduce the time taken to process each case. Although many of the changes to the rules appear to be minor differences in emphasis, when considered in the context of the recent trend towards restricting the parties’ scope for changing their case on appeal, it appears likely that the trend will only continue.

For example, under the existing rules, the Boards are able to find inadmissible facts, evidence or requests that could have been presented, or were not admitted, at first instance. Under the revised rules, however, the default is reversed. The Board’s power is to admit requests, facts, objections, arguments and evidence that were not pursued in first instance proceedings. In fact, those aspects of the case must have been both admissibly raised and maintained at first instance. Moreover, under the new rules, the parties are expected to identify any changes to their case on appeal and provide reasons why they were not submitted at first instance. In the case of the patentee, any amendments of the specification should be accompanied by an indication of the basis for the amendments along with an explanation of how they deal with the objections in the decision.

It should also be noted that arguments and objections have been added to the existing list of facts, evidence or requests that define a party’s case. Accordingly, it will be necessary to argue in support of the admissibility of new lines of attack or defence presented on appeal. This hurdle of admissibility is now at the level previously set only for amendments of a party’s case after filing the grounds of appeal and reply.
The Rules of Procedure of the Boards of Appeal have also been changed in relation to amendments made after the filing of grounds of appeal or the reply to the grounds of appeal of the other party. Under the existing rules, any amendments to a party’s case on appeal may be admitted at the Board’s discretion in accordance with the criteria defined in the case law discussed above. In the updated rules, these developments in the case law have been codified to provide a non-exhaustive list including the state of proceedings, the suitability of the changes to resolve the issues of the appeal, procedural economy and, for an amendment of a patent, whether it overcomes the objections raised without raising others.

More notably, the rules have changed in respect of amendments to a party’s case made after a summons to oral proceedings or the Board’s written opinion. Previously, such amendments were inadmissible if the Board or other party could not be expected to deal with them before the oral proceedings. Under the updated rules, the bar is higher; such amendments will only be taken into account if the party can convince the Board that there are exceptional circumstances that justify an amendment of their case at this stage.

In view of the updated rules, from 1 January 2020, the tasks of preparing a statement of grounds of appeal and the reply to another party’s grounds of appeal will, in most cases, involve a greater emphasis on the procedural aspects of the case that justify or challenge any change in strategy by the other party. Although the rules have changed in tone, clearly with the intention of restricting the parties’ ability to amend, the same element of discretion remains, and so it remains to be seen whether the changes will eliminate the wide range of practices among the Boards.

In view of the need to justify on appeal any aspect of the case that has changed since first instance, it is necessary for both parties to take this into consideration when deciding their strategy during opposition.

From the patentee’s perspective, the result of the increasingly restrictive approach of the Boards is that the only way for a patentee to be sure that a request may be relied upon on appeal is to ensure that it is filed, and admitted, by the Opposition Division. One way to achieve this may be to request that lower-ranking claim requests be admitted into the proceedings even if a higher-ranking request has been allowed. This must be done before the opposition proceedings are officially closed.

Moreover, on appeal, it is now clearly insufficient to merely file arguments in respect of a main request and accompany that with other auxiliary requests without a full discussion of how those additional requests overcome any objections. This can be the case even if they were already filed before the Opposition Division.

In order that a set of requests can be defined during opposition that will subsequently be of use when filing an appeal, it may be advantageous to file multiple auxiliary requests along with the patentee’s reply to the notice of opposition. In this way, those requests can be considered by the Opposition Division when preparing a summons, and the patentee will have the opportunity to file a refined set of requests in advance of the oral proceedings before the Opposition Division if necessary. That latter set of requests can form the basis of the appeal, perhaps supplemented where appropriate.

For an opponent, it should be remembered that a new line of argument, even if based on the prior art documents relied upon at first instance, may be found inadmissible on appeal. It is often the case that such new lines of argument may occur to an opponent in preparation for oral proceedings. The minutes of oral proceedings before the Opposition Division can potentially therefore become the only record of lines of argument raised at that stage. The minutes produced by the Opposition Divisions rarely capture all of the important details
raised. It is therefore expected that parties will increasingly request during oral proceedings that new lines of attack are recorded as such. In addition, it is advisable that the minutes be scrutinised more closely and that important errors or omissions be challenged before the appeal is filed.

There have been a number of further changes in the updated Rules of Procedure of the Boards of Appeal, and one in particular is notable. It was previously the case that remittal to the department of first instance would be likely where the parties agreed and where there were unexplored grounds such as novelty and inventive step, or unexplored attacks such as a different combination of prior art documents. The updated rules indicate that the default position of the Boards from 1 January 2020, will be to not remit the case unless there are ‘special reasons’ for doing so. It will be some time before it becomes clear what will constitute a special reason. One concern is that, contrary to the present practice, Boards may decide that the updated rules mean that they should, if possible, consider all grounds on appeal, even if those grounds were not decided upon at first instance. In some cases, this would deny the parties the opportunity to have issued heard at both instances. Although there is no requirement to have each issue ruled on at two instances, it is nevertheless currently the norm. The denial of remittal by the Boards of Appeal could be a useful tool for reducing the backlog by preventing cases from being shuttled backwards and forwards between the departments of first instance and the Boards of Appeal. However, if it is indeed the intention of the Boards of Appeal to hear grounds not considered at first instance, then this would be contrary to the declared aim of the updated rules to ensure that the appeal process is merely a review of the first instance decision.

Some commentators have suggested that this change might prompt the Opposition Divisions to hear all grounds on each request at first instance. However, at the time of writing, there is no indication that the European Patent Office has any plans to modify the opposition procedure in this way.

In conclusion, the recent practice of the European Patent Office in respect of opposition and appeal practice has been to more strictly apply the rules so as to differentiate the opposition and appeal procedures, and this restriction of the procedure is expected to continue when the updated Rules of Procedure of the Boards of Appeal come into force.
Chapter 2

UNIFIED PATENT COURT

Alan Johnson

I HISTORICAL BACKGROUND

The Unified Patent Court (UPC) is the result of an extremely lengthy effort to streamline the patent system in Europe, a continent comprising four of the top 10 global economies by GDP, but also around 50 separate countries. These efforts date back to the 1950s and the first tangible result was the European Patent Convention 1973 (EPC). The EPC created the European Patent Organisation, with the function, exercised through the European Patent Office (EPO), of examining and issuing patents on a multinational basis. Seven countries acceded to the EPC in 1977, and there are presently 38 member countries. Hence, the EPC provides a very efficient route towards true pan-European patent protection. However, upon grant, its patents are akin to national patents in as far as they are enforced on a national basis. The EPC may, therefore, be seen as having taken one major step toward the objective of a harmonised European patent system, but as lacking the second element of a harmonised enforcement system.

A major initiative started in 1999, with a proposal to create an optional protocol to the EPC. Under this proposal, individual EPC members could (optionally) cede their patent jurisdictions to a common court. Although this concept was abandoned a few years later, it was a catalyst towards the creation of what we now know as the UPC because it spurred the European Community (as it then was) to propose a Community patent and a court in which the patent would be litigated. Naturally, since the EPC proposal was unconnected with the European Community, it did not exclude non-Community states, nor did it propose a common patent. The Community proposal was a little more complicated. It proposed a new international agreement (i.e., a treaty) to create the court, which was envisaged to be signed by the Community (latterly the EU) such that all Member States would participate, but it would also be open to all EPC states. The Community (latterly EU) patent, on the other hand, would be created by a Community (latterly EU) instrument – a regulation – in the same way as the Community trademarks (now known as European Union trademarks).

In 2009, a draft of the court agreement was submitted to the Court of Justice of the European Union (CJEU) for an opinion on its compatibility with EU law. The resulting opinion, rendered in 2011, was widely interpreted as holding that only an agreement among European Union states (as by that time they were known) would be lawful. As a result, non-EU states were excluded from further participation, and a new agreement – a treaty known as the UPC agreement (UPCA) – was prepared, creating a unified patent court.

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that would come into existence when 13 countries had ratified the agreement, mandatorily including Germany, France and the United Kingdom. The UPCA was signed in February 2013 by all EU countries except for Spain and Poland. The EU itself was not a signatory.

In parallel, there was a deadlock among EU states on the issue of the language regime for the EU patent to be created by the Regulation. This was resolved by the use of the EU’s ‘enhanced cooperation’ procedure, supported by all EU states except for Spain and Italy. As this patent would not cover the entirety of the EU, it was dubbed a ‘unitary patent’ rather than an EU patent. Moreover, because it would be litigated in the new unified court, its territorial extent was to depend on the extent to which participating states had ratified the treaty creating the UPC.

In consequence, the regime in place is in many ways a curious beast. It comprises:

- the UPC, which is open to all EU countries, but participation in which:
  - cannot currently extend to Spain or Poland (by virtue of their refusing to sign the UPCA) nor to Croatia (which was outside the EU when the UPCA was signed, and which has failed to sign since its accession to the EU in July 2013); and
  - depends on ratification of the UPCA by individual countries pursuant to their individual national constitutions; and
- a unitary patent covering those EU countries that have joined in the enhanced cooperation process and also ratified the UPCA.

II PATENTS WITHIN THE JURISDICTION OF THE UPC

As explained above, the UPC brings together two separate functions. The first is a jurisdiction to litigate new unitary patents. The second is a jurisdiction to litigate existing and future European patents. These latter patents have been termed ‘classical’ European patents to distinguish them from unitary patents. Both of these types of patent are granted by the EPO by a process that is almost entirely unchanged. All pre-grant and most post-grant EPO processes remain as before. The unchanged post-grant processes include the centralised opposition function, and the centralised limitation (amendment) function. The new element in the post-grant process is the possibility within one month of the grant to elect for unitary protection in respect of those states then in the system by the use of new online procedures and forms. This has the following consequences:

- applicants can elect for unitary protection in respect of any patent applications granted after commencement of the new system, irrespective of when the application was made, provided that all states participating in the system were members of the EPC at the date of application. In practice, this means that all applications made after the date Malta joined the EPC (1 March 2007) may benefit from unitary protection;
- the geographic scope of protection is inflexible (as are the renewal fees payable), with no element of choice by the patentee;
- in addition to unitary protection, applicants may choose to validate their newly granted patents in all other EPC Member States in the conventional way, but may not validate in any state for which unitary effect is claimed; and
- alternatively to unitary protection (with or without additional validations), applicants may validate their newly granted European patent in any one or more EPC states (as at present).
III UPC TRANSITIONAL ARRANGEMENTS

One of the UK’s conditions for agreement to the new regime was that there should be transitional arrangements so that patentees could opt their patents out of the UPC system for a period. These arrangements are to be found in Article 83 of the UPCA. The transitional period is seven years, extensible to up to 14 years. The arrangements have the following key features:

a. all existing patents and applications (and their supplementary protection certificates (SPCs)) may be opted out of the UPC for the life span of those rights;

b. all ‘classical’ European patents that are granted during a transitional period, and all applications published during this transitional period (in both cases together with their SPCs, existing or future) may also be opted out of the UPC for the life span of those rights;

c. any opt out may be withdrawn at any time, provided that no national litigation has been conducted under the patent; and

d. during the transitional period, in addition to the above arrangements, national litigation is also possible even if the patent (or SPC) has not been opted out.

As will immediately be appreciated, due to the longevity of patent rights, with additional periods of SPC and paediatric extension protection, the transitional arrangements have the potential to be relevant until at least around 2050; and if the transitional period is extended, until the late 2050s.

IV FORUM SHOPPING BETWEEN NATIONAL COURTS AND THE UPC

The legal basis for the conclusion that during the transitional period, even patents that are not opted out may still be litigated in national courts, is Article 83(1) UPCA. It reads:

During a transitional period of seven years after the date of entry into force of this Agreement, an action for infringement or for revocation of a European patent or an action for infringement or for declaration of invalidity of a supplementary protection certificate issued for a product protected by a European patent may still be brought before national courts or other competent national authorities.

Although reference is made only to actions for infringement or revocation, it is widely understood that this is shorthand for any action that comes under the UPC jurisdiction. That this provision is a particular source of potential problems is most conveniently illustrated by this example.

Suppose a patentee wishing to take the benefit of the UPC’s broad geographic jurisdiction decides not to opt its patent out of the system. It finds an infringer and writes a warning letter threatening UPC litigation. The alleged infringer responds by seeking a declaration of non-infringement in one participating state (e.g., in respect of the EP(UK) in the United Kingdom). Where does this leave the patentee? Can it nonetheless bring its intended UPC action in respect of the alleged infringing activities? And if not, what can it do?
To answer these questions, one must consider Articles 34 and 76(1) of the UPCA and various provisions of the updated recast Brussels Regulation (1215/2012). Article 34 UPCA reads as follows:

Decisions of the Court shall cover, in the case of a European patent, the territory of those Contracting Member States for which the European patent has effect.

This suggests that UPC decisions must apply to all parts of European patents then in force in countries participating in the UPCA.

Next one must consider Article 71c(2) of the Brussels Regulation. This requires that the rules on *lis pendens* and related actions in Brussels Regulation should be applied during the UPC transitional period to cases involving UPC actions and national actions. Those rules are in Articles 29 and 30, which provide that the court first seised of an action shall have priority to deal with it over a second seised court. Article 29 applies in cases of the same cause of action between the same parties, and requires a mandatory stay of the second case, while Article 30 applies in cases of related actions and a stay is discretionary.

Putting together these various provisions, and bearing in mind that under CJEU case law a declaration of non-infringement action is regarded as being equivalent to an infringement action, one can see that there is a strong argument that if a party that is threatened by UPC proceedings launches a national declaratory action, the patentee cannot then pursue its threatened UPC infringement action, because in part the subject matter is the same. If so, this amounts to what has been termed a ‘UPC torpedo’.

However, can the patentee dodge the torpedo by limiting the relief it requests from the UPC so as to exclude the jurisdiction (in this example the UK) where the national action has been commenced? Arguably, support for this comes from Article 76(1) UPCA, which reads:

The Court shall decide in accordance with the requests submitted by the parties and shall not award more than is requested.

However, can a patentee really avoid the torpedo in this way? Is the concept of limiting relief by territory in a unified patent court compatible with the aims of the system? Again, it is necessary to consider the meaning of Article 34 UPCA. Does it mean that UPC decisions must cover all parts of the European patents in force, or does it merely mean that ordinarily UPC decisions will cover all European Patents (EPs), but this does not exclude the possibility of restricting the relief voluntarily to individual parts of the EP?

This question requires some analysis, not only of the language but of policy considerations. As to language, it is worth comparing the French and German equivalent language.

Les décisions de la Juridiction couvrent, dans le cas d’un brevet européen, le territoire des États membres contractants pour lesquels le brevet produit ses effets.

and

Die Entscheidungen des Gerichts gelten im Falle eines europäischen Patents für das Hoheitsgebiet derjenigen Vertragsmitgliedstaaten, für die das europäische Patent Wirkung hat.
Neither ‘couvernt’ nor ‘gelten’ have the same imperative as is arguably present in the English ‘shall cover’.

Further, as a matter of policy it may seem obviously preferable that a tactic manifestly aimed at avoiding the jurisdiction of the UPC should be capable of being met with a response that neutralises that tactic. However, the consequences of such an approach are not necessarily desirable. For example, by the same logic, a patentee could start proceedings as follows:

- **English Patents Court proceedings, including an application for an interim injunction taking the benefit of the low threshold to show only an arguable case;**
- **Dutch summary proceedings for an interim injunction even if the patentee had delayed starting the case, because in the Netherlands, in patent infringement cases, delay seems not to be so crucial (such proceedings can be with or without Dutch main proceedings);**
- **German district court proceedings benefiting from the German bifurcated procedure to avoid any immediate consideration of validity; and, crucially, together with any or all of the above; or**
- **UPC proceedings for all other states, taking the benefit of the centralised procedure.**

‘Gaming the system’ in this way was, in effect, outlawed by the group of judges and practitioners who devised the UPC rules of procedure when they mandated (Rule 5.1(b)) that if a European patent was to be opted out, this should be effective for all designations. This would make it odd for the same gaming to be achievable by not opting out, even if it were only for a more limited period of time. Nonetheless, the issue is less than clear and will no doubt form a major part of early UPC case law as the matter is litigated.

**V STRUCTURE OF THE UPC**

The UPC is a two-instance court (plus a Registry), and while straightforward at the appellate level, its first-instance organisation is complex, comprising local, regional and central divisions having competence to hear UPC actions in differing situations. It should be stressed, however, that while different first-instance divisions have differing and limited competence to hear actions, all first-instance divisions have jurisdiction over the whole of the ‘UPC zone’ and can order injunctions, damages and revoke patents across the whole territory.

**VI ORGANISATION OF THE UPC AT FIRST INSTANCE**

The competence of the central division is primarily as a court for hearing revocation actions and actions for declarations of non-infringement. It can, however, additionally hear counterclaims for infringement, actions for infringement when there is infringement in a state where no local or regional division has competence, and cases transferred to it by local or regional divisions.

The central division has its seat in Paris, but also sections in London and Munich. The competence of each division depends on the technical subject matter of the patents in suit. This is set out in full in Annex II to the UPCA, but the main areas of work covered are:

- **London – pharmaceuticals and chemistry;**
- **Munich – mechanical engineering; and**
- **Paris – physics and electricity.**
Every contracting state has the right to host a local division or co-host a regional division. Both types of division are primarily concerned with determining claims arising from acts of infringement within their territory, or where a defendant is domiciled there. Additionally, however, they have the competence to hear revocation counterclaims. The distinction between local and regional divisions, aside from the extent of their competence arising from their territory, is in judicial staffing (see Section VIII). To date, the following countries have indicated that they will host a local division: Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Slovenia and the United Kingdom. Four countries will share a regional division: Estonia, Latvia, Lithuania and Sweden. The remaining countries will either definitely not host any division, or have yet to decide. It should also be noted that Germany has indicated that it will host four local divisions.

VII LANGUAGE REGIME OF THE UPC AT FIRST INSTANCE

The central division operates in English, German and French. This is not, however, dependent upon the location of the relevant section, but the language of the patent. As a result, it may be expected that English will be the language of the case in 75 per cent of cases, German in 20 per cent and French in 5 per cent.

Local and regional divisions can operate in their local language (or languages) plus one or more of English, German or French. It is highly likely that all divisions will offer English. To date, only the Belgian division has indicated that it will offer all of English, German and French as well as a local language (Flemish or Dutch).

VIII JUDICIAL STAFFING OF THE UPC AT FIRST INSTANCE

All divisions of the UPC comprise multinational panels, most comprising both legal judges and a technical judge. The staffing regime, however, is also quite complex. In brief it is as follows:

a. Central division – two legal judges of different nationalities plus a technical judge of any nationality.

b. Local divisions – three legal judges, plus a technical judge in many cases, notably where validity is in issue. The technical judge may be of any nationality, but the nationality of the legal judges is determined by the experience of the division in terms of numbers of patent cases heard in the country concerned prior to the UPCA coming into effect. More experienced divisions will have two local judges and one non-local judge, while less experienced divisions will have one local judge plus two non-local judges.

c. Regional divisions – as with local divisions, three legal judges, plus a technical judge in many cases, notably where validity is in issue. However, in this case, the nationality of the judges is determined differently, with two of the legal judges being local and the other being non-local. The technical judge may be of any nationality.
IX  UPC COURT OF APPEAL

At the appellate level, there is a single court. It comprises two panels, but these may, in important cases, sit together. The panels will comprise three legal judges of mixed nationalities plus two technical judges of any nationality. The language of the proceedings will usually be that of the first-instance proceedings. The Court’s seat is in Luxembourg, but that does not imply any connection with the CJEU.

X  THE ROLE OF THE CJEU

The CJEU is not formally a part of the UPC system, but acts as a reference court in the same way as it does at present for individual EU Member State courts regarding the interpretation of Union law. The primary role of the CJEU is, therefore, in relation to matters of interpretation of the Brussels Regulation, the SPC Regulations, the Biotech Directive, Unitary Patent and Translation Regulations and EU competition law.

XI  HOW VALIDITY IS DEALT WITH IN THE UPC

As already explained, the UPC is a court that hears both infringement and validity. The competence of divisions within the UPC and how in practice the two types of claims are determined is somewhat complex, however. This is mainly because of the political desire to maintain an option for litigants to choose between a system where infringement and validity were determined together (as in the UK, France, Netherlands, etc.), or a bifurcated system (as used in Germany and elsewhere).

Revocation claims may only be brought in the central division, but only where there is no pre-existing infringement action. (If there is an existing infringement action, validity may only be challenged by bringing a revocation counterclaim in that action, and hence in the division where the claim was initiated.) In the case of a revocation claim, however, a patentee wishing to counterclaim for infringement has the option of doing so in the central division or in a competent local or regional division. If it chooses the latter option, the central division case is stayed until the local or regional division decides what to do. (A similar arrangement exits with declarations of non-infringement, save that in such cases the stay depends on the infringement action being brought within three months.)

Where a local or regional division infringement claim is met with a revocation counterclaim, the local or regional division may proceed in one of four ways. It may:

a  hear both the infringement claim and the revocation counterclaim;
b  transfer the whole case to the central division (but only with the agreement of the parties);
c  refer the counterclaim to the central division and stay the infringement case; or
d  refer the counterclaim to the central division and proceed with the infringement case.

The last two options (bifurcation) will probably not be so prevalent as may have at one time been thought, for two reasons. First, requests for bifurcation may also be less common than anticipated since Rule 40(b) of the Rules of Procedure mandates the acceleration of the central division proceedings, with a requirement to endeavour to set the central division oral hearing for before the hearing of the infringement action in the local or regional division. Second, few European patent judges (even German) have expressed public support for the practice, although there may occasionally be appropriate cases – even the English Patents Court has bifurcated cases in the past.
It is possible to amend or limit patent claims in the course of UPC proceedings, although it appears that amendments should be introduced as early as possible (in the response to the counterclaim) and conditional amendments requests be reasonable in number.

XII PROCEDURAL LAW OF THE UPC

The UPC Rules of Procedure are a blend of the procedures of the major European patent jurisdictions, shaped by judges and practitioners taken from the UK, Germany, France and the Netherlands. A UPC action, at first instance, comprises three stages: a written procedure (lasting six to nine months), an interim procedure (lasting three months) and an oral procedure (featuring an oral hearing typically lasting only one day). Hence the stated aim to have a system that brings cases to a conclusion within one year should be achievable. The procedure also involves a procedure for making costs decisions, and may include a procedure for the award of damages.

The system is a heavily front-loaded one with a requirement to set out the case in detail in terms of arguments, facts, evidence and ‘where appropriate’ an explanation of the proposed claim interpretation. The burden is equally large for the defendant, whether counterclaiming or not.

The system envisages that most of the procedural decisions will be taken by a designated ‘judge rapporteur’. While this may theoretically be the position, it is likely that for at least the more important procedural decisions, there will be consultation, formal or informal, with the other panel members, and to this end there are provisions permitting reviews by the panel.

One interesting aspect of the procedure arising from the blend of systems is that the rules provide ample opportunities for parties to seek evidence in the form of documents, inspections and the like during, but also before proceedings. The notable provisions are those that permit parties to seek:

a a pre-action saisie-contrefaçon to preserve evidence;
b an order against a party at any stage of the proceedings to ‘take any step, answer any question or provide any clarification or evidence’; and
c an order at the interim conference regarding the ‘production of further pleadings, documents, experts, experiments, inspections, further written evidence’.

The requirement to set out the case very fully at the outset makes it unclear whether, despite the apparent limitation of the scope of saisie-contrefaçon orders to preserve evidence (as compared with French procedure where they are used to obtain evidence regardless of whether preservation is necessary), many claimants will routinely make use of the procedure, or whether they will wait and make use of the other procedures instead. One danger of delaying is that an order for production of documents at the interim conference may seem very late when a case has already been the subject of multiple detailed pleadings, especially given the apparently strict limitation of the duration of the interim stage.

As regards the final oral hearing, cross-examination of witnesses is possible, although this may in practice only be relatively extensive if an separate witness hearing is appointed, and may very likely to be not only strictly under court control, but largely conducted by the court. Oral hearings lasting more than one day for oral evidence and one day for submissions seem unlikely, even in very complex cases.
XIII SUBSTANTIVE LAW

The law to be applied by the UPC may be dependent upon the right being asserted. In the case of ‘classical’ European patents, it may be a harmonised law as described below, while in the case of unitary patents, it may depend upon the identity of the proprietor. This curious situation, therefore, requires an explanation.

Article 5 of Unitary Patent Regulation 1257/2012 provides that infringement – technically this is referred to as ‘the right to prevent any third party from committing acts against which the patent provides protection’ – shall be as defined by the law of the state whose national law is applicable to the patent in accordance with Article 7. That Article in turn specifies the relevant law to be determined according to a cascade that considers the nationality of the first named applicant, and if that is not an EU state, the second named applicant, with a fall-back of German law. Hence, a patent with a first-named EU applicant will have infringement considered on the basis of that national law, but if the applicant is not an EU national, the nationality of the subsequent names applicants will be considered. To give examples:

a the law applicable in cases where there are two applicants, one German and one English, will depend on which is named first;
b the law applicable to a patent where the application was in the name of any one EU national and any non-EU applicant or applicants will always be that of the state of the EU applicant; and
c if there are no EU applicants, the law will be German.

Of course, the infringement laws of many EU states are at least very largely the same. This is for two reasons. First, with regard of scope of protection, all participating states are signatories to the EPC that includes Article 69, which governs that topic. Second, many participating states modelled their laws concerning actionable acts of infringement on the Community Patent Convention 1975 (CPC), even though that never came into force. Further, harmonisation is increasing, with, for example, the law of the Netherlands and the UK having been amended as part of the process of UPC ratification. However, differences do remain in certain areas, notably experimental use or Bolar provisions, and accessory liability.

In contrast to this, for ‘classical’ European patents a largely harmonised approach is more likely. This is because the UPCA, in Article 24(1), prescribes a seemingly prioritised cascade of applicable laws (in which national law is last), and in Articles 25–27 a common law relating to actionable acts of infringement (based on the CPC). Only in the areas of prior use defences does the UPCA mandate that national law applies, although the absence of any UPCA provisions on accessory liability gives rise to the question of whether a harmonised approach will be taken or national law applied.

Another issue is the extent to which EPO case law will be applied by the UPC. Undoubtedly, respect will be given to enlarged board case law and established board of appeals case law in the initial years of the UPC, but in due course it is to be expected that the UPC will establish its own case law, and to the extent that there is divergence from current EPO case law, it is to be hoped that at that point the EPO will follow UPC case law.
XIV RELIEF – INTERIM INJUNCTIONS

The court can entertain interim or provisional injunction applications, with the rules providing great flexibility for urgent, and potentially ex parte relief, as well as more routine cases. There is also a protective letter system under which potential defendants can register their request to be heard in the event of an ex parte application. The standard for obtaining interim relief is, like other aspects of the system, a blend of current national approaches. It features a requirement to establish infringement and validity with a ‘sufficient degree of certainty’, or have regard to ‘unreasonable delay’ and to ‘weigh up the interests of the parties’. All orders made on an interim basis are subject to an automatic right to claim compensation in the event that it is later found that an order should not have been granted, and security may optionally be required.

XV RELIEF – FINAL INJUNCTIONS, DAMAGES AND COSTS

Relief in the EU is theoretically harmonised by the Enforcement Directive, and the UPCA was drafted with its provisions in mind. In terms of injunctions, Europe has a tradition of granting injunctive relief virtually automatically, subject only to cases involving standard-essential patents. Hence, although strictly a matter of discretion, it is entirely to be expected that injunctions will routinely follow a finding of infringement of a valid claim except in the most exceptional of circumstances. This is not to say that an injunction will be granted with immediate effect in all cases. Stays pending appeal are possible (but injunctions are not automatically suspended pending appeal), and in some other cases (such as where the decision is final) a grace period may be permitted so as to permit the defendant to move to a non-infringing product or process. The period of such stays may, however, be limited to not more than a few months.

Damages are also granted in accordance with the Enforcement Directive. They are to be largely compensatory in nature, with only the possibility of additional awards in cases where the defendant has enjoyed ‘unfair profits’. While this term lacks clarity, it does not suggest any awards of multiple damages as in the United States.

Costs are awarded to the successful party in most cases on a largely compensatory basis, but subject to caps based on the value of the action. In the highest value, most complex cases, such awards can be of up to €5 million, though the standard range of costs awards will be €38,000 to €2 million depending on the value of the case.

XVI ENFORCEMENT

Under the UPCA, enforcement of orders is a matter for national law.

XVII APPEALS

Although the system is complicated by the possibility of reviews by the panel in the case of certain procedural orders made by the judge rapporteur, in principle, appeals from both procedural orders and final orders lie to the Court of Appeal. Procedural orders may be decided by an interim appeal process, or may be combined with a final substantive appeal. Final appeals will, in contrast to EPO procedures, rarely result in remittals back to first instance, with the Court of Appeal having the right to decide any matters undecided by the first-instance division. The nature of appeals will be somewhere between the extremes of de novo and de jure

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systems, but with relatively strict rules on the introduction of new evidence. Appeals should be completed within one year in most cases, making it entirely reasonable to expect final decisions in UPC cases within a total of two years in all but the most complex cases.
I  OVERVIEW

Australian patent litigation is governed by the Patents Act 1990 (Cth) (the Act), which provides the legislative framework for the Australian patent system, and the rules and procedures of the Federal Court of Australia, in which Australian patent litigation is almost entirely conducted. As Australia is a common law jurisdiction, the decisions of the Federal Court and other Australian courts vested with the relevant jurisdiction have precedential value in providing guidance on the meaning and application of the Act.

In 2013, the Act was amended by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth) (RTB amendments). The RTB amendments bring Australia’s patent system more in line with other jurisdictions. The Act as amended applies to all patents or patent applications for which examination has not been requested before 15 April 2013. For all other patents or patent applications, the pre-RTB amendments law applies. This effectively establishes a class of ‘new law’ patents to which higher validity thresholds apply, while the lower validity thresholds continue to apply to ‘old law’ patents.

There is currently patent litigation activity in the Federal Court across a range of sectors, including pharmaceuticals, telecommunications, medical devices and mining.

II  TYPES OF PATENT

There are currently two tiers of patents under the Act: standard patents and innovation patents.

Standard patents, as the name suggests, are the traditional form of patent protection available under Australian law. Standard patents have a term of 20 years, and can only be granted and enforced following examination by the Australian Patent Office and the expiry of an opposition period (or the successful resolution of any third-party opposition).

Innovation patents are intended to cover lower level inventions (innovations). Innovation patents provide the same scope of rights and remedies for infringement as standard patents but have a lower threshold for patentability (i.e., ‘innovative step’ rather than ‘inventive step’). Innovation patents have a shorter term of eight years, but can be granted quickly upon compliance with formal filing requirements. To be enforced, an innovation patent must be certified, which requires completion of examination by the Australian Patent Office. In practice, an enforceable innovation patent can be obtained...
quickly (in four to five months) and there is no pre-grant opposition available to third parties. However, legalisation has recently been tabled by the federal government, which, if passed, will result in the phasing out of innovation patents.

Australia has a patent term extension regime available for certain standard patents relating to pharmaceutical substances. Eligible patents may have their term extended by up to a further five years. The rights of a patentee during the extended term of the patent are limited compared with a patentee’s rights during the initial 20-year term.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

Australian patent litigation can be conducted in the Federal Court of Australia and the Supreme Courts of the Australian States. In practice, patent cases are brought in the Federal Court (primarily in Sydney and Melbourne), which has judges experienced in intellectual property cases. For this reason, this article deals with the practice and procedure of the Federal Court.

Patent litigation is heard at first instance by a single judge. Jury trials are not available. The Federal Court has adopted an individual docket system, such that proceedings are allocated to a single judge from commencement, and that judge is then involved in all stages of the proceeding, including the final hearing.

i Standing and commencing patent infringement proceedings

Infringement proceedings may be started by the patentee or an exclusive licensee. An exclusive licensee is a ‘licensee under a licence granted by the patentee and conferring on the licensee, or on the licensee and persons authorised by the licensee, the right to exploit the patented invention throughout the patent area to the exclusion of the patentee and all other persons’.

The limitation periods applicable to torts under the laws of each state apply to the commencement of patent infringement proceedings – for example, in New South Wales, the relevant limitation period is six years from the date on which the cause of action accrues.

There is a cause of action available against any person who makes an unjustified threat of patent infringement, which can result in an injunction against the continuance of the threat and the recovery of damages sustained as a result of the threat.

ii Procedure

Proceedings for patent infringement are commenced by an applicant by filing an originating application and statement of claim and serving the filed documents on the other party or parties (referred to as the respondents).

The statement of claim is a pleading that sets out each allegation of fact relied upon by the applicant to establish its claims. The respondent is then required to file a defence outlining the respondent’s case against the claims of the applicant, including by admitting, not admitting, or denying each fact alleged by the applicant. The applicant may file a reply to the defence. In each pleading there must be included a certificate signed by the parties’ legal representative, which certifies that the material available provides a proper basis for each claim in the pleading.

It is common that, in addition to the defence, a respondent will also file a cross-claim for revocation of the patent (in which case the applicant or cross-respondent can file a defence to that cross-claim). The Federal Court will normally hear both infringement and revocation claims together. This is in contrast to other jurisdictions where revocation proceedings are sometimes heard separately and can provide a basis for staying infringement proceedings.
Together, the pleadings identify the issues in dispute between the parties that are to be resolved by the court.

Following the filing of the originating application and statement of claim, the usual course of patent proceedings involves the following.

a. An initial directions hearing (the ‘first return date’) in which orders will be made establishing a timetable for the next steps in the proceeding including the filing of remaining pleadings, the filing of evidence and potentially setting a hearing date.

b. Following the close of pleadings (which occurs once the time to file a reply expires), the parties may apply for discovery (disclosure) of documents. Orders for discovery are not automatically made and it may be necessary to satisfy the court that discovery is necessary. In some cases, the court will only order discovery after evidence so that the scope of discovery can be narrowed.

c. The exchange of evidence usually occurs in three stages: evidence in chief, evidence in answer, and evidence in reply. The same procedure is adopted in relation to both the claim and any cross-claim (e.g., the evidence in chief on an infringement claim and the evidence in chief on a validity cross-claim are often ordered to be filed at the same time).

d. A hearing of infringement and validity issues (which usually takes one to two weeks per patent) followed by the handing down of the judgment likely at least three months (but may be more than six months) after the hearing.

e. Any appeal.

It is possible for the patentee to apply for an amendment during the course of patent infringement or revocation proceedings, although the court has a discretion as to whether to allow such amendments. In exercising this discretion, the court will take into account issues such as delay and whether the patentee has given full and frank disclosure of its reasons for seeking the amendment.

iii  Evidence and burden of proof

The general rule in Australian civil litigation is that a party who asserts a certain fact has the burden of proving it on the balance of probabilities. Consequently, in infringement proceedings, this burden normally rests on the patentee (or exclusive licensee) who asserts that particular conduct infringes their patent. Similarly, a party who seeks to revoke a patent has the burden of proving that the patent is invalid.

Evidence is typically provided in the form of an affidavit from a witness, who is then made available for cross-examination at the hearing. Witnesses may be factual or expert. Evidence can also take the form of documents (including discovered documents) or other exhibits tendered at the hearing. There is no deposition regime in Australia.

In patent matters, expert evidence is nearly always filed, with the purpose of providing an explanation of the specification’s technical terms, the invention, and whether it is capable of being conducted by a skilled person, and to give evidence as to the common general knowledge. Expert witnesses must comply with a set of guidelines that explain to the witness the need to remain independent and uphold their overriding duty to the court, rather than the retaining party.

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2  See Evidence Act 1995 (Cth), Sections 140 and 142.
If parties to the proceeding each intend to call expert witnesses at the hearing, the court may direct that such evidence be delivered concurrently. This has become the court’s preferred approach to receiving expert evidence in patent proceedings in the Federal Court.

iv Timing and costs

A proceeding in the Federal Court where both infringement and revocation are in issue usually takes between 12 and 24 months from filing (assuming the matter is fully contested) but, if it is complex, proceedings may take longer. Where there are particular circumstances justifying an urgent hearing, the Federal Court has demonstrated in a number of recent cases that it can accommodate a much shorter timetable from commencement to final hearing.

The costs of bringing patent infringement or validity proceedings depends on the complexity of the factual and legal issues, number of experts, the approach of each party, the solicitors and counsel chosen to act, and the length of the hearing. The cost of complex infringement proceedings with a cross-claim for revocation, which continues to a final hearing in Australia are in the same order as costs of a complex commercial litigation matter, for example, the costs may be around A$1 million or more.

In Australia, costs usually follow the event, which means that the unsuccessful party is responsible for the costs of the successful party. However, where the successful party is not successful on all issues, the court may apportion costs according to each party’s degree of success in the proceeding. A party awarded costs will generally not receive 100 per cent of the actual costs incurred by the party, but would typically expect to receive approximately 60 per cent of their actual costs.

However, a court may order that costs be assessed on an indemnity basis, including in cases where the successful party made a settlement offer, which was not accepted, and went on to achieve an equal or more favourable outcome in the final judgment. Where indemnity costs are awarded, the successful party will receive costs that are close to the actual costs incurred.

v Preliminary relief

The court has wide discretion to grant interlocutory relief to maintain the status quo and to prevent a party from engaging in allegedly infringing conduct pending a final hearing. An application for interlocutory relief is typically commenced by filing an originating application (without the need for a statement of claim) and evidence, and is often used before the allegedly infringing product has been put on the market. For an interlocutory injunction to be granted, an applicant must establish that:

- there is a prima facie case on infringement (and issues of validity may also be considered); 3
- the applicant would suffer irreparable harm for which damages would not be adequate compensation; and
- the balance of convenience favours the granting of the injunction.

The balance of convenience test primarily concerns the nature and degree of harm to the parties if the injunction is, or is not, granted. Other factors that may be considered include preservation of the status quo and any delay in commencing proceedings.

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3 For example, in Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd (2019) 139 IPR 409, the Full Federal Court affirmed a decision to reject an interlocutory injunction on the basis that the invalidity case was sufficiently strong to qualify the conclusion that there was a prima facie case on infringement.
An interlocutory injunction is rarely granted on an *ex parte* basis, except for an interim period until the respondent has the opportunity to contest its continuation, and provided the applicant can demonstrate a risk of irreparable harm if such interim relief is not granted.

In the event that an injunction is granted, the applicant will be required to give an undertaking as to damages. This means that if the applicant is granted an interlocutory injunction, but is unsuccessful when the matter is finally decided at trial, the applicant undertakes to submit to such order (if any) as the court may consider to be just for the payment of compensation, to any person adversely affected by the operation of the interlocutory order, whether or not that person was a party to the proceedings.

**IV SUBSTANTIVE LAW**

**i Infringement**

Section 13(1) of the Act sets out the scope of the patentee’s rights as being ‘the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention within the patent area’ (i.e., Australia). ‘Exploit’ includes:

- where the invention is a product – make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- where the invention is a method or process – use the method or process or do any act mentioned above in respect of a product resulting from such use.

A person can be sued for direct, or indirect or contributory, infringement.

Direct infringement occurs when a person, without the authorisation of the patentee, performs any of the acts falling within the scope of exclusive rights conferred by a patent, as defined by Section 13(1) of the Act and the definition of ‘exploit’ (see above).

The applicant must establish that the allegedly infringing product or process contains all the essential integers of a claim of the patent. This necessarily involves a comparison between the patent claims and the alleged infringing product or process.

Section 117 of the Act provides a statutory basis for a finding of contributory infringement for the supply of infringing products where the use of such products by the person to whom they are supplied falls into one of the following categories:

- if the product is capable of only one reasonable use, having regard to its nature or design – that use;
- if the product is not a staple commercial product – any use of the product, if the supplier had reason to believe that the person would put it to that use; or
- in any case – the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, from the supplier.4

A person may also be liable for indirect patent infringement at common law by authorising the infringement, jointly participating in the infringement or otherwise contributing to the act of infringement.5

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ii Invalidity and other defences

Invalidity is dealt with in Section 138(3) of the Act (which sets out the grounds on which a patent may be invalidated) in combination with Section 18 of the Act (which provides the requirements for an invention to be patentable as a standard or innovation patent). In broad terms, the main grounds upon which a standard patent may be invalidated are:

- not a ‘manner of manufacture’ (i.e., patentable subject matter);
- lack of novelty;
- lack of inventive step;
- inutility – that is, the claimed invention does not attain the result promised by the patentee,6 and also a specific, substantial and credible use is not disclosed in the specification;
- the invention was secretly used before the priority date by, or on behalf of, or with the authority of, the patentee;
- the patentee is not entitled to the patent;
- the patent (or an amendment to the patent) was obtained by fraud, false suggestion or misrepresentation;
- the complete specification does not disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art;
- the complete specification does not disclose the best method known to the applicant of performing the invention;
- the claims are not clear and succinct; and
- the claims are not supported by matter disclosed in the specification.

The above list applies for innovation patents, except that rather than the patent requiring an ‘inventive step’ (see (c)), an ‘innovative step’ (which is a lower threshold) is required.

The key tests for manner of manufacture, novelty and inventive or innovative step are summarised in subsections iii, iv and v. One consequence of the RTB amendments is that, in addition to inventive step (as discussed below), the grounds of inutility, disclosure, best method and support (previously fair basis) have been amended to bring them into line with the requirements in other jurisdictions, in particular Europe, including the United Kingdom.

iii Manner of manufacture (patentable subject matter)

Apart from the exclusions for human beings (for standard and innovation patents) and for plants and animals (for innovation patents only) in Subsections 18(2) and (3) of the Act, there are no categories of inventions that are automatically excluded from patentability under Australian patent law.

Rather, the boundaries of what may constitute patentable subject matter are controlled by the requirement that an invention must be a ‘manner of manufacture’ within the meaning of Section 6 of the Statute of Monopolies 1623.

The leading High Court case on this ground (NRDC)8 established that it is neither possible nor desirable to give a specific definition to the expression ‘manner of manufacture’

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6 ESCO Corporation v. Ronneby Road Pty Ltd [2018] FCAFC 46.
7 Section 7A of the Act.
8 National Research Development Corp v. Commissioner of Patents (1959) 102 CLR 252.
and that it is a flexible concept capable of adapting to changing needs and times. The key test, as established by NRDC, is that the invention must give rise to an artificially created state of affairs that is of practical utility and economic significance.\(^9\)

The High Court has since held that the two requirements from NRDC are not a mechanistic test conferring a presumption of patentability.\(^{10}\) If the two NRDC criteria are met, the subject matter may be patentable, but other relevant factors must be considered, in particular consistency with the purposes of the Act and the international context.

### iv Novelty

Section 7(1) provides that an invention is novel unless it is not novel in light of prior art information that is publicly available anywhere in the world prior to the priority date.

The information can be gleaned from a single document, or through doing a single act. It is permissible to combine information from two or more related documents or from two or more related acts but only if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a single source of information. A patent can also be invalidated on novelty grounds if the prior art information is contained in a single complete specification that, even though published after the priority date of the claim under consideration, has a priority date that precedes it, provided that the information was contained in the specification both on its filing date and when it was published (commonly referred to as a ‘whole of contents’ novelty citation).

Other than whole of contents novelty citations, prior art published after the asserted priority date of a claim can only be considered for novelty or inventive step if the priority date of the claim is found to be later than the date asserted by the patentee (and the prior art was published before that later date). In assessing claims to priority, the same test for fair basis (before the RTB amendments) or support (after the RTB amendments) is applied to the priority document relied upon to confer the asserted priority date.

To assess whether an invention is novel over (or not anticipated by) any particular piece of prior art, the courts apply the ‘reverse infringement test’, that is ‘whether the alleged anticipation would, if the patent were valid, constitute an infringement’.\(^{11}\) In other words, prior art will only anticipate an invention if it discloses all of the essential integers of the claimed invention.\(^{12}\) The cases emphasise that a clear and precise disclosure of the subject matter of what is claimed is required. In particular, the prior art must contain ‘clear and unmistakable directions’ to carry out the invention in order to render it not novel.\(^{13}\)

### v Inventive step

Standard patents are subject to the inventive step test, while innovation patents are subject to the innovative step test, which has a lower inventive threshold.

Following the RTB amendments, under Section 7(2) of the Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art, in the light of the

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9 National Research Development Corp v. Commissioner of Patents (1959) 102 CLR 252 at 277.
common general knowledge as it existed (anywhere in the world) before the priority date of
the relevant claim, considered separately or together with the prior art information specified
in Section 7(3).

Various observations have been made by the courts as to how to approach obviousness,
although none are intended to replace the test laid down in Section 7(2). The most commonly
applied test for inventive step (or obviousness) is whether the skilled person would directly
be led as a matter of course to try the claimed invention in the expectation that it might well
produce a useful result.\textsuperscript{14} However, this test may not be appropriate in all cases.

It is also important to recognise the limits imposed on the extent to which different sources
of prior art information can be combined for the purposes of inventive step. Under Section 7(3)
of the Act, the prior art information assessed for inventive step can be either any single piece of
prior art information, or a combination of any two or more pieces of prior art information that
the skilled person could, before the priority date of the relevant claim, be reasonably expected
to have combined. It is impermissible to make a ‘mosaic’ of a number of independent items of
information and then allege that the mosaic reveals the claimed invention.\textsuperscript{15}

The RTB amendments significantly expand the scope of the prior art base and the
can be combined for the purposes of inventive step. As a consequence, ‘new law’ patents must satisfy a higher threshold of
inventive step as compared with ‘old law’ (i.e., pre-RTB amendments) patents.

\textbf{vi} Defences to infringement

In addition to the ability to rely on a licence from the patentee (express or implied) as
defence to infringement, there are other limited defences available, some of which are
discussed below.

Section 119 of the Act provides a prior use defence. This defence is available in limited
circumstances where the alleged infringer can establish that, immediately before the priority
date of the relevant claim, they were exploiting the claimed invention in the patent area or
had taken definite steps to do so.

Section 119A of the Act provides a defence for acts done solely for purposes connected
with obtaining regulatory approval for pharmaceutical products. The RTB amendments
extend this defence to non-pharmaceutical products under Section 119B.

The RTB amendments also introduced a defence under Section 119C of the Act if an
otherwise infringing act is done for experimental purposes relating to the subject matter of
the invention.

\textbf{V} FINAL REMEDIES FOR INFRINGEMENT

The main remedies that can be sought in an infringement proceeding are the following:
\begin{itemize}
  \item \textit{a} a permanent injunction;
  \item \textit{b} delivery up or destruction of infringing goods;
  \item \textit{c} damages or account of profits;
  \item \textit{d} additional damages; and
  \item \textit{e} declaratory relief.
\end{itemize}

\textsuperscript{14} Aktiebolaget Hässle v. Alphapharm Pty Ltd (2002) 212 CLR 411 at [53].
\textsuperscript{15} Minnesota Mining and Manufacturing Co v. Beiersdorf (Australia) Ltd (1980) 144 CLR 253 at 292–293.
i **Permanent injunction**

If a patent is held to be valid and infringed, the court will almost always grant a permanent injunction, although the remedy is discretionary. The injunction will restrain the infringing party from infringing the patent during the remainder of its term, and set out clearly the conduct that is prevented.

The infringing party may apply for a stay of injunction pending the determination of any appeal. Whether a court will grant such a stay will depend on the factual circumstances and in particular the desirability to preserve the status quo.

ii **Damages or account of profits**

Quantum (damages or an account of profits) is not usually considered until after liability has been determined (i.e., after the first instance judgment has been delivered and after any appeals have been exhausted). In practice, the issue of quantum is often settled between the parties if the court makes a finding of infringement of a valid claim.

In the event of an infringement, the applicant may seek, at its election, damages or an account of profits (not both).

Damages are assessed so as to compensate the applicant for the loss that has been caused to it as a result of the infringement. Damages can include loss of profits on the basis of lost sales where the applicant was either the patentee or an exclusive licensee.

Under the Act, the court may order ‘additional damages’ owing to, for example, the flagrancy of the infringement or the need to deter similar infringement in future. However, such damages are less common.

An account of profits involves the infringing party accounting to the applicant for all its profits that are attributable to the infringement.

VI **OTHER TYPES OF PATENT PROCEEDING**

In addition to proceedings for patent infringement and revocation, the Federal Court also hears appeals from administrative decisions of the Australian Patent Office concerning patent applications and oppositions.

In addition, the Act also provides for a number of other types of applications relating to patents that can be heard and determined by the Federal Court, including applications for:

- a declaration of non-infringement;
- relief from unjustified threats of patent infringement;
- amendment of a patent; and
- a compulsory licence.

VII **APPEAL**

Appeals from first instance decisions are conducted before the Full Federal Court, which is usually made up of three judges of the Federal Court. There is an automatic right to appeal single judge final (but not interlocutory) decisions of the Federal Court to the Full Federal Court. Typically, no further evidence is allowed on appeals, with the appeal to be determined based on the material accepted into evidence at first instance.

Parties may also seek to appeal decisions of the Full Federal Court to the High Court of Australia (which is the highest court in Australia). There is no automatic right of appeal. A party must apply for ‘special leave to appeal’. Special leave is difficult to obtain and is
rarely granted (although the High Court has shown recent interest in some patent cases) and typically requires that the appeal involve a genuine question of public importance, a difference of opinion between courts, or is otherwise required in the interests of justice. The appeal must also have significant prospects of success.

Following the date of judgment at first instance, the parties have 21 days to file a notice of appeal to the Full Federal Court. An appeal to the Full Federal Court is usually resolved within 12 months, with an appeal to the High Court (if special leave is granted) taking an additional six to 12 months to final judgment.

VIII THE YEAR IN REVIEW

The Federal Court has recently revisited two important issues: the patentability of computer-implemented methods, and the defence of implied licence.

In a recent matter that has been closely followed by those in the Australian patent law profession, a single judge of the Federal Court ruled that a computer-implemented invention was not patent eligible subject matter, on the basis that it did not result in an improvement within the computer (which was patentable) but merely required generic computer implementation.16 The patentee appealed this decision, and the appeal was heard before an expanded bench of five Federal Court judges in November 2018. As at August 2019, the parties are still awaiting judgment on the appeal.

Australian patent law has long recognised the availability of an implied licence as a defence to patent infringement for goods sold by or with the authority of the patentee without limitations on use. However, there have been very few cases on the scope of this implied licence defence (being the Australian equivalent of ‘patent exhaustion’). A recent Full Federal Court judgment has confirmed that it is presumed that the sale of patented goods carries an implied licence to import, use and dispose of the goods, if a patentee does not impose any conditions on the purchaser at the time of sale. While the question as to whether Australian patent law recognises a right to repair was left unresolved, this decision clarified that the implied licence will not shield purchasers from infringement for making, or remaking, the invention.17

IX OUTLOOK

The Federal Court has continued its emphasis on proactively managing cases to seek to ensure procedural time frames and costs are minimised wherever possible.

Proactive case management in the Federal Court is not treated as formulaic, with the court open to applying a number of methods to increase efficiency, including limiting discovery, encouraging parties to limit issues in dispute, the use of case management conferences, which encourage dialogue between the parties and the judge, the separation of issues of liability from issues of quantum, and costs orders that reflect the parties’ relative success on different issues.

16 Encompass Corporation Pty Ltd v InfoTrack Pty Ltd (2018) 130 IPR 387. This decision followed the approach adopted by the Full Federal Court on this issue in two earlier decisions: Research Affiliates LLC v Commissioner of Patents (2014) 227 FCR 378; Commissioner of Patents v. RPL Central Pty Ltd (2015) 238 FCR 27.
Further amendments to the Act are currently under consideration following recommendations by Australia’s Productivity Commission. In July 2019, the federal government tabled legislation that proposed a number of amendments to the Act, including in relation to the availability of compulsory licences, the phasing out of innovation patents and Crown use of patents.
I OVERVIEW

Despite being a relatively small market, quite a few pan-European disputes are litigated in Belgium. This is certainly true for the pharmaceutical and related sectors, which have a strong presence in Belgium and continue to grow. As such, biotech companies are thriving. As a consequence of this presence and growth, the volume of patent litigation before the Belgian courts has steadily increased in recent years. Another reason for this increase of litigation may be related to the fact that since 2015, all patent litigation in Belgium is exclusively handled by the Brussels courts, which facilitates litigation and should enhance the quality and predictability of the decisions.

A topic still hotly debated in Belgian proceedings remains the assessment of the prima facie validity of patents in preliminary injunction proceedings. Although the Supreme Court has ensured that Belgian preliminary injunction judges have to make an effective assessment of the validity of a patent invoked in the framework of descriptive seizure or preliminary injunction proceedings, the scope of this assessment remains unclear.

Finally, the past year has seen an increase in ex parte proceedings by patent owners to obtain an injunction quickly. It remains unclear whether this trend will continue as courts seem more and more reluctant to grant such ex parte measures.

II TYPES OF PATENT

There are several ways to obtain a patent with effect in Belgium:

a The national route: the first one consists of filing the patent application with the Belgian Office for Intellectual Property. These Belgian patents are solely governed by Belgian law.

b The European route: the second one consists of filing the patent application with the European Patent Office (EPO). After publication of the grant of the patent and validation of that patent in Belgium, this European patent confers on the patent owner the same rights as would be conferred by a Belgian patent. The validity of these patents is governed by the European Patent Convention (EPC), whereas the scope of protection and other aspects not regulated by the EPC are governed by Belgian law.

c The international route: Belgium is a member of the Patent Cooperation Treaty (PCT) and it is, therefore, possible to use the PCT procedure, which allows one to file one
patent application for the various members of the PCT instead of filing individual patent applications with the different members. This route will eventually result in a European patent valid for Belgium.

The Belgian Code of Economic Law (CEL), in particular Title 1 (Patents), Title 9 (Civil Aspects of Intellectual Property Rights) and Title 10 (Legal aspects of Intellectual property rights) of Book XI, contain the substantive rules on patent law. Moreover, this Code of Economic Law is complemented by different acts and implementing royal degrees. There are also several EU regulations\(^2\) that have a direct effect in Belgium and complement the Belgian patent legislation.

i National Belgian patent application

National patents are granted following a patent application procedure before the Belgian Office for Intellectual Property. The only person entitled to apply for a patent is the inventor himself or herself or his or her successor in title. As discussed below, several requirements must be met to obtain a valid patent. It should be noted that these requirements are not examined during the Belgian patent application procedure, although a novelty search is done by the EPO. The results hereof are, however, not binding; even if it is clear that the invention is not novel, the patent will be granted. The patent grant explicitly mentions in this regard that the patent is granted without any guarantee. As a result of this simple application procedure without substantive examination, the prosecution costs of a Belgian patent are rather limited. Another consequence of this lack of substantive examination is that Belgian patents are considered ‘weak’ patents and in possible subsequent enforcement proceedings the validity of the patent will be more thoroughly examined.

ii European patent application

A European patent will be granted following a patent application procedure before the EPO. Contrary to Belgian patent applications, the validity of European patent applications is examined during the patent application procedure. On the one hand, this results in more significant prosecution costs for European patents, on the other hand European patents are considered to be ‘strong’ patents as they have been examined. Patent applications that do not meet the requirements for patentability will be refused. A European patent application procedure will result in a ‘bundle’ of patents in the jurisdictions for which a grant was requested, which may include Belgium. In this regard it should be noted that Belgium has implemented the Agreement on the application of Article 65 EPC (the London Agreement) and that it is, therefore, as from 1 January 2017 no longer necessary to provide a translation of European patents granted in English. For patents granted in French or German, no translation was necessary as these languages are official languages of Belgium. Most of the patents enforced in Belgium are actually Belgian parts of European patents that have been issued by the EPO.

\(^2\) Such as the Regulation (EC) 608/2013 on customs enforcement of intellectual property rights, the Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products and the Regulation (EC) 1901/2006 on medicinal products for paediatric use.
iii Requirements for patent protection

Patent protection can be obtained when the invention meets the requirements as set out in the CEL and the EPC. The Belgian legislator has ensured that the conditions of the CEL reflect those of the EPC. In order to be patentable, invention must be new; must involve an inventive step and must be capable of industrial application. In addition, the invention has to be sufficiently disclosed in the patent and needs to be described clearly therein. European and Belgian legislation, moreover, on the one hand, enumerates some subjects and activities that cannot be considered ‘inventions’ (and therefore are not patentable) and, on the other hand, explicitly excludes some inventions from patentability.

As such, the following cannot be regarded as inventions:

a discoveries, scientific theories and mathematical methods;

b aesthetic creations;

c schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and

d presentations of information.

Some inventions are explicitly excluded from patentability:

a Biological material: this relates in the first place to plant or animal varieties. Essentially biological processes for the production of plants or animals are also excluded. In order to safeguard the interests of the biotechnology sector the European legislator has clarified, in this regard, that the following can nevertheless be patented:
• biological material that is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature;
• inventions that concern plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
• inventions that concern a microbiological or other technical process or a product obtained by means of such a process; and
• products consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

b Inventions: the commercial exploitation of which would be contrary to public order or morality. Based on this ground the European legislator has explicitly confirmed that the following are not patentable:
• processes for cloning human beings;
• processes for modifying the germ line genetic identity of human beings;
• uses of human embryos for industrial or commercial purposes;
• processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes; and

3 Article 54 EPC and Article XI.6 CEL.
4 Article 56 EPC and Article XI.7 CEL.
5 Article 57 EPC and article XI.8 CEL.
6 Article 52, 2 EPC and Article XI.4 CEL.
7 Article 53 EPC and Article XI.5 CEL.
methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. This exclusion does not apply to products, in particular substances or compositions, for use in any of these methods.

Finally, it should be noted that the wording of the patent claims determines the scope of protection of a patent. Such patent claims must be interpreted in light of the descriptions and the drawings accompanying the patent, as is confirmed in Article 69 EPC and the Protocol on the Interpretation of Article 69 EPC. Belgian case law takes into account the prosecution file to interpret the scope of protection of patents.

III  PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

The Belgian and European legislator have provided for a strong legal framework to enforce patents at the external borders of the European Union and within Belgium.

To prevent infringing goods from entering the European Union, Regulation 608/2013 of 12 June 2013 concerning customs enforcement of intellectual property rights has established specific procedures relating to the interception and the destruction of counterfeit goods at the borders of the European Union. Belgian customs are very active and are successful in stopping large shipments of counterfeited goods.

Within Belgium, criminal proceedings as well as civil proceedings are available to the patentee. Under certain conditions patent infringement is indeed considered a criminal offence (i.e., if an infringement is committed with malicious or fraudulent intent). Such criminal proceedings may be considered in case of effective counterfeiting (e.g., counterfeiting of medicinal products) or if the source of infringement is unknown. Within the context of criminal proceedings the patentee can obtain compensation to repair the damages caused by the infringement.

In most cases, civil proceedings will be initiated to enforce a patent in Belgium. The Belgian legislator has recently updated all IP-related legislation to have an effective legal and procedural framework in place. Apart from 'normal' proceedings on the merits, the patentee can initiate the following preliminary injunction proceedings or accelerated proceedings on the merits, as explained below.

Preliminary injunction proceedings

In order to obtain a preliminary injunction, enjoining the alleged infringer from commercialising allegedly infringing goods pending a decision on the merits, usually subject to a civil penalty, the patentee may initiate preliminary injunction proceedings before the president of the Brussels courts of commerce. No damages can be obtained in the context of these proceedings. To obtain such injunction, the patentee should establish that:

a  a prima facie valid patent right is invoked;

b  there are some ‘indications’ of an (imminent) patent infringement;

c  the balance of interests tips in favour of the patentee; and

d  there is urgency, that is, immediate measures must be taken to avoid irreparable harm to the patentee.
**Accelerated proceedings on the merits**

In the context of these proceedings (which follow the procedural rules of preliminary injunction proceedings) patentees can obtain an injunction order on the merits, ordering the infringer from ceasing all infringing acts. Within a few weeks to a few months, it is possible to obtain a final cease-and-desist order from a court, including the recall and destruction of all infringing goods. No damages can, however, be granted in the context of these accelerated proceedings on the merits.

Finally, in case of ‘absolute’ necessity patentees can also initiate *ex parte* proceedings in order to obtain an injunction or any other measure. Such *ex parte* proceedings have been more used these last years and this trend seems to continue.

As discussed below, in the several enforcement proceedings, an invalidity defence (possibly on a *prima facie* basis) is available to the alleged infringer. Contrary to the German bifurcated system, in which infringement and validity are dealt with by different courts, the same court will decide on validity and infringement.

**i Requirements for jurisdiction and venue**

If the defendant has its place of business in Belgium, or if the actual patent infringement takes place in Belgium, Belgian courts can assume international jurisdiction to hear the case. Within Belgium, the Brussels courts of commerce have exclusive jurisdiction in first instance to hear all patent infringement and invalidity cases as from 1 January 2015. At the appellate level, the Brussels Court of Appeal has exclusive jurisdiction. The legislator has centralised patent litigation with one court to increase the quality of the decisions.

The language used during the proceedings can be either French or Dutch and is chosen by the claimant when the defendant has its registered office or domicile in the Brussels-capital Region or outside of Belgium. When the defendant has its registered office or domicile in Wallonia of Flanders, the language of proceeding is determined by this location (Dutch for defendants based in Flanders, French for defendants based in Wallonia).

**ii Obtaining relevant evidence of infringement and discovery**

As a general rule under Belgian procedural law, the claimant should establish the facts he or she invokes (*actori incumbit probatio*). As such, there is thus no discovery in Belgium and documents cannot be subpoenaed at will or on the request of other parties. In some circumstances, however, the court may order the production of specific exhibits.

The court may indeed order a party to produce the elements of evidence that it possesses (Article 871 Judicial Code). It may specifically order a party – or even a third party – to produce an exhibit (e.g., a document, DVD or CD) that contains the proof of a relevant fact if there are serious, precise and concurring presumptions that the party concerned is in possession of this document. These specific conditions are included to avoid ‘fishing expeditions’.

In the context of an alleged patent infringement some kind of discovery is, however, available. Under Belgian law a patentee can indeed initiate *ex parte* proceedings to have an independent expert appointed who will have the authority to search the premises and obtain all information necessary to establish a patent infringement. This court-appointed expert must then file a report containing the information gathered, which may be used to assess the

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9 Article XI. 337 CEL. The same goes for all litigation relating to supplementary protection certificates.
alleged infringement as well as the scope thereof. This counterfeit seizure procedure is quite popular and has given rise to important case law. Within the context of these proceedings, the patentee cannot only obtain description measures (the appointment of an expert who will draft a report relating to the alleged patent infringement), but also actual seizure measures (the seizure of infringing goods found during the proceedings).

To obtain a description measure, the patentee should establish that a *prima facie* valid patent right is invoked and that there are some ‘indications’ of an (imminent) patent infringement.

If the conditions are met, an expert will be appointed. As soon as all information has been gathered, the expert will have to file a report. This report can only be used in the context of infringement proceedings and upon the condition that the applicant initiates proceedings on the merits in Belgium or abroad in time (usually within one month of filing the expert report).

The conditions to obtain a seizure measure are more strict. The patentee should indeed establish that:

\[ a \] a *prima facie* valid patent right is invoked;
\[ b \] there are no reasonable grounds to contest the infringement; and
\[ c \] the seizure is justified in the light of the legitimate interests of all parties involved as well as the public interest.

Finally, it should be noted that the court may order the applicant to provide a guarantee in order to compensate the defendant for any possible damages in case the measures are revoked following opposition proceedings, or in case proceedings on the merits eventually result in a finding of non-infringement.

### iii Trial decision-maker

In ‘normal’ proceedings on the merits, the Brussels court of commerce consists of a panel of three judges, one professional judge with a legal background and two lay judges (usually without a technical background). In most other proceedings (accelerated proceedings on the merits, preliminary injunction proceedings and proceedings relating to a counterfeit seizure as discussed above) the cases are heard by one judge with a legal but not technical background. As most judges do not have a technical background, they can appoint independent experts in order to clarify technical aspects of certain validity or infringement issues. The reports filed by these experts are not binding, but usually are followed by the courts. Until some years ago, courts regularly appointed technical experts in patent cases, but this is less frequent, most probably as a consequence of the specialisation of the courts.

### iv Structure of the trial

*Inter partes* proceedings, which may be proceedings on the merits or preliminary injunction proceedings, are conducted mainly by the exchange of written briefs in which the parties set out their arguments and defences. This exchange is followed by a court hearing during which the parties will have the opportunity to present their arguments.

Proceeding are initiated by the service of a summons on the defendant. These summons must contain a statement of the claim. All arguments mentioned should be succinctly explained and may further be developed in later trial briefs. The claimant can indeed add additional claims or arguments in later trial briefs provided that they are based on the facts set out in the first summons. The first hearing is a mere case management hearing during which a
timetable for the exchange of trial briefs is agreed upon. As a general rule, the defendant will have the last word. At this first hearing another hearing is usually scheduled during which the court will hear the case.

In his or her trial briefs, the defendant will be able to raise all defences and file exhibits that support its position. Moreover, the defendant may bring a counterclaim against the claimant. It can do so, for example, to claim the invalidity of the patent in question. It should be noted, however, that under Belgian procedural law the counterclaim should not be linked as such to the writ of summons: the defendant is entitled to file a counterclaim that is not related to the claims developed in the writ of summons (e.g., a counterclaim for infringement based on another patent). The course of events to follow hinges on the proceedings themselves. The last trial briefs of both parties should contain all their arguments, relating to the main claim as well as to the counterclaim, if any.

Once the arguments have been exchanged in writing, the parties have the opportunity to defend their case orally during a hearing before the court. During this hearing, as a general rule no new arguments can be developed nor new exhibits filed. In Belgium, hearings are relatively short (three to six hours), and the parties concentrate on the essence of their claim or defence. It is important to note in this regard that the court only has an obligation to answer the arguments developed in the last trial briefs: arguments developed for the first time during the hearing, if allowed at all, should not be taken into account by the court in their decisions.

Patent cases in which the validity of a patent is challenged offer the patentee the opportunity to file auxiliary requests. Pursuant to such requests, the court may decide to uphold the patent in its present form or in amended form.

In Belgium, evidence in proceedings is usually presented by the production of documents. Similarly, witness testimony is usually produced by filing written statements, which are considered to have the same probative value as oral statements provided that some conditions are met. If the judges want to hear witnesses, a separate hearing has to be scheduled. While this is certainly an option, it rarely happens in patent cases.

v Infringement
Belgian courts will interpret the claims in conformity with Article 69 of the EPC and the Protocol on the Interpretation of Article 69 EPC. In this regard it can be noted that Belgian case law in general refers to the EPO case law. Besides literal infringement, Belgian courts can also establish infringement by equivalence, as discussed in Section IV.i.

It is furthermore generally accepted that the patentee’s actions during the patent’s prosecution can be a relevant factor in the assessment of the scope of patent protection.

vi Time to first-level decision
In general, normal proceedings on the merits (whether infringement or invalidity proceedings) usually take around 12 to 15 months. Complex proceedings may take longer.

Accelerated proceedings on the merits take less time, from a few weeks to eight months, depending on the complexity of the case. Patent cases usually take around six months to obtain a decision.

Preliminary injunction proceedings usually take around two to six months, once again depending on the complexity of the matter.

Finally, it should be noted that ex parte injunctions, which can be obtained in case of absolute urgency, can be obtained within a few days.

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vii Protective letters

Although protective letters are not regulated under Belgian law, such letters can be filed with the Brussels Commercial Court. The Brussels Bar organisation has issued some guidance in this regard, stating that a protective letter must be filed in a sealed envelope and accompanied by a letter explaining that it should only be opened and read by the judge if and when an application for a descriptive seizure is filed. The protective writ should contain arguments explaining why the court should not order descriptive or seizure measures, at least not before having heard the defendant.

The impact of this letter is difficult to assess as there is no published case law in this regard. However, it is usually recommended to file a protective letter as it shows that the alleged infringer did consider the patent at stake and explains why no infringement can be accepted.

viii Liability for enforcing a patent

Belgian procedural law provides that judicial decisions are enforced at the risk of the parties. If a first instance decision is enforced while an appeal is pending, the party that has enforced the decision will be liable for all damages if the decision is overturned in appeal (strict liability).

It is, however, a controversial topic whether the same goes for the enforcement of a preliminary injunction decision if the claimant loses in subsequent infringement proceedings on the merits. It should be noted in this regard that under Belgian law preliminary injunction proceedings are separate proceedings from the proceedings on the merits and are heard by different judges. When implementing Article 9.7 of the Enforcement Directive, the Belgian legislator has included some new rules that provide that the court ‘can’ order the patentee to pay damages following a counterfeit seizure or preliminary injunction if it is established afterwards that there was no (imminent) infringement of the patent at stake. It is, however, not clear whether this liability should be construed as a strict liability or a fault based liability (which is difficult to establish).

The case law in this respect is divided. The Brussels Court of Appeal recently rejected the theory of strict liability in these circumstances. Other case law argues that the principle of strict liability should be applied.

A preliminary question on the interpretation of Article 9.7 of the Enforcement Directive is currently pending before the CJEU (C-688/17). On 11 April 2019, advocate general G Pitruzzella delivered his opinion to the CJEU, in which he seemed to consider that the party against whom a preliminary injunction was wrongfully issued should in any case be compensated, which tends more towards the application of the principle of strict liability. We now have to wait and see whether the CJEU will follow this opinion and how Belgian courts will construe it.

ix Costs

The costs of patent infringement or invalidity proceedings mainly relate to the fees of the lawyer, the fees of the patent attorneys or other experts and the translation costs (as most clients require an English translation of all trial briefs). The total amount of these costs will vary significantly depending on, inter alia, the complexity of the case, the technology involved and the amount of patents invoked. For first instance proceedings on the merits, these costs may range from €80,000 to €300,000.
The fees for patent attorneys and other experts can, in principle, be recovered in full from the losing party. According to the leading case law of the Supreme Court, these costs are directly and closely linked to enforcement of the patent relied on and, therefore, eligible for reimbursement.

With regard to the lawyer’s fees, Belgian procedural law provides for reimbursement on a lump-sum basis (up to a maximum of €36,000), depending on the value of the case. The CJEU ruled in United Video Properties v. Telenet (C-57/15) that such cap is not per se prohibited, as long as the amounts in question cover at least a significant and appropriate portion of the reasonable costs actually incurred by the successful party. The impact of this decision is not clear yet, as some case law considers that, even if it was established that the capped amounts do not cover at least a significant and appropriate portion of the reasonable costs actually incurred by the successful party, the prevailing party could only bring a claim against the government for failure to implement in a timely manner Article 14 of the Enforcement Directive. A decision from the Supreme Court may clarify these issues.

IV SUBSTANTIVE LAW

This Section provides an analysis of the main substantive law aspects relating to patent infringement and validity in Belgium.

i Infringement

Under Article XI.29, §1 CEL, the following acts are considered a ‘direct’ patent infringement:

a the manufacturing, offering, bringing to market or use of a product that is the subject matter of a patent, or the importation or storage of a product for such purposes;

b the application of a patented process or the offering of a patented process for application on the Belgian territory; or

c the offering, bringing to market or use of a product directly obtained from a patented process, or the importation or storage of a product for such purposes.

In most cases Belgian courts assess (direct) patent infringement by comparing the (essential) features of the allegedly infringing process or product with those of the patent claims, leaving aside any (minor) differences between them. Article XI.28(2) CEL furthermore explicitly provides that in the event of a patent infringement, account shall be taken of any element equivalent to an element described in the claim.

Apart from direct infringement, Article XI.29, §2 CEL provides that the patentee can also initiate patent infringement proceedings in relation to alleged ‘indirect’ infringement (i.e., acts that contribute to a direct patent infringement by another party). As such, the patentee can enforce his or her patent against any person who, in Belgium offers or delivers, in or for his or her business, means relating to an essential element of the invention for the application of the patented invention in Belgium, to persons other than those who are entitled to apply the patented invention (for instance by way of a licence), provided that that person knows, or that it is evident considering the circumstances, that those means are suitable and intended for that application. However, if the means delivered or offered are products that are generally available in commerce, there will be no indirect infringement, unless the third party induces the party supplied to commit infringing acts.
ii Invalidity and other defences

In Belgian patent infringement proceedings, the alleged infringer will usually challenge the 
(prima facie) validity of the patent. Unlike Germany, Belgian courts can deal with invalidity 
defences in the same proceedings that involve the actual infringement. The alleged infringer 
will, in most cases, also dispute the infringement, arguing that the challenged acts cannot be 
considered an infringement under Article XI.29 CEL or invoking the several limitations or 
exemptions provided under Belgian patent law as well as in legislation. The main defences in 
this regard are the following:

a. The private use exemption, exempting acts that were carried out privately and for 
   non-commercial purposes;

b. The research exemption, exempting acts that are committed on or with the subject 
   matter of the patented invention for scientific purposes, or both, including acts for 
   mixed commercial and scientific purposes, provided that the scientific purposes prevail. 
   This exception extends not only to experiments involving the subject matter of the 
   invention, but also to the use of the patented invention as a tool to develop new 
   inventions. It should be noted that this exception is broader than in other European 
   jurisdictions;

c. The Bolar exemption, exempting acts, such as conducting the necessary studies and 
   trials with a view to obtaining a marketing authorisation for medicinal products using 
   the abridged procedure;

d. The exhaustion of the patent rights;

e. Competition law defences, such as a FRAND defence; and

f. Prior personal use: under Article XI.36 CEL the patent cannot be invoked if it is 
   established that the alleged infringer already used or possessed the patented invention 
   in Belgium before the date of application or the priority date.

In line with international agreements, Belgian patent law furthermore provides specific 
exemptions in relation to the use of inventions in pharmacies or on aeroplanes, etc.

Belgian case law also recognises a Gilette defence, which is a hybrid defence between 
an invalidity defence and a non-infringement defence. If an alleged infringer established that 
it had applied a product or a process that was already known in the prior art, or an obvious 
variant thereof, such use cannot be considered an infringement or otherwise the patent would 
be invalid as not novel or not inventive. This defence implies that the patent invoked should 
not even be considered.

Apart from other procedural arguments (e.g., lack of urgency in preliminary injunction 
proceedings), the alleged infringer may moreover argue that the action of the patentee is 
time-barred. Patent infringement actions are indeed subject to a specific five-year statute of 
limitations (Article XI.61 CEL). The limitation period is suspended by a summons, claim for 
penalties, or seizure.

Finally it should be noted that lack of knowledge (or alleged good faith) is never a 
defence against infringement. It could, however, be relevant in a damages claim.
V FINAL REMEDIES FOR INFRINGEMENT

If the court decides following proceedings on the merits that the patent has been infringed, an injunction will be ordered (or the preliminary injunction will be confirmed) to ensure that the infringer ceases and desists from (further) engaging in infringing activities (often under penalty of a certain amount in case of non-compliance) and other remedies may be granted (as provided in Articles XI.334 and XI.335 CEL).

It is generally accepted that an injunction should automatically be granted if infringement has been established. The wording of the injunction usually consists of general terms – *inter alia*, ‘the defendant is ordered to cease and desist infringement of the patent in suit’. The duration of the injunction is indefinite and will last until it has been lifted in appeal or until the patent expires, unless the parties reach an agreement. The territorial scope of an injunction is limited to Belgium.

Apart from an injunction, the patentee may also claim damages (except in cease-and-desist proceedings) and reimbursement of some costs, as discussed above. Compensation for patent infringement in Belgium is usually calculated on the basis of the following criteria:

a loss of profit (i.e., the profit that the patent holder would have made by selling his or her product); and

b the damage suffered (e.g., damage to his or her reputation and the cost of stopping the infringement, including the costs of patent attorneys). As already stated, the lawyer’s fees are capped under Belgian procedural law.

In case of bad faith, the court may order, as part of the compensation, the handover of profits derived from the infringing activities. It may also order the forfeiture of the products that have been manufactured in violation of the patent rights and of the tools that have been used for manufacturing the same.

The court may also order certain additional or ancillary remedies. As such the court may order the recall, removal or destruction of the infringing products and, if reasonable, of the materials used to manufacture the infringing products. The court can also impose an obligation to disclose the origin and distribution channels of the products, as well as order the publication of the decision (or a summary thereof).

VI OTHER TYPES OF PATENT PROCEEDING

Except for patent proceedings relating to infringement or invalidity, various other types of proceedings relating to patents may be initiated.

As such, Belgian procedural law allows a party to seek a declaratory judgment of non-infringement, provided that the proceedings are initiated in order to prevent that its rights are seriously jeopardised. The fact that proceedings in other jurisdictions have been initiated or that warning letters have been sent, is sufficient to initiate these proceedings. Based on this rule, it seems possible to obtain an *Arrow* declaration (i.e., a declaratory judgment of the court that a certain product was already known in the prior art that offers the opportunity to a party to already acquire more certainty about the infringing nature of its own product before entering the market, even though the patents of the patentee are not (all) granted in their final form yet).

Other proceedings relating to patents are, among others, proceedings relating to patent licenses, compulsory licences and challenges of ownership.
Finally, Belgian law also provides for possible proceedings against intermediaries whose services are used by a third party to infringe a patent, in line with Article 11 of the Enforcement Directive.

VII APPEAL

In proceedings on the merits and preliminary injunction proceedings, either party can appeal the decision within one month from service of the decision. This deadline is extended when the defendant is domiciled or resides abroad.

In the context of appeal proceedings, the court of appeal has the power to review the case fully, in fact as well as in law, but only insofar as appealed by the parties. The respondent in appeal can file a cross-appeal on points not appealed by the petitioner in appeal.

The court of appeal is not bound by the facts established in the first instance judgment that is under review, and may indeed also require additional evidence. The parties are allowed to raise new arguments. They may even extend the original claim or modify the legal basis of the claim (also, a counterclaim may be filed for the first time at the appellate level), provided that it is based on facts that are recited in the original writ of summons. The extension, modification or filing of a (counter)claim in appeal may, however, not prejudice the rights of defence of the other party (e.g., filing a totally new counterclaim in the last trial briefs in appeal).

As discussed above, the enforcement of measures granted pending an appeal is at the claimant’s risk: if the appeal is successful the party that has enforced measures granted in first instance will be liable for all damages resulting from the enforcement (strict liability).

The timelines depend on the type of proceedings. Appeal proceedings relating to preliminary injunction proceedings or accelerated proceedings can take up to one year, depending on the backlog of the court of appeal. Appeal proceedings relating to proceedings on the merits usually take up to two years.

The costs in appeal proceedings are similar to the proceedings in first instance, although they usually are a bit lower.

VIII THE YEAR IN REVIEW

The past year has confirmed the trend that patent owners are more willing to litigate before the Brussels courts, solely competent to hear patent cases in Belgium. More cases seem to be initiated each year, making Belgium’s patent litigation market increasingly active. This is certainly true for litigation relating to biosimilars.

This increase in litigation activity may also be the result of the fact that Belgian law provides for several possibilities to obtain ex parte measures and preliminary injunctions, which should be confirmed in later proceedings on the merits. As discussed in Section III. viii in relation to the liability for enforcing a patent it remains a hotly debated topic to what extent a patentee is liable if the patentee, who has obtained (ex parte or preliminary) measures, loses in subsequent proceedings on the merits, either because the patent at stake is invalidated, or because no infringement of the patent has been established. Case law and legal scholars remain divided in this respect and all look forward to some clarification by the CJEU in this regard.
IX OUTLOOK

As in most European jurisdictions, the hottest topic by far for Belgian patent law practitioners remains the possible arrival of the Unitary Patent and the Unified Patent Court, in particular in the light of the ongoing Brexit discussions. This could potentially change or even disrupt the Belgian patent litigation landscape, even though most practitioners no longer seem to believe it will happen any time soon.
Chapter 5

BRAZIL

Márcio Junqueira Leite and Victor Rawet Dotti

I OVERVIEW

Brazil has a civil law system. Its legal framework is composed of numerous ordinary laws, subject to the provisions of the Federal Constitution of 1988 (the Constitution). The protection and enforcement of patents is governed by the Industrial Property Law (Law 9279/96) (IP Law), a Federal Law. Brazil is a party to several international treaties, including:

a the Paris Convention for the Protection of Industrial Property;
b the Patent Cooperation Treaty; and

Besides the IP Law, civil patent actions must comply with the standards of the Brazilian Civil Procedure Code (Law 13.105/15), while criminal patent proceedings follow the Criminal Procedure Code (Decree Law No. 3.689/41).

The normative rulings of the Brazilian Industrial Property Office (BPTO), the governmental body in charge of granting patents in Brazil, are also relevant to patent litigation.

Brazil recognises arbitration proceedings, which are governed by the Brazilian Arbitration Law (Law 9307/96) and also by the Civil Procedure Code. Brazil is a signatory of the UN Convention on the Execution and Enforcement of Foreign Arbitral Awards 1958, subject to the recognition of foreign awards by the Superior Court of Justice.

All proceedings in Brazil (both court and administrative) must be carried out in Portuguese, which is Brazil’s official language. In arbitration proceedings, the parties can agree on a different language.

Although the law is the main source, Brazilian legal system also recognises jurisprudence, analogy, common customs and the general principles of law as methods of resolving disputes. The Brazilian Civil Procedure Code also allows parties to produce any evidence not forbidden by law.

II TYPES OF PATENT

The IP Law establishes types of patents:

a patents of invention; and
b utility models (industrial designs are not considered a patent in Brazil, but the litigation proceeding is quite similar).

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A patent of invention must fulfill the following requirements:

- novelty;
- inventive step or non-obviousness; and
- industrial utility.

Some subject matters are not considered as inventions (Article 10 of the IP Law), and others are not patentable (Article 18 of the IP Law).

The patent of invention will remain valid for a 20-year period, counted from the date of publication of the application. This period cannot be renewed. However, owing to the BPTO’s backlog, the IP Law states that the validity of a patent of invention will be effective for at least 10 years, irrespective of the date of filing.

The patent administrative proceeding is very time-consuming. Currently, the average time to obtain a patent is about 10 to 12 years from the filing date.

A utility model can be granted for an object of practical use, or part of it, if it:

- is susceptible to industrial application;
- has a new form or arrangement;
- involves an inventive act; and
- results in a functionality improvement in its use or manufacture.

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2 Article 10:

The following are not deemed to be inventions or utility models:

I. discoveries, scientific theories, and mathematical methods;
II. purely abstract concepts;
III. schemes, plans, principles or methods of a commercial, accounting, financial, educational, advertising, lottery or tax nature;
IV. literary, architectural, artistic and scientific works or any aesthetic creation;
V. computer programs per se;
VI. the presentation of information;
VII. game rules;
VIII. operating or surgical techniques and methods, as well as therapeutic or diagnostic methods, for use on the human or animal body; and
IX. all or a portion of natural living beings and biological materials, including the genome or germ plasm of any natural living being, when found in nature or isolated therefrom, and natural biological processes.

3 Article 18

The following are not patentable:

I. whatever is contrary to good morals, the community interest, public security, public order and health;
II. substances, matters, mixtures, elements or products of any kind, as well as the modification of their physical and chemical properties and the respective processes for obtaining or modifying them, whenever resulting from nuclear transformation thereof;
III. living beings, in whole or in part, except for transgenic microorganisms that meet the three patentability requirements – i.e., novelty, inventive activity and industrial use – pursuant to Article 8 hereof, and provided that they do not merely arise from discoveries.

Sole paragraph.

For the purposes of this law, transgenic micro-organisms are shall be taken as the organisms – other than plants or animals, in whole or in part – that display, due to direct human intervention in their genetic composition, a characteristic that is not usually attainable by the species under natural conditions.

4 See the BPTO proposal to overcome its backlog in patents.
Utility models remain valid for a 15-year period, counted from the date of publication of the application (this period is not renewable). The IP Law also states that the validity will never be less than seven years. The average time to attain a utility model is six to nine years.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

Patent infringement actions are filed before state courts. Some states (such as São Paulo and Rio de Janeiro) have lower civil courts and chambers specialised in corporate law, which also includes industrial property matters (such as patent litigation). Otherwise, the majority of judges are not familiar with these matters.

Patent invalidity actions are filed before federal courts, with the necessary participation of the BPTO as a defendant. For invalidity actions filed exclusively before the Federal Court of Rio de Janeiro, the court issued an Ordinance stating that BPTO will figure, in principle, as a defendant. This Ordinance has not yet been challenged at the Court of Appeals. The BPTO is a simple party at patent invalidity actions, decided exclusively by federal judges, with the support of court technical experts. The parties are also allowed to hire their own technical assistants.

Only lawyers duly registered before the Brazilian Bar Association can represent parties before the courts.

The following can bring an infringement action:

- the patent holder;
- an exclusive or non-exclusive licensee (with powers to enforce the patent);
- distributors (with specific powers to enforce the patent); and
- any party that has a procedural interest to defend the patent (such as a commercial representative, franchisee, etc.) and is formally invested by the patent holder with the powers to defend the patent.

Invalidity actions can be filed by the BPTO or any party with ‘lawful interest’, who is defined as any party affected by the exclusivity given by the patent.

i Statutes of limitation

The patent owner will be barred from collecting damages for its unwarranted exploitation for five years following the occurrence of the infringement act, by express disposition of the IP Law. With respect to an inhibitory order, the term will be 10 years upon the occurrence of the infringement act. In this case, there is divergence in the jurisprudence and doctrine. In certain cases, judges understand that the statute of limitations begins when the patent owner becomes aware of the infringement act. However, another doctrinal line understands that patent infringement is a constant act, so the statute of limitations period is continually renewed while illicit acts are practised, thus lengthening the end of the deadline for filing a lawsuit.

The Brazilian IP Law also establishes that a nullity action may be filed at any time during the validity of the patent.

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5 Ordinance JFRJ-POR-2018/00285
ii  Level of proof

The assessment of patent infringement is made through a technical comparison between the patent claims and the product, process or service put on the market by the infringer. The parties, their technical experts and the court expert present their technical reports. The judge is not obliged to follow the opinion of the court expert and can decide, based on other evidence attached to the records, as long as they explain the reasons for such adoption.

According to the most recent jurisprudence, the damages for patent violation are presumed (in re ipsa) once the patent violation is evidenced. The injured party will only need to prove the extent of the damages for the purposes of calculating the indemnity amount.

For granting of injunctions to compel the defendant to immediately cease exploitation of the patent, the patent owner must show the infringement beyond a reasonable doubt. Considering the technical aspects involved in patent infringement cases, injunctions are more difficult and granted only when the judge is convinced by the technical reports attached by the plaintiff.

In invalidity actions, the plaintiff must prove the lack of fulfilment of the legal requirements or the violation of any section of the IP Law by the patent. A court expert will be listened to, together with technical experts speaking on behalf of the parties. The BPTO will also bring its own technical opinion, based on its analysis during the administrative process.

There is no discovery in Brazil.

iii  Amendments

Any claims amendments must be filed before the request for examination. According to the IP Law and BPTO Resolutions, after the request for examination of a patent application, amendments (voluntary or not) to the claim set that broaden the scope of the claimed subject matter will not be accepted and that claim set will be totally refused, even if just one claim was broadened.

iv  Time and costs

Apart from the fees privately agreed between a party and its lawyer, the official fee for filing a lawsuit in Brazil varies from state to state and is around 1 per cent of the total value of the lawsuit, as indicated on the claimant’s complaint. There are minimum and maximum caps on this fee, independent of the percentage.

In addition, there is a mandatory loss of suit fee, payable to the winning party’s lawyer, fixed by the judge and ranged between 10 per cent and 20 per cent of the total value of the lawsuit.

There are additional non-regular expenses, for example, the remuneration of technical experts and the technical assistants hired privately by the parties to follow up on the production of the official expert evidence and to present an independent technical report, agreeing or disagreeing with the official report.

To conduct a patent infringement or invalidity lawsuit in Brazil, that runs through all instances, we estimate that around US$150,000 could be spent. This amount will vary depending on the complexity of the case value comprises the attorney fees, the court costs (as the official fee for filing a lawsuit, among other things) the official expert’s and one particular expert’s fees. If the case involves two or more technical evidences then the costs will be higher.

These fees (except for the fees privately agreed between a party and its lawyer) are recoverable from the losing party, at least in part. The judge will fix the sums due by the defeated party in the final decision.
Nowadays, as most courts have already adopted electronic proceeding, a lawsuit could last about one to two years to be judged in the first instance, depending on the level of proofs, the need to produce expert evidence, etc. At the court of appeals, the lawsuit could last another one to two years until a final decision. If the lawsuit is sent to the superior courts, the average time for a final judgment is about two to three years.

v Injunctions

There are two types of preliminary orders in Brazil: evidence-supported relief and urgent relief.

An urgent relief is granted to protect a right that must be fully confirmed by a final decision. The urgent relief can be requested in advance of or during the lawsuit. The urgency must be contemporary with the filing of the lawsuit. The plaintiff will only request the granting of the urgent relief, without indicating the basis for the main proceedings in the first instance. After that, if the urgent relief is granted in advance, the plaintiff will have 15 days from the granting to start main proceedings to confirm the measure. In addition, the defendant will have the same deadline to appeal against the decision. If the defendant files no appeal, the decision will become final and unappealable, and the urgent relief will stabilise and become definitive, without the need for the plaintiff to file for main proceedings.

To obtain an urgent relief during the lawsuit, the claimant must start the main proceeding and request the judge to anticipate some parts of the final decision. The requirements for an urgent relief are:

a unequivocal evidence of the likelihood of the rights invoked;
b grounded fear of irreparable, or hardly repairable, injury (urgency); and
c the injunction requested cannot be irreversible.

Preliminary injunctions can be granted without hearing the other party (ex parte) when there is a real risk that this party can frustrate the hearing, or in cases where urgency is so great that it is not possible to wait for a hearing of the other party. The judge has discretion to require the posting of a bond or another fiduciary guarantee as a condition for the injunction.

In patent invalidation actions, it is also possible to request a preliminary injunction order to stay the effects of the patent until the issuance of a final decision. However, injunctions are rarely granted in these actions, as the existence of the right relies on the patent owner, who followed all administrative procedures for granting of the patent by the BPTO. Therefore, the patent is prima facie valid.

Finally, there is the evidence-supported relief, granted by the judge regardless of urgency, based on the following hypothesis applied to patent infringement actions when:

a it is characterised as the abuse of the right of defence or manifest interest in extending the lawsuit by a party;
b the allegations are proved only with documents and there is an identical precedent (this is very hard to admit in patent infringement actions, owing to the need to produce independent technical evidences); and
c the initial petition is instructed with sufficient documentary evidence to prove the plaintiff’s right, and the defendant does not present other evidence capable of generating reasonable doubt in the judge’s conviction (this is also very hard to admit in patent infringement actions owing to the need to produce independent technical evidence).
Patent holders could face liability for threatening infringement proceedings if they falsely accuse the other party, bringing a lawsuit for an infringement that has not occurred, or even if they misrepresent the other party’s customers. In this case, an indemnification action could be filed.

**IV SUBSTANTIVE LAW**

i **Infringement**

The patent protection is determined by its claims, and interpreted based on the specifications and drawings. Those claims must:

- be substantiated in the specifications;
- characterise the particulars of the application; and
- define clearly and precisely the subject matter that is the object of the protection.

According to the IP Law, the patent owner has the right to prevent third parties from, without its consent, producing, using, offering for sale, selling or importing a product that reproduces the object of the patent and a process or a product directly obtained from a patented process. The patent holder also has the right to prevent third parties from contributing to infringing acts committed by others.

The assessment of patent infringement is usually made through a technical comparison between the patent claims and the product, process or service put on the market by the alleged infringer.

In those cases, the defendant should prove that they did not reproduce the object of the patent, taking into account all the independent claims and specifications of the patent. That argument should be confirmed by means of technical evidence stating that the defendant’s products or services do not reproduce the object of the plaintiff’s patent.

Criminal proceedings must be preceded by a preliminary search and seizure measure, conducted by two court experts who will prepare an expert report on the infringement. In such cases, the judge appoints a person to act as legal depositary of the products. If the report confirms the infringement, the judge will ratify the technical report and the patent owner can file a private criminal action (the public prosecutor cannot file criminal actions for patent infringement).

Under the Industrial Property Law (Law 9279/96), the penalties for criminal patent infringement include terms of imprisonment from one month up to one year, or fines, often replaced by alternative penalties, such as payment of low amounts or rendering of community services.

The crime of patent infringement is considered to have been committed when the infringement either:

- does not affect all the claims of the patent; or
- is restricted to the use of means equivalent to the object of the patent (doctrine of equivalents).6

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6 According to the ‘doctrine of equivalents’, an infringement may occur if some characteristic or element of a product or service used by an unauthorised third party can be considered technically equivalent to the characteristic or elements of the claims of the patent. Courts also recognise the doctrine of equivalents in civil actions, as the IP Law allows the party to pursue applicable civil actions.
ii Invalidity and other defences

Invalidity can be argued at any time as a defence strategy, and is a standard argument in patent infringement actions. However, the Superior Court of Justice held that the invalidity of a patent can only be argued through a specific invalidity action, to be filed before a federal court, with the necessary participation of the BPTO.

A patent granted in violation of any provision of the IP Law could be declared null and void. The most common grounds are:

- a non-fulfilment of the legal requirements: novelty; non-obviousness or industrial utility;
- b lack of invention or utility model: according to Article 10 of the IP Law (see Section II);
- c non-patentable subject matter: according to Article 18 of the IP Law (see Section II);
- d lack of clear and sufficient description: according to Article 24 of the IP Law – ‘The specification shall describe the subject matter in a clear and sufficient manner so as to enable a person skilled in the art to carry it out, and shall also indicate, to the extent applicable, the best mode of execution thereof’;
- e amendments after the examination: if the patent application is amended after the date of the examination request, it could be declared null (Article 32 of the IP Law); and
- f exhaustion: the patent owner cannot block third parties when the product manufactured according to the patented technology is placed directly on the domestic market by the patent owner, or with his or her consent (national exhaustion). Also, imports by third parties of a product manufactured under a process or product patent shall likewise be allowed, considering that it has been placed on the foreign market directly by the patent owner or with his or her consent (international exhaustion).

V FINAL REMEDIES FOR INFRINGEMENT

The patent holder can seek some specific measures or orders to cease its violation.

i Permanent injunction

If the patent infringement is duly proved through the evidence produced during the lawsuit, the judge can grant a permanent injunction prohibiting the defendant from continuing to practise infringement acts; and condemn him or her to pay an indemnification. The final injunction must refer specifically to the acts of infringement, but can also affect suppliers and distributors of the infringing product. The effects of an injunction are limited to the defendant in the lawsuit, and cannot be opposed to third parties. Brazilian courts only have jurisdiction in Brazil; hence, an injunction only has effect on the national territory, but can be extended to other jurisdictions through letters rogatory.

ii Monetary remedies

According to the IP Law, the compensation can be calculated upon three different bases:

- a the benefits that the patent infringer would have earned if the violation had not occurred;
- b the benefits that the patent infringer actually earned; or
- c the amount owed by the patent infringer to the patent holder under a hypothetical licence agreement signed between the parties.
The plaintiff can choose the most favourable criterion among the three above. Based on the chosen criterion, the judge will start a new phase of the lawsuit specifically to calculate the amount of the indemnification, and an accounting expert is often used to perform such analysis and calculations.

The plaintiff can also request indemnification for moral damages suffered by means of the patent infringement, when the plaintiff can prove that the company’s business or reputation has been adversely affected by the infringement acts. However, moral damages are rarely granted in patent infringement cases.

There are no punitive damages in Brazil.

The indemnification values on infringement actions vary according to the nature of the patent, the time of violation, the economic capacity of the parties and their performance in the market. Thus, it is very difficult to provide statistics about the damages in patent infringement actions. According to the Brazilian Civil Code, the indemnity amount is calculated according to the extent of the damages, so the indemnity amount may vary depending on the specific case.

### iii Delivery up or destruction of infringing goods

On infringement actions, the judge can also order the destruction of all illegal materials, matrices, moulds, negatives and other elements used to perpetrate the infringement acts. The judge can also order search and seizure measures to confiscate any machinery, equipment and device used for the infringement purposes.

### iv Recall order

The judge can decide that the infringing party must withdraw from marketing all products, moulds and machines that unduly reproduce the patent. A recall order can be issued as a preliminary injunction or as a final decision, and the judge can impose a daily fine or other supporting measures in the event of non-compliance with the order.

The decisions will become enforceable only after the due service of the defending party and the attachment of the summoning letter to the case records.

### VI OTHER TYPES OF PATENT PROCEEDING

#### i Compulsory licence

It is very difficult to obtain the compulsory licence of a patent in Brazil. Under the IP Law, to date, there has been only one case concerning an HIV drug. Compulsory licences can be applied against a patent granted in Brazil in the following events:

- **(a)** abusive exercise of the patent rights or abusive exercise of economic power duly evidenced and declared by an administrative or judicial decision;
- **(b)** lack of exploitation of the patent in Brazil (except in case of economical infeasibility to do so, a situation in which the importation of the product will be authorised);
- **(c)** commercialisation that is insufficient to meet market demand;
- **(d)** a situation involving dependent patents; and
- **(e)** national emergency or public interest events declared by the Brazilian government.

A compulsory licence based on items **(a)** to **(d)** can only be requested by one with a legitimate interest in its exploitation, and that shows technical and economic capacity to efficiently exploit the patent within the Brazilian market.

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The interested party must submit a request to the BPTO, by proposing the licence terms and conditions. The BPTO will notify the patent owner, who must reply within 60 days. Once all the information required for the analysis of the pleading is gathered by the BPTO, it will decide as to whether the compulsory licence should be established and, if the parties does not reach an agreement on the remuneration (royalties) owed to the patent owner, the BPTO will determine such amount based on the circumstances of the case and the economic value of the licence.

ii Border measures

According to the IP Law:

[T]he customs authorities, ex officio or at the request of an interested party, may seize, at the time of clearance, any products carrying falsified, altered or imitated marks or otherwise bearing a false indication of source.

Despite the express mention of trademarks, this Article is also applied to patents. Therefore, there is a legal basis to require a preliminary injunction seeking the blocking of products at the border.

The judge can send an official letter to the customs authorities to block the entry of counterfeit products in Brazil. In patent infringement cases, however, this analysis by Customs is difficult because it is very technical. The common procedure in Brazil is to send a sample of the product seized by Customs to the trademark or patent owner, to ascertain whether or not there is a violation of its rights.

VII APPEAL

The unsuccessful party has several routes of appeal according to the Brazilian Civil Procedure Code. Each kind of appeal has a particular object, which could be the reform, the invalidation, the clarification or the integration of a judicial decision. The most common appeals are as follows.

i Interlocutory appeal

These are filed against decisions that do not close the proceeding, but only decide on incidental issues (named interlocutory decisions), such as decisions that grant or deny preliminary injunction requests. The interlocutory appeal will be sent to the respective court of justice and the case records will be sent to a reporting judge. The appellant can ask for the granting of a staying effect. For this, the appellant must prove that the interlocutory decision could cause him or her serious damage, and demonstrate the urgency of the case. The merit of this sort of appeal is judged around six months from the filing date, but this deadline could be extended or reduced depending on the complexity of the case, the court in charge of analysing the appeal, etc. The official fee for filing an interlocutory appeal varies from state to state. In some locations, the filing is free of costs, but in other places, there are official fees that may vary from 1 per cent up to 5 per cent of the total value of the lawsuit.
ii Motions for clarification

These are filed against any decision rendered during the lawsuit, in any instance. This sort of appeal must have as its object the clarification of any addition, omission, lack of clarity or contradiction in the appealed decision. The same judge or court that rendered the challenged decision will judge the motion. The motion for clarification is judged more quickly, in about one to three months from the filing date, depending on the judge or court in charge of analysing it. There are no official fees to file a motion for clarification.

iii Appeals against a final first instance decision

These are filed seeking to overturn the final first instance decision. The appeal will be sent to the respective court of appeals, where it will be decided by three judges, and all the issues discussed at first instance could be re-analysed.

iv The appeals phase

In general, appeals have a staying effect. There are some exceptions, such as appeals against decisions that involve injunction reliefs, when the staying effect is not granted automatically. Nevertheless, the appellant can ask for the granting in a separate motion that will be examined by the reporting justice in charge of the appeal’s judgment.

The main object of an appeal is to reform or invalidate the first instance decision. It is possible to raise all the arguments on the merits already raised at first instance. The final decision is adopted by a majority vote. It is difficult to predict the exact time frame, but an appeal is usually judged in about one to two years from being received by the court of appeals. However, this deadline can be extended or reduced depending on the specific court and the complexity of the case.

New evidence can be brought at the appeal phase. However, some requirements must be fulfilled. For example:

- new evidence cannot be an indispensable document that should have been presented with the complaint;
- new evidence cannot be presented at the appeal phase as a bad faith strategy; and
- the counterparty must have the opportunity to access the new evidence and to present its manifestation about it.

Usually, at patent infringement or invalidity lawsuits, it is quite common to present a legal opinion drafted by a specialist in patents to strengthen the appellant arguments.

There are also the appeals against second instance decisions (named special appeals) that can be directed to the Superior Court of Justice (STJ) for judgment. Special appeals are only admitted when one of the following specific requirements are met:

- clear violation of federal law provisions; or
- different interpretations of the same issue by second instance courts.

Also, the special appeal cannot seek to discuss again the facts and evidence already presented and discussed at the lower instances (for this reason, it is difficult to admit the delivery of a special appeal to the STJ). If the special appeal is admitted, it will take two more years for the STJ to issue a decision. A final decision could last about two to three years to be issued.
VIII THE YEAR IN REVIEW

On April 2018, the Federal Court of Rio de Janeiro issued the Ordinance JFRJ-POR-2018/001100, which determined that on patent invalidity actions before that Court, the BPTO would no longer figure as a defendant, but as a ‘special assistant’. However, on September 2018, the Federal Court of Rio de Janeiro issued another Ordinance (JFRJ-POR-2018/00285) changing its position, determining that INPI will figure as a defendant on patent invalidity actions. This Ordinance remains in force to date.

The BPTO has entered into several multinational agreements to expedite the process of patent analysis in Brazil, called the Patent Prosecution Highway. Currently, the most relevant agreements were signed with the State Intellectual Property Office of China, the United States Patent and Trademark Office, the Danish Patent and Trademark Office and the Intellectual Property Office of the United Kingdom. This last one is limited to a total amount of 100 patent applications per year, for an initial period of two years, starting in the third quarter of 2018. Each patent office will be exclusively responsible to examine the applications according to the applicable law, regulations and technical criteria.

IX OUTLOOK

In July 2019, the Ministry of Finance announced measures to reduce the patent backlog by 80 per cent by 2021, and to reduce the waiting time for granting a patent registration by the BPTO from 11 to two years. To this end, two new Resolutions (Resolutions Nos. 240/2019 and 241/2019) were published.

Resolution No. 240/2019 of 1 August 2019 disciplines the examination of patent applications that have been filed a long time ago, but do not have searches about priorities performed by patent offices in other countries. In such cases, a preliminary search report will be issued by the BPTO and the applicant will have the opportunity to amend the application regarding the patentability requirements, prior to the start of the technical examination. Upon the submission of the response, the BPTO will proceed with the substantive examination of the application, without conducting additional priority searches.

Resolution 241/2019 of 22 July 2019 regulates the initiative to take advantage of the results of searches carried out by patent offices in other countries. The BPTO will publish a preliminary requirement indicating the existence of search reports issued abroad for cases equivalent to the Brazilian application, and will request the applicant to adapt its application proving the novelty, non-obviousness and industrial utility of the invention.

The plan to reduce the patent backlog does not include applications that: (1) have already been submitted to the technical examination by the BPTO; (2) have received subsidies from third parties or from the National Health Surveillance Agency (ANVISA); (3) have a priority examination requirement; or (4) were filed after 31 December 2016.

The BPTO has also published a public consultation about a proposal to change the biotechnology patent application examination guidelines. The changes are mainly related to the technical subsidies necessary for the examination of such patent applications.
Chapter 6

CANADA

Steven B Garland, Jeremy E Want and Daniel J Hnatchuk

I OVERVIEW

As a result of recent developments in patent legislation, jurisprudence and improved court procedures designed to facilitate fast and effective litigation, Canada has been receiving positive international attention from patent owners and practitioners.

Canadian courts have recognised the need to create an environment for timely and efficient disposition of civil litigation. Over the past several years, the Federal Court, where most patent proceedings are commenced, has implemented a number of procedures to permit litigants to achieve quick and cost-effective results. This has included implementing court procedures that assist in having matters progress to trial in an economical and expeditious manner, including proactive case management and imposing limitations on the discovery process. Additionally, the Court has also adopted summary trial provisions to facilitate the summary disposition of proceedings on issues that do not require a full trial on the merits.

There are also several other features of the legal system in Canada that make it an attractive jurisdiction for patent litigation, including:

- the availability of flexible remedies, including damages, disgorgement of a defendant’s profits and injunctive relief;
- costs of the proceeding, namely a percentage of lawyers’ fees and reimbursement of all reasonable disbursements (e.g., expert fees), are typically awarded to the successful party;
- because the Federal Court has national jurisdiction, issues such as forum shopping typically do not arise in Canada; and
- in the Federal Court, jury trials are not available and as such patent actions are decided by the trial judge alone.

II TYPES OF PATENT

The Canadian Patent Act provides the ability to obtain a patent, which provides protection for an invention across Canada. Canada does not have other forms of protection, such as regional patents, utility models or short-term patents.

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1 Steven B Garland and Jeremy E Want are partners, and Daniel J Hnatchuk is an associate at Smart & Biggar. The assistance Bram Schwartz, Erin Stuart and Brendan Peters, articling students, Smart & Biggar, in the preparation of this article is acknowledged with appreciation.

2 Patent Act, RSC 1985, c P-4, Section 42.
A patent is obtained by filing a patent application with the Canadian Intellectual Property Office (CIPO). The patent application is examined by CIPO, and if it is determined that the requirements of the Act have been met, the application issues to patent.

A Canadian patent has a term of 20 years from the filing date. Historically, Canada did not have a patent term extension regime. However, as discussed in greater detail below, Canada has recently implemented a certificate of supplementary protection (CSP) regime for new pharmaceutical products that provides a *sui generis* term of protection for up to two years beyond the expiry of relevant patent.

### III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

#### i Patent proceedings before Canadian courts

**Canadian court systems**

There are two separate court systems in Canada: a Federal Court system with national jurisdiction and a provincial court system in each of the country’s 13 provinces and territories. A patentee can commence an action for patent infringement in either the Federal Court or the appropriate provincial or territorial court. However, most patent infringement actions are brought in the Federal Court because it has national jurisdiction and is more experienced with patent matters. Additionally, the Federal Court has exclusive jurisdiction to expunge a patent (invalidate a patent *in rem*). Thus, a patent expungement proceeding can only be brought in the Federal Court.

**Court procedure in Canada**

**Pleadings**

An action is commenced by the plaintiff filing a statement of claim, setting out the material facts that support the action and the relief claimed. In response, the defendant must file a statement of defence. A reply may be filed by the plaintiff in response to the statement of defence. In the statement of defence and reply, the party must admit or deny the allegations set out by the other party and plead any additional relevant material facts upon which the party intends to rely.

The pleadings also typically include a counterclaim by the defendant (e.g., a claim seeking to expunge the patent), and may also include a cross-claim between defendants or a third-party claim by the defendant against a party not previously named in the proceeding.

**Discovery**

Evidence relevant to patent proceeding is obtained through the discovery process. The first step is documentary discovery, wherein each party must list all relevant documents in its possession, power or control. All non-privileged documents must be produced to all adverse parties.

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3 ibid, Section 44.
4 ibid, Sections 115 and 116.
5 ibid, Sections 54(1) and 54(2).
6 ibid, Section 60.
7 Federal Courts Act, RSC 1985, c F-7, Section 20.
After documentary discovery, each party is permitted to conduct an oral examination of a representative of each adverse party. The representative must answer any relevant and proper question based upon the information of the party. In the Federal Court, a party that is adverse to the patentee is also permitted to examine the inventors of the patent.

**Trial**

All patent actions in Canada are heard and decided by a judge alone.

The plaintiff bears the onus of proving infringement. However, a patent is *prima facie* valid so the defendant bears the onus of demonstrating invalidity. The standard of proof in patent proceedings in Canada is a balance of probabilities.

Evidence is submitted at trial by testimony of witnesses, by the admission of documents or by reading in the testimony of an adverse party on oral discovery. Expert evidence is admissible in a patent proceeding in Canada provided that the party who calls the expert produces an expert report setting out the expert’s evidence in advance of trial.

**Interim and interlocutory injunctions and stays**

In Canada, interim or interlocutory injunctions are available. A tripartite test must be satisfied to obtain such an injunction, namely:

- Is there a serious question to be tried on a preliminary assessment of the merits of the case?
- Will the plaintiff suffer irreparable harm if the injunction is refused?
- Considering all of the circumstances, does the balance of convenience favour the granting of an injunction?

The second element of the test, namely irreparable harm, can be difficult to establish in patent proceedings given that ‘irreparable’ harm is harm that cannot be quantified in monetary terms or which cannot be cured.

Stays of proceedings are also available in Canada, and are subject to the same tripartite test as applicable to interim or interlocutory injunctions.

**Standing**

**Patent infringement proceeding**

In Canada, a patent infringement action can be commenced by the patentee or any person ‘claiming under the patentee’. This has been interpreted broadly to include anyone that can trace an express or implied interest under the patent to the patentee, which includes exclusive, non-exclusive and implied licensees as well as distributors.
Patent invalidity proceedings
In a patent infringement action, a defendant will typically attack the validity of the patent as part of its defence, and if the action is in the Federal Court, the defendant will also typically counterclaim seeking to expunge the patent.

The Patent Act also provides the ability for any interested party to commence an action to expunge a patent in the Federal Court. The threshold to qualify as an interested party is low as the term has been held to have a broad definition, including anyone in competition with the patentee or who has received a cease-and-desist letter from the patentee.

Limitation periods
In Canada, remedies are only available for infringing activities that occur within a six-year limitation period prior to the commencement of the action.

Timing and costs of patent proceedings
Patent proceedings in Canadian courts typically take between two and four years from the commencement of the proceeding to judgment, and cost C$700,000 million to C$1 million or more depending on the complexity and number of issues in the proceeding.

Summary disposition
The Federal Courts Rules include summary trial and summary judgment motion provisions that aim to facilitate the summary disposition of proceedings on issues that do not require a full trial on the merits. These may be particularly appropriate in cases where the cost in taking the matter to trial as a regular action could well exceed any monetary award that would have accrued, and where the parties have worked together to narrow the issues in dispute.

There are also summary default proceedings that are available should a defendant not respond to the commencement of an action within the time limits provided.

ii Threats of patent proceedings
The Patent Act does not include any provisions that limit how a patentee may enforce its patent (other than the abuse provisions discussed in Section III.iii, 'Abuse Proceedings'). That said, provisions contained in the Competition Act and the unfair competition provisions in

15 Patent Act, RSC 1985, c P-4, Section 60(1).
17 Patent Act, RSC 1985, c P-4, Sections 55.01 and 78.2. For patents issued from applications filed prior to 1 October 1989, the limitation period may be governed by the relevant legislation in the province in which the infringing activities take place. These limitation periods range from two to six years depending upon the province. If the infringing activities take place in more than one province, a six-year federal limitation period applies (Federal Courts Act, RSC 1985, c F-7, Section 39).
20 Competition Act, RSC 1985, c C-34, Sections 52, 74.01(1).
the Trademarks Act can be used to protect against unfair competition-type behaviour by a patent owner, including making unjustified allegations of patent infringement to the public or third parties, such as to customers of a competitor.

### iii Post-grant proceedings before the Canadian Patent Office

#### Re-examination

Pursuant to the Patent Act, any person, including the patentee, may request a re-examination of an issued patent based upon prior art consisting of patents, published applications and printed publications. A re-examination has two stages. First, the re-examination board determines whether a substantial new question of patentability affecting any claim of the patent in issue has been raised in the re-examination request. If it is decided that a substantial new question has not been raised, the board will notify the requesting party, and the board's decision is final and is not subject to appeal or review by a court.

If the board decides that the re-examination request raises a substantial new question of patentability, the patentee is notified and has an opportunity to make submissions, including proposing amendments to the claims or new claims for the patent (provided the proposed amendment or new claim does not enlarge the scope of the patent).

The re-examination board then renders a decision as to patentability of the claims in issue. The board has the power to cancel any unpatentable claim or incorporate in the patent any proposed amended or new claim submitted by the patentee. The board’s decision can be appealed by the patentee to the Federal Court. A third party requesting re-examination has no right to be part of the second stage of the re-examination process or to appeal the re-examination board’s decision.

#### Abuse proceedings

At any time three years after the grant of the patent, any person interested may apply to the Commissioner of Patents alleging that there has been abuse of the exclusive rights granted by the patent, and request relief. The remedies available in such a proceeding include the grant of a compulsory licence or revocation of the patent. The exclusive rights under a patent are

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22 See, for example, E Mishan & Sons v. Superdek, 2016 FC 986 and Escalibre Oil Tools Ltd v. Advantage Products Inc, 2016 FC 1279.
25 ibid, Sections 48.2 and 48.3(2).
26 ibid, Section 48.3.
27 ibid, Section 48.4.
28 ibid, Section 48.5; Genencor International Inc v. Canada (Commissioner of Patents), 2008 FC 608 at Paragraph 48; Newco Tank Corp v. Canada (Attorney General), 2015 FCA 47 at Paragraph 12.
deemed to be abused in certain circumstances enumerated in the Patent Act, although abuse may not be restricted to only those grounds.\textsuperscript{32} The abuse provisions have not been extensively used in Canada.

IV SUBSTANTIVE LAW

i Patent construction

In Canada, the scope of the exclusive rights granted by a patent is defined by the claims.\textsuperscript{33} The claims of a Canadian patent are construed purposively, not in a purely literal fashion.\textsuperscript{34} Purposive construction involves identification of the particular words or phrases in the claims that describe what the inventor considered to be the essential elements of the invention.\textsuperscript{35}

A Canadian patent is construed based upon a review of the whole patent specification through the eyes of a 'person skilled in the art'.\textsuperscript{36} The person skilled in the art may include a combination of the collective expertise of a number of skilled workers, scientists and technicians.\textsuperscript{37}

The doctrine of file wrapper estoppel formerly did not apply in Canada as the Supreme Court of Canada had expressly stated that that Canadian or foreign file wrappers are inadmissible to construe a Canadian patent.\textsuperscript{38} However, recent amendments to the Patent Act have set out that written communications between the applicant for a patent or a patentee and the Patent Office or member of a patent re-examination board, which are prepared in respect of the prosecution of the application for the patent, a disclaimer made in respect of the patent, or a request for re-examination or a re-examination proceeding, are admissible into evidence to rebut any representation made by the patentee in an action or proceeding as to the construction of a claim in the patent. This provision has not yet been judicially construed so its full scope and effect is yet to be determined. Additionally, these amendments do not appear to pertain to foreign file wrappers.

\textsuperscript{32} ibid, s. 65(2); and Torpharm Inc v. Canada (Commissioner of Patents), 2004 FC 673 at Paragraph 38; but see Torpharm Inc v. Merck & Co (2000), 9 CPR (4th) 520 at 539 (Pat App Bd).
\textsuperscript{33} Free World Trust v. Électro Santé Inc, 2000 SCC 66 at Paragraph 33.
\textsuperscript{34} Whirlpool Corp v. Camco Inc, 2000 SCC 67 at Paragraphs 42–50.
\textsuperscript{35} ibid at Paragraphs 45–48.
\textsuperscript{36} ibid at Paragraphs 48–49.
\textsuperscript{38} Free World Trust v. Électro Santé Inc, 2000 SCC 66 at Paragraphs 64 and 66. However, recently several Federal Court decisions have drawn a distinction between statements or admissions made in the course of patent prosecution and a change to a claim as a result of an objection from CIPO, which was characterised as an objective fact that can be properly considered when construing a claim. See: Distrimedic v. Dispill, 2013 FC 1043 at Paragraphs 209–210; Eli Lilly Canada Inc v. Mylan Pharmaceuticals ULC, 2015 FC 125 at Paragraph 154. It remains to be seen whether this approach will be approved by the Federal Court of Appeal or Supreme Court of Canada.
Infringement

Direct infringement

The Patent Act does not define infringement, but does provide the patentee with ‘the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used’. Canadian courts have held that any act, direct or indirect, that interferes in whole or in part with the full enjoyment of the exclusive rights granted to the patentee during the term of the patent constitutes an infringement.

There is no infringement in Canada if an essential element of the patent claim is different or omitted. However, there may be infringement if non-essential claim elements are substituted or omitted. For infringement to be established in circumstances where a variant from the claimed invention is incorporated, it must be shown that:

a. the variant has no material effect upon the way the invention works, namely, the variant performs substantially the same function, in substantially the same way, to obtain substantially the same result;

b. at the date of publication of the patent, it would have been obvious to a person skilled in the art that such a variant would have no material effect on the way the invention worked; and

c. a person skilled in the art would have understood from the language of the claim that the patentee did not intend that strict compliance was an essential requirement of the invention such that the immaterial variant of interest was not intended to be excluded from the claim.

Inducing infringement (indirect infringement)

Although Canada does not have a doctrine of contributory infringement per se, a person may be liable for infringement for inducing or procuring another person to infringe the patent. Three elements are required to establish liability, namely:

a. an actual act of infringement was completed by a direct infringer;

b. the completed act of infringement was influenced by the alleged inducer, to the point where without such influence, infringement by the direct infringer would not otherwise have taken place; and

c. the alleged inducer knowingly exercised the influence, such that the alleged inducer knew that the influence would result in the completion of the act of infringement.

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39 Patent Act, RSC 1985, c P-4, Section 42.
43 AB Hassle v. Canada (Minister of National Health and Welfare), 2002 FCA 421 at Paragraph 17, leave to appeal to SCC refused [2002] SCCA No 531; MacLennan v. Gilbert Inc, 2008 FCA 35 at Paragraph 13; Weatherford Canada Ltd v. Corlac Inc, 2011 FCA 228 at Paragraph 162, leave to appeal to SCC refused, 34459 (29 March 2012). However, the inducer is not required to have knowledge of the patent to be liable for inducing infringement, see Bauer Hockey Corp v. Easton Sports Canada Inc, 2010 FC 361 at Paragraphs 197–203, aff’d without comment on this issue 2011 FCA 83.
**Director and officer liability**

In Canada, officers and directors of a company are typically not personally liable for the company’s infringing activities. That said, personal liability can be established if a director or an officer engages in activities that constituted a deliberate, wilful and knowing pursuit of a course of conduct that was likely to constitute infringement or reflected an indifference to the risk of it.44 Canadian courts have stated that personal liability can be established when the behaviour of the officer or director is itself tortious or when the actions serve a personal interest rather than that of the corporation.45

### iii Invalidity and other defences

#### Invalidity

**Subject matter**

Pursuant to the Patent Act, a patent may be granted for any invention, defined as ‘any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter’.46 Mere scientific principles or abstract theorems are not patentable.47 Although a mere discovery, for example a scientific observation, is not patentable, a new and useful application of a discovery is an invention.48

#### Novelty

As referenced above, the definition of ‘invention’ in the Patent Act requires the subject matter to be new (referred to as ‘novelty’). When the scope of a patent claim encompasses subject matter within the relevant prior art, the claim is invalid as being anticipated. Pursuant to the Patent Act, a claimed invention is new unless:

- the invention is disclosed in a Canadian patent application that has an earlier effective filing date (either the actual Canadian filing date49 or the convention priority date, if applicable);
- the invention was, more than one year before the Canadian filing date, disclosed by the applicant, or a person who obtained knowledge directly or indirectly from the applicant, in such a manner that it became available to the public in Canada or elsewhere; or
- the invention was, before the Canadian filing date (or the convention priority date, if applicable), disclosed by any third party in such a manner that it became available to the public in Canada or elsewhere.50

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47 *ibid*, Section 27(8); *Riello Canadian Inc v. Lambert* (1986), 9 CPR (3d) 324 at 338 (FCTD).

48 *Calgon Carbon Corp v. North Bay (City)*, 2005 FCA 410 at Paragraphs 9–19, leave to appeal to SCC refused, 31306 (30 March 2006).

49 ‘Canadian filing date’ is the date a Canadian patent application was filed with the Canadian Patent Office or the date of filing a PCT patent application.

Anticipation can be based upon a prior publication, including a prior patent or patent application, as well as a prior public use or sale of the claimed invention. It is impermissible to rely upon multiple pieces of prior art (referred to as ‘mosaicing’) to establish lack of novelty.\(^{51}\)

The legal test for lack of novelty is a rigorous one.\(^{52}\) Two requirements must be satisfied for a patent claim to be invalidated on the basis of anticipation, namely prior disclosure and enablement.\(^{53}\) For the prior disclosure requirement, the prior art must disclose subject matter that, if performed, would necessarily result in the infringement of the patent. For the enablement requirement, a person skilled in the art must be able to perform the invention, which may include trial and error experimentation.\(^{54}\)

**Obviousness**

In Canada, a patent cannot be granted for subject matter that lacks inventive ingenuity (inventive step) or is obvious. In assessing obviousness, the Supreme Court of Canada has adopted the four-step approach of the House of Lords in the *Windsurfing* case,\(^{55}\) namely:

\(\begin{align*}
\text{a} & \quad \text{identify the notional person skilled in the art and the relevant common general knowledge of that person;} \\
\text{b} & \quad \text{identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;} \\
\text{c} & \quad \text{identify what, if any, differences exist between the matter cited as forming part of the state of the art and the inventive concept of the claim or the claim as construed; and} \\
\text{d} & \quad \text{viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the person skilled in the art or do they require any degree of invention?}\end{align*}\)

The Supreme Court of Canada has also stated that in the fourth step of the analysis for obviousness, an ‘obvious to try’ test may be appropriate, for example, in fields where advances are often won by experimentation.\(^{57}\) The Federal Court of Appeal has clarified that the mere possibility that something might turn up or is ‘worth a try’ is not sufficient to satisfy the ‘obvious to try’ test.\(^{58}\)

\begin{itemize}
\item \(^{51}\) 671905 *Alberta Inc v. Q'Max Solutions Inc*, 2003 FCA 241 at Paragraph 43.
\item \(^{53}\) *Sanofi-Synthelabo Canada Inc v. Apotex Inc*, 2008 SCC 61 at Paragraphs 23–30; *Abbott Laboratories v. Canada (Minister of Health)*, 2008 FC 1359 at Paragraph 75, aff’d 2009 FCA 94.
\item \(^{54}\) *Sanofi-Synthelabo Canada Inc v. Apotex Inc*, 2008 SCC 61 at Paragraphs 26–27.
\item \(^{55}\) *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd* (1984), [1985] RPC 59 (Eng CA).
\item \(^{56}\) *Sanofi-Synthelabo Canada Inc v. Apotex Inc*, 2008 SCC 61 at Paragraph 67.
\item \(^{57}\) ibid at Paragraphs 67–68.
\end{itemize}
Utility

The definition of ‘invention’ includes the requirement that the invention be ‘useful’, and thus it must have utility. The Patent Act does not prescribe the degree of usefulness required but Canadian courts have held that a scintilla of utility will suffice.

The Supreme Court of Canada has recently held that a single use related to the nature of the subject matter as claimed is sufficient to satisfy the utility requirement. The Court also set out a two-step approach for assessing whether a patent discloses an invention with sufficient utility. First, the court must identify the subject matter of the invention as claimed in the patent. Second, the court must ask whether that subject matter is useful? is it capable of a practical purpose (i.e., an actual result)? Additionally, utility of an invention must, as of the Canadian filing date, either be demonstrated or be soundly predicted based on the information and expertise available at that time. The doctrine of sound prediction is typically used when a class of compounds are covered by the patent claims but only a few members within the class are shown to work in the patent disclosure or as of the Canadian filing date. To be able to rely upon a sound prediction of utility, a three-part test applies, namely:

- there must be a factual basis for the prediction;
- the inventor must have at the date of the patent application an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis; and
- there must be proper disclosure.

There is some uncertainty in the Canadian jurisprudence at the moment as to what the proper disclosure requirement entails, and whether it requires the factual basis and sound line of reasoning to be disclosed in the patent specification. Recent cases have held that when the sound prediction relies on data outside the common general knowledge of the skilled person, disclosure of this factual basis in the specification may be required to support the utility of the invention.

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59 Patent Act, RSC 1985, c P-4, Section 2 (invention); Apotex v. Wellcome Foundation Ltd, 2002 SCC 77 at Paragraph 56.
61 ibid. at Paragraph 54.
63 Apotex Inc v. Wellcome Foundation Ltd, 2002 SCC 77 (SCC) at Paragraph 70.
The Federal Court had developed a promise doctrine for the measure of utility where, in the specification of the patent set out an explicit ‘promise’ of a specific result, utility was measured against that promise.\(^{66}\) However, the Supreme Court of Canada has recently stated that the ‘promise of the patent’ doctrine is not appropriate under Canadian law.\(^{67}\)

**Double patenting**

Double patenting is not contained in the Patent Act but is a common law doctrine to prevent the improper extension or ‘evergreening’ of the term of a patent by a series of patents for the same invention.\(^{68}\) The doctrine is used in situations where the earlier patent is not citable as prior art for anticipation or obviousness.

The Canadian jurisprudence has recognised two categories of double patenting. The first category encompasses two patents that have identical or conterminous claims. The second category relates to where the claims are not identical or conterminous, but where the claims of the second patent are not patentably distinct from the first (commonly referred to as ‘obviousness double patenting’).\(^{69}\)

**Other validity attacks**

In addition to novelty, obviousness, utility and double patenting, there are a number of other grounds upon which a Canadian patent can be invalidated, including insufficiency of the specification,\(^{70}\) ambiguity of the disclosure or of the claims,\(^{71}\) and claims broader than the invention made or disclosed.\(^{72}\) A patent may also be invalidated if a material allegation in the petition is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, provided the omission or addition is wilfully made for the purpose of misleading.\(^{73}\)


\(^{68}\) *Pharmascience Inc v. Sanofi-Aventis Canada Inc*, 2006 FCA 229 at Paragraphs 67–73, leave to appeal to SCC refused.


\(^{71}\) *Mobil Oil Corp v. Hercules Canada Inc* (1995), 63 CPR (3d) 473 at 483–484 (FCA).


\(^{73}\) Pat End Act, RSC 1985, c P-4, Section 53(1).
Other defences

Experimentation

It has been held in Canada that use of a patented invention for non-commercial experiments to determine if the patented article can be manufactured in accordance with the patent or improved upon does not constitute infringement.\(^\text{74}\)

In addition, Section 55.2(1) of the Patent Act provides that it is not an infringement to make, construct, use or sell a patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada or any other country that regulates the manufacture, construction, use or sale of the product.\(^\text{75}\) Section 55.3(1) of the Patent Act further provides that an act committed for the purpose of experimentation relating to the subject-matter of a patent is not an infringement of the patent.\(^\text{76}\)

Prior acquisition or prior user rights

Section 56 of the Patent Act\(^\text{77}\) was recently amended to provide that any person who, before the ‘relevant date’,\(^\text{78}\) has, in good faith, committed an act that would otherwise constitute an infringement of the patent in respect of that claim, or made serious and effective preparations to commit such an act is permitted to commit that act, without being liable to the patentee. Previously Section 56 more narrowly stated that any person who, before the ‘relevant date’ has purchased, constructed or acquired the subject matter defined by the claim of a patent, is permitted to use and sell to others the specific article, machine, manufacture or composition of matter so purchased, constructed or acquired, without being liable to the patentee. The previous exception applied only to the ‘specific article, machine, manufacture or composition of matter’ previously purchased, constructed or acquired, although the right of ‘use’ extended to any form of the invention, including the right to use and sell things produced using the article. Additional amendments to Section 56 are discussed in further detail in Section VIII.i below.


\(^{75}\) Patent Act, RSC 1985, c P-4, Section 55.2(1). It is uncertain as to whether this provision would be limited to the pharmaceutical patents in view of the related Patented Medicines Notice of Compliance Regulations that were introduced at the same time as Section 55.2(1).

\(^{76}\) Patent Act, RSC 1985, c P-4, Section 55.3(1). It is left open for future regulations what circumstances and factors the court may consider, must consider or is not permitted to consider in determining whether an act is, or is not, committed for the purpose set out in this section.

\(^{77}\) Patent Act, RSC 1985, c P-4, Section 56.

\(^{78}\) ibid, Sections 56(2), (3), (4): The ‘relevant date’ depends on the filing date of the patent application, namely:

- if filed before 1 October 1989: the relevant date = date the patent was granted;
- if filed on or after 1 October 1989 but before 1 October 1996: the relevant date = the date the application was laid open; and
- if filed on or after 1 October 1996: the relevant date = Canadian filing date (or the convention priority date, if applicable).
Licence or exhaustion

A valid licence granted by the patentee to the defendant to engage in the acts alleged to infringe the patent is a complete defence to a patent infringement claim.\(^{79}\) However, a licence will not provide a defence for any activities that extend beyond the terms of the agreement.\(^{80}\)

The sale of a patented article to a purchaser gives the purchaser an implied licence to use, sell or deal with the patented article as he or she pleases. Any restrictions that a patentee wishes to impose upon a purchaser must be brought to the attention of the purchaser when the patented article is acquired.\(^{81}\)

Unfair competition

In Canada, the Competition Act\(^ {82}\) regulates anticompetitive behaviour and has provisions that may impose limitations on the exercise of certain patent rights. The Federal Court has allowed allegations relating to violations of the Competition Act to be raised as a defence in patent infringement actions, provided there is a direct link or nexus between the alleged unlawful conduct and the patent right at issue in the action.\(^ {83}\) A defendant or third party may also be able to assert causes of action against a patentee on the basis of alleged anticompetitive behaviour. To date, there have not been any cases in Canada where such a defence or cause of action has been successful at trial.\(^ {84}\)

V FINAL REMEDIES FOR INFRINGEMENT

i Monetary remedies

In Canada, an infringer of a patent is liable for any damages sustained by the patentee by reason of the infringement.\(^ {85}\) Alternatively, a patentee may be permitted to elect an accounting of the defendant’s profits made as a result the infringing activity.\(^ {86}\)

Damages are calculated based on the principle of restoration, namely to restore the patentee to the position it would have been in but for the infringement.\(^ {87}\) The jurisprudence has established two measures of damages, namely damages based on the plaintiff’s lost profits

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\(^ {79}\) An expired licence will not provide a defence: *Lubrizol Corp v. Imperial Oil Ltd* (1990), 33 CPR (3d) 1 (FCTD) at 10, rev’d on other grounds, but aff’d on this issue (1992), 45 CPR (3d) 1 at 3 (FCA).


\(^ {82}\) Competition Act, RSC 1985, c C-34.


\(^ {85}\) Patent Act, RSC 1985, c P-4, Section 55.

\(^ {86}\) Ibid, Section 57.

or a reasonable royalty. In contrast, an accounting of the defendant’s profits is to be a measure of the value of the invention through a disgorgement of the profits made by the infringer in using the patent invention. However, an accounting of profits is a discretionary remedy and therefore is not granted as of right.

A patentee is also entitled to ‘reasonable compensation’ for any damages sustained as a result of acts between the date the patent application became open to the inspection of the public until the grant of the patent that would have constituted an infringement if the patent had been granted. Reasonable compensation is not the equivalent of damages, and thus does not include lost profits. Reasonable compensation is typically calculated as a reasonable royalty.

Generally speaking, both pre- and post-judgment interest is awarded on monetary awards by Canadian courts.

ii Punitive or exemplary damages

Punitive or exemplary damages are available in Canada but are only awarded in exceptional circumstances, namely for high-handed, malicious, arbitrary or highly reprehensible conduct that departs to a marked degree from ordinary standards of decent behaviour. Knowingly infringing a patent by itself is typically insufficient for entitlement to punitive or exemplary damages.

iii Permanent injunction and delivery up or destruction of infringing articles

Although a successful patentee is typically awarded a permanent injunction restraining the defendant from future infringing activities, as an equitable remedy it is subject to the discretion of the Court.

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88 ConsolBoard Inc v. MacMillian Bloedel (Saskatchewan) Ltd (1982), 63 CPR (2d) 1 at 7 (FCTD), var’d (1983), 74 CPR (2d) 199 (FCA).
89 Monsanto Canada Inc v. Schmeiser, 2004 SCC 34 at Paragraph 100; Teledyne Industries Inc v. Lido Industrial Products Ltd (1982), 68 CPR (2d) 204 at 208 (FCTD).
94 Dimplex North America Ltd v. CFM Corp, 2006 FC 586 at Paragraph 132, aff’d 2007 FCA 278.
In addition, an order that all infringing articles in the possession of the defendant be either delivered up or destroyed is typically granted in a successful patent infringement action.97

iv Costs
The successful litigant (plaintiff or defendant) is typically awarded its ‘costs’, which consists of a portion of its attorney’s fees and all reasonable disbursements including expert fees. In respect of proceedings before the Federal Court, the Court may fix the costs based on Tariff B of the Federal Courts Rules and may award a lump sum as a percentage of total fees in lieu of, or in addition to, any assessed costs. In exceptional circumstances, full or substantial indemnity for actual attorney’s fees may be awarded.

VI OTHER TYPES OF PATENT PROCEEDING

i Declaration of non-infringement
The Patent Act provides any person who has reasonable cause to believe that its activities in Canada might be alleged by a patentee to infringe a patent with the ability to commence an action in the Federal Court for a declaration of non-infringement.98

ii Notice of compliance regulations for patented medicines99
In Canada, regulatory approval in the form of a Notice of Compliance (NOC) must be obtained before a drug can be marketed.100 Pursuant to the Patented Medicines Notice of Compliance (PMNOC) Regulations,101 a drug manufacturer who files a new drug submission or supplement thereto (a ‘first person’) may also submit to the Minister of Health a list of patents for inclusion on the Patent Register.102 To be eligible for listing on the Register, the patent must contain a claim for the medicinal ingredient, the formulation, the dosage form or the use of the medicinal ingredient.103 The list may include an expired patent but for which a CSP has taken effect.104 For each patent or CSP on the list, the first person must include a statement of entitlement to list: namely that the first person either owns the patent, has an exclusive licence to the patent or has obtained the consent of the owner to include the patent on the list.105

A ‘second person’ (typically a generic drug or biosimilar manufacturer) may file an abbreviated new drug submission that compares the new drug with a drug already marketed in Canada under an NOC (‘reference drug’). If the reference drug has patents listed on the

98 Patent Act, RSC 1985, c P-4, Section 60(2).
99 The contribution of Nancy Pei, partner, and Urszula Wojtyra, associate, at Smart & Biggar/ Fetherstonhaugh in co-authoring this section is acknowledged with appreciation.
100 Food and Drugs Act, RSC 1985, c F-27 and Food and Drug Regulations, CRC, c 870.
101 Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, as amended.
102 ibid, Section 4(1).
103 ibid, Section 4(2).
104 ibid, Section 4(1.1).
105 ibid, Section 4(4)(d).
Patent Register, the second person must, in its submission, indicate it has the consent of the first person, acknowledge that the NOC will not issue until the listed patent expires or assert in a 'notice of allegation' that:

- the statement of entitlement to list of the first person is false;
- the patent or CSP is invalid or void;
- the patent or CSP is ineligible for inclusion on the register;
- the patent or CSP would not be infringed by the second person;
- the patent or CSP has expired; or
- in the case of a CSP, the CSP cannot take effect.\(^\text{106}\)

The first person has 45 days after being served with the notice of allegation to bring a proceeding in the Federal Court in relation to the notice of allegation. Historically, the proceeding was a summary application in the Federal Court for an order prohibiting the Minister from issuing a NOC to the second person until after the expiration of the listed patent or patents. However, the PMNOC Regulations were recently amended\(^\text{107}\) to provide that the first person can bring a full action in the Federal Court for a declaration that the second person would infringe the patent or CSP.\(^\text{108}\) In response to the first person’s action, the second person may counterclaim for expungement of the patent or CSP, or for a declaration of non-infringement.\(^\text{109}\)

The commencement of an action by a first person results in a statutory stay of up to 24 months preventing the Minister of Health from issuing the NOC to the second person until the resolution of the action.\(^\text{110}\) However, the first person may be liable to the second person for any loss suffered as a result of the delay in NOC issuance if the action is discontinued or dismissed, or a declaration of infringement is overturned on appeal.\(^\text{111}\) That said, the first person may renounce the statutory stay and thereby avoid such damages.\(^\text{112}\)

iii Criminal provisions

There are no criminal provisions in Canada that pertain to infringement of a patent. The only criminal provisions contained in the Patent Act relate to:

- falsely marking or selling an article as patented;\(^\text{113}\)
- making a false representation or rendering a false document for the purposes of the Patent Act;\(^\text{114}\) and
- failing to comply with certain provisions under the Patent Act relating to patented medicines.\(^\text{115}\)

\(\text{106}\) ibid, Section 5.
\(\text{107}\) The amendments to the PMNOC Regulations came into force on 21 September 2017. The new PMNOC Regulations apply to any matter relating to a notice of allegation served on a first person on or after that day. Any matter relating to a notice of allegation served prior to 21 September 2017 is governed by the former regulations.
\(\text{108}\) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, as amended, Section 6.
\(\text{109}\) ibid.
\(\text{110}\) ibid, Section 7.
\(\text{111}\) ibid, Section 8.
\(\text{112}\) ibid, Sections 7(5)(b), 7(6) and 8(4).
\(\text{113}\) Patent Act, RSC 1985, c P-4, Section 75.
\(\text{114}\) ibid, Section 76.
\(\text{115}\) ibid, Section 76.1.
VII APPEAL

The Federal Court and each provincial or territorial court system have their own appellate courts. An appeal to the Federal Court of Appeal is available as of right from any interlocutory or final order of the Federal Court. In some provincial court systems, leave is required to appeal interlocutory orders.

The Supreme Court of Canada hears appeals from the Federal Court of Appeal and provincial appellate courts. For patent proceedings, leave to appeal to the Supreme Court of Canada is required.

VIII THE YEAR IN REVIEW

i Prior user rights

Section 56 of the Patent Act concerning the rights of prior users of patented technologies, was amended and came into force on 13 December 2018.116

Section 56 now protects any acts ‘that would otherwise constitute an infringement’ if the act had been completed before the claim date (i.e., the priority date for a particular claim), or if ‘serious and effective preparations to commit such an act’ were made before the claim date. The previous Section 56 limited prior user rights to the right to ‘use and sell to others the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired’ before the claim date. This change is significant as it appears to broaden the protection, including to indicate that prior user rights can be invoked for patented processes. Previously, courts had provided differing conclusions on prior user rights to patented processes.

Right to transform or sell

While it was previously protected, it is unclear if prior users will have the ability to transform or sell articles produced prior to the relevant date after the relevant date if they have not done so in the past. This may depend on how courts construe the phrase ‘serious and effective preparations to commit such an act.’

Good faith requirements

The amended section includes a good faith requirement and provides that users cannot invoke the prior use defence if they obtain knowledge of the subject matter defined by the claim, either directly or indirectly, from the applicant of the application on the basis of which the patent was granted and they knew that the applicant was the source of the knowledge.117 Prior jurisprudence under the previous section suggests that the good faith requirement may be limited to breach of confidence or secrecy between the parties.118


**Purchasing from a prior user**

Section 56 now provides rights to purchasers of an article from a prior user, including the rights to use and sell the article which extends to the use of ‘an article that is substantially the same as the one used, for that use.’ There is some concern with the extension of these rights to articles that are ‘substantially the same.’

**Substantially similar services**

New subsections 56(4) and 56(9) introduce exemptions for the use of a service or a service that is substantially the same as one previously used, respectively. However, the term ‘service’ has not been used in previous provisions and it remains to be seen how ‘service’ will be interpreted.

**Transferee of a business**

Subsections 56(2), (7) and (10) provide that a transferee of a business or a part of a business may acquire the prior user rights of the transferor. The permitted activities are not limited to the same locations or sites as the original prior use.

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**Canadian Competition Bureau updates Intellectual Property Enforcement Guidelines**

In 2019, the Canadian Competition Bureau updated its Intellectual Property Enforcement Guidelines (IPEGs), which help to explain how the Bureau addresses matters relating to competition policy and intellectual property (IP) rights and conduct involving IP that may raise an issue under the Competition Act. The overall approach of the Bureau in circumstances involving IP is first broken into two broad categories: conduct involving the mere exercise of IP rights; and conduct involving ‘something more’ than the mere exercise of IP rights. The Bureau will generally not presume a violation of the Competition Act when there is a mere exercise of IP rights, and views its approach to non-IP forms of property as sufficiently flexible to apply to IP.

The updated Guidelines provide several examples of activities where the Bureau might investigate or pursue enforcement as follows:

- **a** Price fixing: where a price-fixing agreement between parties with patented technologies relating to a particular product tends to limit competition between them, the Bureau may investigate.
- **b** Abuse of dominance: the Bureau may investigate conduct under Section 79 of the Competition Act, which would include conduct such as a large firm using its market dominance to obtain exclusive licences in order to shut competitors out of the market.
- **c** Patent pools: when a number of firms cross-license patents relating to one product, they may be subject to investigation if there is evidence that the patent pool is an agreement between competitors.
- **d** Refusal to licence: generally, refusing to license an IP right is not subject to review by the Bureau. However, the Bureau may investigate where the refusal created an undue restraint of trade or unduly lessened competition, which requires first that the refusal

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120 Competition Act, RSC, c C-34.
adversely affected competition in a market that is different or larger than the subject matter of the IP, and second that the refusal would alter other firms’ incentives to invest in research and development.

e Product switching: abuse of dominance provisions may be applied where a party removes Product A from the marketplace and replaces it with a similar Product B whose patent protection extends later than the previous product (‘hard’ switching). However, a party that merely stops promoting Product A in favour of Product B would not raise concerns.

The Guidelines also discuss the Bureau’s treatment of patent assertion entities (PAEs), also known as non-practising entities (NPEs) or, colloquially, patent trolls. In the Guidelines, the Bureau acknowledges that there is an increasing roll of competition law enforcement relating to PAEs and provides some examples of its approach to PAEs. For example, if a PAE sends out a notice of patent infringement threatening legal action and includes false statements, these statements may be reviewable under the misleading advertising and deceptive marketing provisions of the Competition Act. On the other hand, the mere assignment of patent rights to a PAE for more effective enforcement will not likely raise issues.

iii Implementation of Canada-European Union Comprehensive Economic and Trade Agreement

As a result of its obligations under the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), Canada made amendments to the Patent Act and implemented new regulations. Below are some notable updates regarding these new regulations.

**Patented Medicines Notice of Compliance Regulations (PMNOC Regulations)**

Almost two years have passed since substantial amendments to the PMNOC Regulations came into force on 21 September 2017, including a significant procedural change where there is no longer the possibility of dual litigation and all matters wherein an innovative drug company seeks to prevent Health Canada from issuing market approval to a generic (via an NOC) must be brought by an action for patent infringement. As of 30 June 2019, 78 actions (relating to 26 drugs) under the new regime had been commenced in the Federal Court and 56 of the actions (relating to 17 drugs) were ongoing. The first trial is scheduled to start on November 4, 2019: *Bristol-Myers Squibb v. Apotex*(Eliquis).

To date, several procedural decisions in respect of the new enforcement regime have been issued by the Court which are of interest, including: (1) common invalidity issues raised by different generic manufacturers were ordered to be heard concurrently; and (2) only second
persons \( ^{125} \) can be named as defendants (although this could include a person other than the regulatory submission filer) \( ^{126} \) and (3) an infringement claim based on making or selling under a notice of compliance for one strength was struck from an action triggered by a notice of allegation based on a different strength. \( ^{127} \)

**Certificate of Supplementary Protection regime**

Following Canada's commitments under CETA, the Patent Act was amended to add a new Certificate of Supplementary Protection (CSP) regime that provides additional protection for a new drug after the expiry of the relevant patent. \( ^{128} \) The term of the CSP is calculated by subtracting five years from the difference between the filing date of the application for the patent and the day on which the NOC is issued, up to a maximum of two years. Regulations for the new CSP regime came into force together with the Patent Act amendments, on 21 September 2017. As of 11 July 2019 Health Canada had issued 29 CSPs for drugs for human use and two veterinary drugs, and four applications for CSPs were pending.

CSPs have been refused for seven drugs, for a variety of reasons pursuant to the regulations.

In addition to patent protection and CSPs, small molecule (human and veterinary) and human biologic drugs approved in Canada that meet the definition of an ‘innovative drug’ are also protected by data protection. An innovative drug is ‘a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.’ \( ^{129} \) A subsequent manufacturer seeking approval on the basis of a direct or indirect comparison to the innovative drug cannot file its submission until six years after the innovator drug’s first approval and cannot receive approval until eight years after such approval, or eight-and-a-half years if a pediatric extension is granted. In assessing the value of any potential CSP, its expiry relative to data protection expiry is important.

**iv Changes to the Patent Act**

There have been several notable amendments to the Canadian Patent Act in the past year.

**Licensing**

Section 52.1 of the Patent Act requires that a licensing commitment made by a patentee regarding a standard-essential patent is also binding upon any subsequent patentee. \( ^{130} \) In other words, if the patent is assigned, the assignee is also bound by the licensing commitment made by the assignor. This provision extends to CSPs. As of yet, the terms ‘licensing commitment’ and ‘standard-essential patent’ have not been further defined by regulation.

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125 Second persons are persons who file a submission or supplement for a notice of compliance in respect of a drug.


130 Patent Act, RSC 1985, c P-4, Section 52.1.
Prosecution history as evidence
Pursuant to previous Canadian jurisprudence, the prosecution history of a patent was inadmissible to determine the scope of patent protection. However, the Patent Act was amended to include new Section 53.1, which provides that written communications made between an applicant for a patent or patentee and the Patent Office may be admissible in any action or proceeding that has not been finally disposed of as of 13 December 2018. This form of evidence is only admissible when it is used to rebut a representation made by a patentee in an action or proceeding as to the construction of a claim. It has not yet been judicially considered such that the full scope and application of the section remains to be determined.

Research exemption
In Canada, there is a common law exemption to patent infringement for non-commercial experimental use of an invention. This exception has now been codified in Section 55.3(1) of the Patent Act. It is often difficult to determine what constitutes ‘experimental use’, and Section 55.3(2) provides the government with authority to make regulations regarding the factors the court may consider, must consider or is not permitted to consider in determining whether an act is committed for the purpose of experimentation, and the circumstances in which an act is, or is not, committed for the purpose of experimentation. It remains to be seen what factors will be included in the eventual regulations.

Written demand letters
Section 76.2 of the Patent Act has been added to address written demands (e.g., cease-and-desist letters) related to patented inventions. In particular, written demands received by a person in Canada, relating to an invention patented in Canada or elsewhere must comply with ‘prescribed requirements’. If such requirements are not met then the section gives the receiver of a demand letter the ability to commence a proceeding in the Federal Court upon which the Federal Court may, if the note does not meet the requirements, grant relief that it considers appropriate including recovery of damages, punitive damages, an injunction, a declaration or an award of costs. To date, the government has not published regulations setting out the requirements. This Section appears to apply to any cease-and-desist letter, so long as the recipient is located in Canada. For example, it does not matter that the patent is a foreign patent, that the alleged infringement occurs elsewhere or that the complainant sending the letter is located in another country.

Interlocutory injunctions
For many years, interlocutory injunctions relating to patents have only been granted in exceptional circumstances in the Canadian Federal Court. Typically, it has been difficult for the plaintiff meet the requirement of demonstrating that it will suffer irreparable harm. However, there have been signals from the Court in recent times that it would be more open to granting injunctions in appropriate circumstances, and a plaintiff was recently granted

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131 ibid, Section 53.1.
132 ibid, Section 55.3(1).
133 Patent Act, RSC 1985, c P-4, Section 55.3(2).
134 ibid, Section 76.2.
an interlocutory injunction in a patent case. The Court found that there was irreparable harm based on the loss of goodwill, a risk of losing distributors of the patented product, a risk of loss of distributors for other products as a result, and in view of the patented product comprising 30 per cent of the sales of the plaintiff while comprising only 5 per cent of the defendant’s sales.

IX OUTLOOK

i International agreements

Canada has become party to a number of significant international agreements over the past few years, many of which have led to legislative changes that impact on patent litigation in Canada. In particular, changes resulting from the CETA agreement between Canada and the European Union have already had an impact on patent litigation and further changes are coming as a result of the NAFTA 2.0 agreement between Canada, the United States and Mexico.

CETA

Continued development of jurisprudence is expected, particularly in the following areas in view of Canada’s commitments to CETA:

a the new PMNOC Regulations; and
b the CSP regime.

NAFTA 2.0

Canada, the United States, and Mexico signed the Canada-U.S.-Mexico Agreement (CUSMA), dubbed at the time as ‘NAFTO 2.0’, on 30 November 2018. In a step towards ratifying the CUSMA, the Canadian government introduced Bill C-100 on 29 May 2019. The Bill passed second reading and has been referred to committee for review. If ratified, CUSMA would replace the North American Free Trade Agreement (NAFTA) and would require a number of changes to Canada’s IP laws, including:

a increase of the data protection term for biologics from eight years to 10 years; and
b introduction of a patent term adjustment procedure to compensate for the Patent Office delay in issuing a patent.

ii Prior user rights

It is expected that there will be development of jurisprudence regarding the scope of prior user rights under amended Section 56 of the Patent Act.

136 ibid, at Paragraphs 78-84.
137 Bill C-100, An Act to implement the Agreement between Canada, the United States of America and the United Mexican States, 1st Sess, 42nd Parl, 2019.
iii Demand letter requirements

Although legislation has been passed which allows the creation of requirements for written demand letters relating to patented inventions, regulations setting out the requirements have not yet been enacted. Once regulations are in place, the practice of sending demand letters is likely to adapt, and demand letters may ultimately result in litigation before the Federal Court initiated by recipients of alleged non-compliant letters.
I

OVERVIEW

All patent litigation in Denmark is handled in the first instance by a specialist intellectual property (IP) court – the Maritime and Commercial Court of Copenhagen, which includes tribunals consisting of one to three legal judges and two to four lay judges, being either patent agents or commercial persons. The only exception is actions for seeking evidence of an infringement, which are handled by the bailiff’s courts associated with the 18 city courts spread around the country.

Denmark is a fairly litigious country in relation to patents, despite its small size. This most likely stems from the fact that the cost of litigation is not extremely high, combined with Denmark being a highly technically developed country with many specialist industries, particularly in the pharmaceutical field, with high revenues to be obtained owing to relatively high prices on medicinal products.

Recently, courts have dealt with a number of cases involving patents for secondary medical use and the consequences of having obtained unjustified interlocutory relief. In several cases, the second medical use patents have been invalidated and the defendant has been awarded compensation for lost sales. Furthermore, courts have continuously used the doctrine of equivalence in patent litigation.

II

TYPES OF PATENT

It is currently possible to obtain patent protection in Denmark through three different systems (soon to be four). It is also possible to apply for a utility model.

The first option is a Danish national patent granted by the Danish Patent and Trademark Office. The system only covers the Kingdom of Denmark, including the Faroe Islands and Greenland. Some later changes to the law have not been implemented in the Faroe Islands or Greenland. The application must contain a written description of the invention, the patent claim, and a summary. The submitted application is the object of a thorough test.

Under Danish patent law, patent registrations cannot be obtained for certain types of invention. Computer software can only be covered by patent protection to the extent that the software forms part of a technical solution that is using the computer software as a part of it. The doctrine to this rule is that software cannot be granted protection unless it has

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Denmark

a technical result that provides some kind of technical contribution. The same applies to business methods – a patent for a business method cannot be granted unless the business method includes some sort of technical result.

It is not possible to obtain a patent for methods for surgical or therapeutic treatment or for determination of diagnoses practised on humans or animals. The reasoning behind this is that they are not regarded as inventions. However, it is possible to obtain patent protection for products, substances and compounds for use in any of the above-mentioned methods.

Secondly, a European patent granted by the European Patent Office (EPO) may cover Denmark and be valid in Denmark to the extent that the patent has been validated in Denmark. This is also considered a national patent, therefore only allowing enforceable patent protection for the countries where validation is made. The EPO assesses whether or not the requirements for patentability are fulfilled.

Thirdly, Denmark has ratified the Patent Cooperation Treaty in 1978, making it part of the International Patent System. This has also resulted in a national patent, allowing patent protection for the designated countries. In Denmark, the Nordic Patent Institute or the EPO have the authority to assess the novelty requirement for the patent applications. Hereafter, the application must be transferred to each designated country that performs the patentability assessment. This process is handled by the Danish Patent and Trademark Office.

In 2012, the EU Commission adopted the Unified Patent Regulations currently covering 26 Member States including Denmark. This system, which entered into force on 20 January 2013, allows for the issuance of a single patent covering all participating Member States. The patent will be issued by the European Patent Office in Munich. As of the time of writing, the system is not up and running because the unified patent is closely linked to the Unified Patent Court Agreement, which will create a supranational court system to handle all disputes stemming from a unified patent. The Unified Patent Court Agreement will only enter into force when 13 Member States, including the big three countries in the EU, Germany, France and the United Kingdom, have ratified the Agreement. That has not taken place yet, but is expected to happen in 2019.

It is possible to extend patent protection for certain types of patents covering products for which extensive governmental control is applied, such as pharmaceutical products and plant protection products, through a Supplementary Protection Certificate (SPC). The SPC system is regulated through EU Regulation Nos. 469/2009 and 1610/96, and covers the whole of the EU. The system allows for an extension of patent protection for the subject matter for an additional period of up to five years after expiry of the original patent; however, the length of the supplemental grant depends on the length of the period extending from the application date to the date of grant of authorisation to market the product minus five years. The SPC may, however, only be valid for a maximum of five years.

Further, it is possible to apply for utility model protection. The biggest difference between a patent and a utility model is that a utility model is granted without examining whether or not the invention is novel. The test for novelty is slightly different for a utility model, and the protection time is shorter (10 years from application date). A utility model is granted by the Danish Patent and Trademark Office. Utility models are often used to speed up enforcement, since they are issued much more quickly than ordinary patents.
III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

In Denmark, the Maritime and Commercial Court of Copenhagen is the designated IP court for handling, among other things, disputes involving patents. This means that all cases on the merits involving patents will be heard before this Court, no matter where the infringer is located. Cases will be heard by a tribunal of between three and seven judges, of which one to three judges have a legal background and two to four judges may be chosen among a pool of designated lay judges who either have a relevant commercial background or are patent agents – normally one of each.

Both actions of infringement and invalidity actions are heard by the same tribunal, and it is quite common that the purported infringer brings a claim for invalidity as an act of defence against a claim for infringement.

Decisions of the Maritime and Commercial Court of Copenhagen may be appealed either to the Supreme Court or to one of two appellate courts (covering each part of the country), depending on whether the case has fundamental importance or not. The Supreme Court can decide not to hear a case brought before it. The appellant then has the option of bringing the case before an appellate court instead.

i Interim proceedings

The Maritime and Commercial court is a relevant venue for interim proceedings in patent litigation, although it is possible to bring such cases before the local city courts. If a case is brought before a local city court, either party has the option of requesting referral of the case to the Maritime and Commercial Court of Copenhagen, and such referral is mandatory for the city court.

ii Preservation of evidence

It is possible to initiate an action for preserving evidence. Such case must be brought before the bailiff’s court in the local city court, and such cases cannot be referred to the Maritime and Commercial Court of Copenhagen. This means that if the plaintiff is seeking a combined interim injunction and a search order, he or she must involve two courts and two judges. It is possible to have two judges go to the premises and hear a combined case.

iii Administrative invalidation actions

It is possible to ask the Patent and Trademark Office to invalidate a patent according to Article 53b; however, this is rare. A court is not obliged to halt the handling of litigation involving a patent because of administrative proceedings being initiated against the patent.

If a court action is initiated involving the patent while an administrative review of the patent is pending before the Patent and Trademark Office, the Office will halt the proceedings until a final decision has been reached (Article 53b(3)) through the court system unless the administrative review has been initiated by the patent holder himself or herself.

iv Patent infringement and patent invalidity proceedings

The patent owner, or someone who has licensed the right to exploit the patent (Article 63), may bring an action in Denmark for patent infringement. It is possible to bring an action in Denmark when the purported infringer is domiciled in Denmark or has property in Denmark and also, in the case of EU-based companies, if the infringement takes place in Denmark. Actions regarding invalidity can only involve rights issued for the territory of Denmark.
A patent infringement action is initiated by submitting a writ to the relevant court. The writ must be accompanied by a specification of claims to be considered, a statement of facts and legal arguments and must be accompanied by relevant evidence to support the claims. All evidence must be presented orally in court during the trial, which results in patent litigation cases normally involving several days in court – sometimes up to two weeks in complicated cases.

The burden of proof in cases of infringement or invalidity actions lies with the claimant. In interim actions, the claimant only needs to show ‘plausible’ proof of infringement in order to obtain an injunction. If the infringement is proven beyond doubt during the action for interim measures, the court is likely to issue the injunctions without conditioning it on posting of a bond.

In cases involving a process patent for manufacturing new products, the burden of proof is reversed (Article 64A). Thus it is the infringer who has to prove that the products have not been produced by infringement. This is a direct consequence of European Patent Convention (EPC) Article 64(2).

The main rule regarding presentation of evidence is that the party bringing an action must present evidence to support his or her claim. It is not possible to force a counterparty to present evidence – even if it is obvious that the party is in possession of the relevant proof. There is no discovery process. However, a court may hold it against the holder of the relevant evidence if such evidence is not submitted upon request by the counterparty.

Evidence is often present in the shape of a court-appointed independent expert, having been asked to answer relevant questions about the infringement from both sides. Parties may, to a certain extent, present one-sided declarations from experts chosen by the parties themselves, but they will normally be given less weight by the judges than opinions rendered by a court-appointed expert.

The Civil Code was changed as of 1 July 2017 in this regard, and it is now possible for the parties to an action to agree to only rely on one-sided opinions prepared by experts chosen by each party. The system has not yet been used in a court action, but it is likely that the judges will put more weight on even one-sided expert opinions in future in such actions. It is, however, worth noticing that this requires both parties to agree to such procedures. Having a court-appointed expert is thus advisable to the extent that one party is certain that the expert will issue a declaration in his or her favour, while the new system may be advisable to the extent that a party is uncertain about the outcome of an opinion from an independent expert or in situations where it is difficult to find an independent expert with sufficient skills in the subject matter of the case.

It is very common to commence proceedings by asking the bailiff’s court to conduct a search for evidence on the premises of the purported infringer, and it is quite easy to have the courts agree to conduct such a search to the extent that the plaintiff can present convincing evidence that the purported infringer is actually infringing the rights of the plaintiff, and that the evidence of the existence of the infringement and the size of the infringement may be present on the premises covered by the search order. It is also possible to ask for a search order in cases involving process patents. The search is conducted by the judge and a court-appointed expert, but the plaintiff’s lawyer may be present at the search to identify relevant evidence. Once the search has been conducted, the court or the court-appointed expert will write a report including the relevant evidence discovered on the premises, and the report will be handed over to the plaintiff. The plaintiff then has 30 days to consider whether to use such evidence in a case on the merits. If he or she does not introduce such evidence into a case on

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the merits within this deadline, the purported infringer may claim the evidence back and the evidence is then inadmissible in court proceedings. Normally, the courts will condition the search on the posting of a small bond of between US$3,000 and US$8,000, which is meant to secure the infringer against losses, should the search order later on prove to be unfounded.

It is possible to put forward claims involving alterations of claims during a legal process, to the extent that the alterations are kept within the scope of the original claims and do not extend protection to new areas. The courts may issue a decision resulting in the rewording of the claim or simply deletion of a part of the claim. It is unlikely that the court will make such corrections without having been asked to do so by one of the parties.

It is possible for an alleged infringer to challenge the validity of the patent in connection with an infringement proceeding. In this case, the Maritime and Commercial Court in Copenhagen will be the exclusive venue. A patent can be invalidated if:

- the patent is granted protection for a subject matter that is not patentable under the Danish Patent Act;
- the invention was not new in relation to the state of art prior to the date of filing of the patent application, or did not differ essentially therefrom; or if the invention did not fulfill the requirements for industrial applicability;
- the description of the invention covered by the patent is not disclosed in a sufficiently clear manner to enable a person skilled in the art to carry out the invention;
- the subject matter of the patent extends beyond the contents of the application as filed;
- or
- the protection conferred by the patent has been extended after the patent authorities have notified the patent owner that the patent will be granted.

In a recent decision – Novartis v. Orifarm (T-9-14) – a second medical use patent was invalidated because the subject matter of the patent extended beyond the contents of the application as filed. The decision was upheld on appeal (B-2278-16) and the Appeal Court stated that they did not have the power to approve the patent with revised claims, since that would mean that the court would act as an administrative body, since the lower court had invalidated the patent.

Patent litigation in Denmark is not too expensive compared to the surrounding countries. When considering when to sue, it is important to be aware of the fact that a request for an interim injunction will be rejected by the courts unless the plaintiff files the request in a timely fashion following the discovery of the infringement and, more importantly, following the date of having approached the infringer with a cease-and-desist letter. There are no specific time limits specified in the law, but if the plaintiff has sent a cease-and-desist letter to the infringer or has engaged in negotiations with the infringer, it is strongly advisable to file a request for an injunction as soon as possible. The latest precedence suggests that filing a request for an injunction more than six months after having approached the infringer for the first time may be too late. Furthermore, very recent case law – EPDPP ApS v. Norgo ApS et al (A-28-15) – states that knowledge of the existence in the market of a product does not in itself result in laches to the extent that extensive testing is needed to determine that the product is infringing.

In general, it is advisable to file the action as soon as enough evidence has been gathered to support the action. This normally includes relevant testing and preparation of an expert opinion.
In patent infringement cases, it is crucial to consider the strength of the patent before asking for an interim injunction. This is owing to the fact that liability for having obtained an unjustified interim injunction is very strict and may result in very large awards of damages. In a recent case – AstraZeneca v. Sandoz (T-2-12) – the court awarded Sandoz 100 million Danish kroner in damages for unjustified injunction because the second medical use patent held by AstraZeneca was invalidated by the court.

For that reason, the plaintiff must consider whether to ask for a quick interim injunction or for a case on the merits, which may take as long as four to six years to be decided, including appeals.

The judgment by the court includes a decision regarding costs, and it is the winner who will be awarded costs and reasonable lawyer’s fees. The courts will never award full compensation for lawyers’ fees. The award of costs will depend on the value of the case and normally amount to 25 to 40 per cent of the actual expenses to lawyers’ fees. Costs incurred during the trial – such as fees for expert witnesses and court-appointed experts – must normally be borne by the loser, but only to the extent that the court finds that the expert witnesses’ work has had direct relation to the court action.

A case on infringement of a patent will normally take one to two years at the Danish Maritime and Commercial Court. If the judgment by the Maritime and Commercial Court is appealed to the Supreme Court, the appeal case takes around one and a half to three years.

It is possible to obtain an interim injunction against patent infringements. This requires almost the same preparation as a case on the merits, and will be heard by a tribunal of three judges like a case on the merits. The procedure is the same as a case on the merits except for the fact that there is no real bar against presentation of new facts and evidence during the proceedings.

A decision on interim injunctions is often conditioned on the plaintiff posting a significant bond, the size of which is decided exclusively by the court. This is based on the likelihood of the injunction order being overturned on appeal or in a follow-up case on the merits and evidence presented by the parties in relation to the possible losses suffered by the defendant as a result of a possibly unfounded injunction having been issued. In patent cases the bond may be significant, and in a recent case between two companies producing hearing aids, the bond was set at US$800,000. In actions involving infringement of pharmaceutical patents the bonds are normally very high.

If the plaintiff obtains an interim injunction, such decision must be followed up by a case on the merits within two weeks after the interim decision being final. If the bond is not posted or the case on the merits is not brought in a timely fashion, the injunction will not be issued and the defendant may claim compensation for unjustified actions having been brought against them.

Claims for invalidity cannot be brought during interim proceedings, and in general there is a presumption of validity of a patent. However, in connection with deciding on the likelihood of infringement, the courts will also, to a certain extent, consider the validity of the patent in question, and it is possible to cast such uncertainty over the validity of the patent that the court may reject the infringement action. In a recent decision (Ely Lilly vs. Mylan AB et.al SH2019.BS-33415/2018-SHR) the Maritime and Commercial Court affirmed the presumption of validity despite the fact that EPO had limited the scope of protection of the patent on the request of the patent-holder. The purported infringer had claimed that in such a case, the presumption of validity should not apply.
It is possible, but extremely rare under competition law or the Danish Marketing Act, for lawyers and their parties to become liable if they issue statements or send letters to distributors of purportedly infringing products that include false or misleading statements. It is furthermore possible for a party that has been met with a claim for infringement to initiate litigation based on a claim for non-infringement. However, this is very seldom used as a result of the cost of litigation in general, and the fact that a party to a legal action will never recover the full amount spent on litigation from the counterparty, even if they win.

IV SUBSTANTIVE LAW

i Infringement

According to Article 3 of the Danish Patent Act, without permission of the patent owner, no one may exploit the invention by making, offering, putting on the market or using a product that is the subject matter of the patent, by importing or possessing a product for these purposes, by using a process that is the subject matter of the patent or by offering the process for use in Denmark, if the person offering the process knows or it is obvious in the circumstances that the use of the process is prohibited without the permission of the patent owner, or by offering, putting on the market or using a product obtained by a process that is the subject matter of the patent, or by importing or possessing the products for these purposes.

Under the Danish Patent Act, no one but the patent owner may exploit the invention by supplying or offering to supply anyone who is not eligible to exploit the invention with the intention of utilising it in Denmark, if the supplier’s resources relate to any essential element of the invention and the supplier or person offering supply knows or it is obvious that the resources in question are suitable and intended for exploitation.

Furthermore, it is possible to face liability for infringement if one assists or incites an infringement. It is possible to face liability as multiple parties in the same case, and foreign activities can be subject to infringement in Denmark if the infringing activity has an impact on Danish territory. Otherwise, only activities performed inside the territories of Denmark can constitute an infringement.

A director of a company may be held directly liable for infringement under certain circumstances; namely when he or she has control over the company and is the person who has either initiated the infringement or performed the infringement.

The patent claim is the basis for evaluating the infringement. If an act by a third person falls within the natural understanding of the scope of the claims, it normally results in an infringement. This is the doctrine on patent claims. However, a Danish patent is also interpreted according to the Rule in Article 69 of the EPC, which states:

*The extent of protection conferred by a European patent or a European patent application shall be determined by the term of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.*

In this regard, a protocol exists on the interpretation of Article 69. Article 1 lists the general principles; thus, Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be defined by the strict, literal meaning of the wording used in the claims, nor should it be interpreted in the sense that the claims serve only as a guideline. It is to be interpreted as defining a position between these extremes.
that combines a fair protection for the patentee with a reasonable degree of certainty for third parties. Article 2 lists that equivalent elements should be taken into account when determining the extent of the protection of a patent.

Thus, the patent claims are the central element when looking at the scope of protection, but it is possible in each case to expand the protection to more than just the wording of the claim, allowing acts that are very equivalent to the patented invention to constitute an infringement. When checking whether or not a patent is infringed, the alleged infringing product is compared to the patent claim. The crucial thing is whether the central or essential parts of the invention can be found in the alleged infringing product, and whether deviations only occur in minor areas. However, if the deviation in question is obvious to a person skilled in the art, it will normally result in an infringement.

If any ambiguities exist in the patent claim, it may be taken into consideration if the patent applicant himself or herself has interpreted any ambiguities in the claim to the Danish Patent and Trademark Office.

Furthermore, precedence shows that language in the claims that is not relevant to the core of the invention may be given lesser weight, or entirely disregarded, when assessing the scope of the invention.

Finally the doctrine of equivalence is accepted according to precedence from the Supreme Court in the case U2009.1532H Guldager, according to which the use of a method that applies almost the same features in order to fulfil the same purpose in almost the same manner as described in the claim will also result in infringement being stated.

ii Invalidity and other defences
The validity of a patent can be challenged by anyone who wishes to do so. The validity is challenged when a written request to re-examine a registered patent is filed with the patent authorities.

A patent is invalidated if:

a. the patent is granted protection for subject matter that is not patentable under the Danish Patent Act;

b. the invention is not new in relation to the state of art prior to the date of filing of the patent application, or does not differ essentially therefrom, or if the invention does not fulfil the requirements for industrial applicability;

c. the description of the invention covered by the patent is not disclosed in a sufficiently clear manner to enable a person skilled in the art to carry out the invention;

d. the subject matter of the patent extends beyond the contents of the application as filed, or

e. the protection conferred by the patent has been extended after the patent authorities notified the patent owner that the patent would be granted.

In Denmark, the Danish Patent and Trademark Office makes decisions on challenges to the validity of patents. A decision by the Danish Patent and Trademark Office can be appealed to the Danish Board of Appeal on Patents and Trademarks. The decisions by the Danish Board of Appeal on Patents and Trademarks can be brought before the Danish Maritime and Commercial Court.

It is possible for an accused infringer to argue for a prior use defence as a defence to infringement claims. However, private use by the accused infringer does not give him or her the right to continue the private use begun before the priority date commercially after the
priority date. The prior use defence is limited to a commercial use when the exploitation does not constitute an obvious violation of the patent applicant’s rights. There is no limitation to which types of patents the defence applies to. The defences may only be used if commercial use has commenced before the date of filing, and the continued use may not extend beyond the use that had been initiated before the priority date.

It is also legal to use the patented invention in experimental use. Likewise, it is legal to file for market authorisation of a generic variation of a patented drug and preparation to go on the market when the patent expires.

Enforcement of a patent can expose the patent owner to liability under competition law and marketing law. According to the Danish Marketing Act Article 3, all traders shall exercise good marketing practice with reference to consumers, other traders and public interests. It is possible for a patent owner to face liability under the Marketing Act if he or she issues false or misleading statements. It is also possible that a patent owner may abuse his or her dominant position and thus face liability under competition law. Only one example on precedent exists in Denmark. In 2005, the European Commission conducted an inspection at the premises of Lundbeck Pharma. The purpose was to identify whether Lundbeck Pharma had misappropriated a dominant position or had been involved in anticompetitive agreements in the markets for antidepressant drugs. In 2013, the European Commission found that Lundbeck Pharma had violated competition law because they used ‘pay-for-delay’ agreements, and imposed a fine of €93.8 million.

V FINAL REMEDIES FOR INFRINGEMENT

As part of a final decision on infringement, the patent holder may obtain a final injunction against the infringers’ exploitation of the invention. Courts may also order the infringer to perform certain tasks that aid in terminating the illegal actions such as withdrawal of products from the market, destruction of goods, surrender of goods to the patent holder or alterations of products to avoid infringement (Article 59).

Furthermore, the patent holder is entitled to compensation, which will be calculated based on their proven losses. Compensation thus requires proof of actual lost sales or market disturbance. As damages are calculated based on lost sales of the patent holder, damages may in fact be higher than the profit obtained by the infringer.

If the patent holder cannot prove actual losses, he or she will be entitled to reasonable compensation calculated based on an evaluation of how much the infringer had to pay under normal market conditions for obtaining the right to exploit the invention. This is comparable to a royalty payment, and payment of such an amount does not allow the infringer to continue the infringement after the decision has been issued.

It is also possible to claim non-economic damages, for example, because of bad will or disturbance of the market in which the patent holder operated.

Damages can be claimed from the date the patent application was published in Denmark, but the amount of damages awarded will often be fairly low because it can be difficult to prove actual losses.

It is only possible to obtain a final injunction at the Maritime and Commercial Court, the Appeal Courts or the Supreme Court, if the goods in question have been put on the market or sold before the final injunction is issued by the court, the patent-holder may request the withdrawal of the products from the retailers and the market, but never from the consumers.
OTHER TYPES OF PATENT PROCEEDING

Under Danish patent law, it is possible to obtain a compulsory licence agreement. However, the provisions concerning compulsory licences are seldom used in Denmark. Once a threat to get a compulsory licence is made before the patent owner, the patent owner often enters into a licence agreement with the interested person. A compulsory licence is obtained by filing a writ with the Maritime and Commercial Court. The requirements for obtaining a compulsory licence are that the person wishing to obtain a compulsory licence is capable of exploiting the invention in a reasonable and responsible manner that complies with the licence. Furthermore, the requirements imply that the person seeking the compulsory licence needs to be technically and economically able to sustain the invention’s required standard on the market, and capable of paying the licence fee.

Before being able to obtain a compulsory licence, the person seeking the licence must have already unsuccessfully attempted to obtain a voluntary licence.

The circumstances under which one can obtain a compulsory licence include:

a) lack of use, namely, where the patent owner does not produce the invention in question; and

b) patent repression, namely, where a company buys patents and then does not use them for anything other than to reinforce their market position

It is possible to challenge the ownership of a patent, which is done by filing a writ of summons with the Maritime and Commercial Court, presenting evidence in support of one’s claim.

Furthermore, patents may form the basis for customs seizures. The patent holder must file a petition with customs, supplying them with information about the patent. The procedure is free of official fees, but the patent holder must agree to not hold the customs authorities responsible for claims made by third parties as a result of unjustified seizures.

If a product is seized, the patent holder must either present evidence of acknowledgement of the infringement within 10 working days (an extension of another 10 days may be granted) to customs or file a writ of summons with the Maritime and Commercial Court claiming the infringement.

The infringer may ask customs to release the goods while the case is pending in court, to the extent that he or she posts a bond, the size of which is decided by customs. Furthermore, Denmark accepts the small consignment exemption, according to which small consignments may be destroyed by customs without the parties having been involved, to the extent that the infringement is proven beyond doubt.

The Danish patent system contains procedures for modifying, re-examining or revoking already registered patents. It is possible to file objections for granting a patent and request re-examination of a registered patent. This is done by filing the objection and filing the request to the Danish Patent and Trademark Authorities. The Authorities can either partially invalidate the patent or revoke it. The Maritime and Commercial Court can decide whether or not a patent claim should be amended, but they are primarily reluctant on this matter.

APPEAL

A judgment by the Maritime and Commercial Court on a patent case can be appealed to the Danish Supreme Court or an appellate court. The judgment by the Danish Supreme Court is final and cannot be appealed.
The Danish procedural system is not a front-load system, and the ability to add new evidence to a case on appeal is very liberal. However, it is not possible to add entirely new claims to the case on appeal, unless the parties and the court agree to such additions.

VIII THE YEAR IN REVIEW

Approximately 25 decisions have been published within the past two years, including decisions on interim injunctions, on cases on the merits and on award of damages. The most interesting cases are detailed below.

The courts have issued several rulings involving the issue of urgency in preliminary injunction (PI) matters. In A-35-15 Minkpapir A/S v. Jasopels A/S, the court ruled that the fact that the alleged infringing product had been on the market for four years prior to the filing of the PI led to a rejection of the claim, since there was not sufficient urgency. During the trial, the director of the patent holder stated that he had had the allegedly infringing product in his possession for several years to see how it worked. On the contrary, in A-28-15 EPDPP ApS v. Norgo ApS et al, the court held that the fact that the allegedly infringing product, which was an electronic device for parking control, had been on the market for several years did not deprive the action of sufficient urgency, since it was not possible to discover the infringement unless thorough examination had been performed. Once such examination indicated infringement, the patent holder filed suit immediately. The case was the first in Denmark to state that patent holders are not time-barred from asking for a PI just because the infringing product has been on the market for a long time, as long as the infringement is not easy to detect and requires in-depth examination.

In an ongoing battle between Novartis and Orifarm involving patents on the rivastigmine plaster, the Eastern Appelate Court issued the first decision on lifting a granted PI in case U2017.2417. Orifarm had asked for lifting of the PI and had referred to the fact that the EPO had invalidated the patent, that the Danish Maritime and Commercial Court had invalidated the patent and likewise several foreign courts in different countries. The Eastern Appellate court started out by establishing the general rule of presumption of validity in PI cases and stated that neither the EPO decision nor the Maritime and Commercial Court decision were decisive, because they were both on appeal. However, those interim decisions, together with a range of other foreign decisions and the expert opinions given in the course of the trial, created such uncertainty about the foundation for the PI that the court decided to lift the injunction. The case shows that presumption of validity still stands, but it may be challenged if sufficient evidence can be submitted to the contrary.

In the same battle, the Maritime and Commercial Court granted Orifarm damages of 13 million Danish kroner for unjustified PI in case T-9-14.

In the case T-1-17 Coloplast A/S v. Hollister Incorporated, the dispute was over whether Coloplast A/S could be considered a co-inventor and thus co-owner of a European patent application for catheter devices submitted by Hollister Incorporated. The Court found that since Coloplast only contributed with already known techniques and did contribute to the part of the invention that resulted in patentability they could not be considered co-inventors. The Court reiterated that co-ownership of a patent requires contribution that meets the requirement of inventiveness for a patent.

In a recent case, U.2018.1572S, Minkpapir A/S brought a decision by the Danish Patent Appeal Board to the Maritime and Commercial Court. Minkpapir A/S claimed that an application partitioned from an EP application should be consider equal to an
application partitioned from a Danish Application and thus should be granted the same filing date as the original application. The Board of Appeal did not accept this argument and the partitioned application was given priority from the filing date of the partitioned application. It is possible to split a Danish patent application and gain priority from the first application's filing date. The Maritime and Commercial Court agreed with the Patent Appeal Board that there is no direct legal basis to split a Danish patent application from a European patent application. The Maritime and Commercial Court also found that a specific provision in the Danish Patent regulation that equated European patent applications with national Danish patent application, could not be used as a legal basis in this case. The purpose of the specific provision is to, ‘amongst others’ (per the wording of the legislative preparatory comments), take earlier European patent application into consideration when assessing the newsworthiness of a Danish patent application. The majority of the dissenting Court did not find the wording ‘amongst others’ in the legislative work to be a legal basis for splitting a Danish patent application from a European patent application. The decision has been confirmed by the Supreme Court (U2019.1768).

In case T-9-15 Hamberger Industrierwerke GmbH v. jem & fix A/S, the question of whether an opposing party had lost their right to enforce its patent owing to laches was decided upon. The two opposing parties had corresponded for about four and a half years before the plaintiff sued the defendant. The Court did not find that the plaintiff had lost their right to enforce their patent since the defendant had wrongfully declared two years earlier that it would cease all sale of the infringing product. The defendant could not prove to have a justified expectation that the plaintiff would not enforce its patent rights.

Patent applicants must be sure that translations of their patent claims are identical to the claims in the original application. Millenium Pharmaceuticals Inc almost paid dearly for this in the case A-22-17 Millenium Pharmaceuticals Inc. v. Teva Danmark A/S when an active ingredient in one of its patent claims was not included in the Danish translation owing to a mistake in connection with the validation of the patent. A new translation was submitted almost five years later. The court stated that when there is a difference in a claim's translation, the scope of protection will only be considered based on the wording found in both versions simultaneously. SPCs were at the centre of the case. The opposing party claimed that Millenium Pharmaceuticals Inc's SPC was invalid owing to 'the basic patent being limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent', cf. the SPC Regulation Article 15(3), litra c. The Court referred to the EU cases C-392/97, C-322/10 and C493/12. The Court found that an SPC can be granted protection by all the active ingredients that are mentioned in the basic patent's claims. According to the Court, it did not matter that the SPC referred to a claim in the basic patent that did not mention the relevant active ingredient (this was the earlier mentioned claim that was inadequately translated). It was enough for the SPC to be valid that the relevant active ingredient was mentioned in another claim in the basic patent.

An SPC was also at the centre of another case, A-23-17 Gilead Sciences Inc. v. Accord Healthcare Limited, where the plaintiff was seeking an interim injunction. The Court found that the opposed pharmaceutical product would infringe upon the opposing party's SPC if it was found to be valid. The Court then had to decide if the SPC was valid. To gain an SPC for a combination product consisting of two active ingredients, the two active ingredients must be mentioned in the basic patent's claims. The active ingredients can be named specifically by name, or with a chemical name, a structural formula or be covered by a Markush formula. The Court found that the active ingredients were not named in the plaintiff's basic patent's
claims in any of these manners. The term ‘other therapeutic ingredients’ in the patent claims was not found to be a sufficient mentioning of the active ingredients. For that reason, an injunction was not granted.

In the recent landmark decision SH2019.BS-39398/2018-SHR Fresenius Kabi Deutschland GmbH vs. Biogen, the Maritime and Commercial court had to deal with biosimilar patents for the first time. Fresenius tried to enforce two utility models against Biogen on the pharmaceutical Idacio. Fresenius did not prevail as the court found that Biogen had a right of prior use of the claimed infringing pharmaceutical under Article 9 of the Act on Utility Models before the priority date of the two utility models and that the two utility models were invalid for lack of basis.

IX OUTLOOK

The hottest topic right now is the EU patent and the coming into force of the Unified Patent Court (UPC). Denmark is part of both systems, and it is expected that this system will lead to a significant increase in the number of patents that will cover Denmark and, as a result of this, to an increase in litigation. Denmark has decided to establish a national chamber of the UPC, and this may lead to a significant amount of litigation on Danish soil. However, as the UPC system is supranational, this may not directly affect the Danish patent litigation landscape directly.

It is expected that many patent holders may initially opt out of EU protection, owing to the significant risks associated with pooling all countries in one registration. Thus, for the foreseeable future, there will be many litigation actions involving national Danish patents conducted in the Danish courts.
FRANCE

Pauline Debré and Jean-François Merdrignac

I  OVERVIEW

France is an attractive jurisdiction in which to bring a claim for patent infringement, not least because of the powerful ‘saisie-contrefaçon’ mechanism that enables claimants to gather evidence ex parte, which can then be used in parallel infringement proceedings in other jurisdictions.

The Paris courts have exclusive jurisdiction to hear both validity and infringement claims, and these cases are heard by specialist judges. Recent developments in French patent litigation include both procedural and legal changes. As regards procedural changes, the major change relates to preliminary injunctions, which appear to be less difficult to obtain than a few years ago. The Paris courts have also increased the amount of the awarded damages. As regards legal developments, a new bill (the PACTE law) has recently modified the landscape of patent law.

II  TYPES OF PATENTS

The French Intellectual Property Code (IPC) provides three types of titles that protect inventions and confer upon their owners an ‘exclusive right of exploitation’. These are patents, utility certificates and supplementary protection certificates. An invention can be protected under one of these titles if the relevant patent, utility model or supplementary protection certificate is delivered by the French Intellectual Property Office (IPO).

i  Patents

National patents

French national patents are granted for inventions that are new, inventive and capable of industrial application. Such patents last for 20 years.

Under French law, various fields of inventions are expressly excluded from patentability, including:

a  the human body (and notably the total or partial sequence of a gene);

b  methods of surgical or therapeutic treatment of the human or animal body and diagnostic methods applied to the human or animal body; and

c  inventions whose commercial exploitation would be contrary to the dignity of the human person, public policy or morality.

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Contrary to the case law of the European Patent Office (EPO), the patentability of a dosage regime remains unsettled. Although one decision indicated that a particular dosage could be patented where the purpose of such dosage is to achieve a specific technical effect, it is usual for patent applications for dosage regimes to be rejected to allow doctors freedom and flexibility in their provision of treatment.

The PACTE law provides some very significant changes with respect to the examination and opposition proceedings before the IPO. Indeed, it will notably introduce the reinforcement of the examination process by the IPO, which will be entitled to assess inventive step of French patent applications and an opposition procedure before the IPO, so that the latter can review the main grounds of validity (including inventive step).

The IPO will continue to verify that the application conforms to other classical substantive conditions: the application should relate to a technical invention, respect the principle of unity of the invention, and the claims should be based on the description. Once this examination has been carried out, the IPO provides a search report to the applicant that lists patents and documents relevant to the invention that is the subject of the application, along with an indicative opinion on the patentability of the invention. The applicant then has the option to respond and amend its claims. Following any submissions or amendments from the applicant in response to the IPO’s first search report, the IPO will grant or reject the application.

**European patents**

France is a party to the European Patent Convention (EPC) and can consequently be a designated jurisdiction in a European Patent.

**International applications**

France is a party to the Patent Cooperation Treaty (PCT) and can be designated in a PCT application, as a member of the EPC.

**ii Utility certificates**

Utility certificates are issued by the IPO for six years, without the need for a search report. However, such report will be required if infringement proceedings are initiated.

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2 Paris Court of Appeal, 30 January 2015, 10/19659 (MSD/Actavis). See also Supreme Court, Commercial Ch., 6 December 2017, No. 15-19726 (MSD/Teva).

3 Paris Court of Appeal, 19 June 2015, 13/08566 (Mylan/Richter Gedeon), confirmed by Paris Court of Appeal, 2 March 2018, 15/16651 (Richter Gedeon/Mylan).

4 Action Plan for Business Growth and Transformation (PACTE), Law no 2019-486, 22 May 2019 (entered into force as from 23 May 2019; provisions related to utility certificates and opposition procedure will enter into force later, depending on the ratification act of the upcoming regulation).

5 This modified examination procedure shall concern the French patent applications to be filed as from 22 May 2020.

6 Entry into force of this new opposition procedure requires the adoption of a regulation (to be taken before 22 February 2020). Such regulation shall then be ratified by a confirmatory law (to be voted within six months following the publication of the order).
A patent application can be converted into a utility certificate application. The PACTE law provides that a utility certificate application will last for 10 years and can be converted into a patent application.\(^7\)

### iii Supplementary protection certificates (SPCs)

SPCs are governed by Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.\(^8\)

SPCs can be filed at the IPO by any owner of a patent that has effect in France and that relates to:

- a medicinal product;
- a process for obtaining a medicinal product;
- a product necessary for the production of that medicinal product; or
- a process for the manufacture of such a medicinal product, and that is the subject of a marketing authorisation (MA).

SPCs must be filed within six months after the grant of the first MA (or within six months of the grant of the patent if the MA is granted before the patent).

The IPO has implemented both the Seattle Genetics and the Incyte Corporation decisions of the European Court of Justice,\(^9\) regarding the definition of the date of the first MA in the Community (notification date).\(^10\) However, in the case of a French MA, the starting date of the six-month time limit is still the date on which the MA is granted.\(^11\)

SPCs enter into force once the basic patent expires. They last for the duration specified in Article 13 of Regulation (EC) No. 469/2009, and up to a maximum of five years.\(^12\) The maximum term of an SPC can be extended by six months if the medicinal product obtains a paediatric extension.

Several questions regarding SPCs remain unsettled. The question of whether an SPC can be granted for a new application or new formulation of an active ingredient when the latter is already the subject matter of a previous SPC remains open following the Abraxis decision.\(^13\) The scope of protection of an SPC covering a combination of active ingredients has also generated significant litigation in France.\(^14\)

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\(^7\) The procedure to convert a utility certificate into a patent application will be specified in a regulation to be issued and should enter into force, at the latest, on 23 May 2020.

\(^8\) Prior French regime applied before 1993.

\(^9\) ECJ, 6 October 2015, C-471/14 (Seattle Genetics Inc).

\(^10\) ‘Communication from the IPO on SPC examination’, 12 January 2016. This concerns all SPCs that have not been delivered yet and that are based on a Community MA. Communication from the IPO on the calculation of the expiry date of SPCs, 15 January 2018: For SPCs that have already been delivered and are still in force, the owner may have the expiry date of their SPCs corrected by the IPO.


\(^12\) ‘The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.’

\(^13\) CJEU, 21 March 2019, C-443/17 (Abraxis) and the Referral C-673/18 (Santen, 30 Oct 2018) on the interpretation of a ‘different application’.

\(^14\) Supreme Court, 16 May 2018, 16-21638 (Government of the USA/INPI); Paris Court of First Instance, 25 May 2018, 17/09565 (Biogaran/Gilead Sciences Inc) and 16/14214 (Mylan/ Gilead Sciences Inc), and
New Regulation (EU) No. 2019/933 entered into force on 1 July 2019 and modified former Regulation (EC) No. 469/2009 by introducing waivers to the protection conferred by an SPC. These waivers allow for the manufacturing of medicinal products and all ‘related acts’, within the territory of protection of an SPC, for holding and export (outside the EU) purposes. The notion of ‘related acts’ being undefined in the regulation, we may expect some litigations in the near future on this topic.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Competent jurisdictions
The Paris courts have exclusive jurisdiction to hear civil actions relating to patents (which include infringement and invalidity proceedings).

ii General procedural aspects
The burden of proof (in both infringement and nullity actions) rests with the claimant. The claimant’s writ of summons must contain detailed arguments in law and in fact, so that the Court can form a judgment by itself. A case management judge sets the timeline of the proceedings and it is typical for both sides to file two or three briefs. Once the case is ready to be heard, the instruction is closed, which means that the parties can no longer exchange any brief or exhibit, and a final oral hearing is set. Hearings generally last between three and five hours, depending on the complexity of the case.

Infringement and nullity can be dealt with during the same hearing, as both can be invoked as counterclaims (unless they are time-barred, in which case nullity could be raised only on an exception basis, namely inter partes).

The claims of a patent can be amended during the proceedings, even throughout an appeal.

The total average length of first instance proceedings is between 18 and 24 months. Appeals last for a similar length of time. In cases where urgency is demonstrated within an ex parte request, a summons to appear on a fixed date under special emergency rules can be authorised to obtain a quick judgment on the merits (approximately five to six months). This is rarely sought but has been attempted in the context of the revocation of a patent and a declaration for non-infringement.15

Summary proceedings may last between three and five months in first instance (and around six months on appeal).

iii A unique tool: the saisie-contrefaçon
Infringement can be proved by any means, for example a bailiff’s report or a saisie-contrefaçon. Unlike litigation in the United States or the United Kingdom, French proceedings do not include discovery or disclosure and there is no incentive for a party to admit or concede any points (for example, there is no cost consequence). As such, any affirmation must be proven by written evidence.

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15 Paris Court of First Instance, 28 March 2013, 12/16540 (Somfy/Gaposa).
The *saisie-contrefaçon* is a very specific and efficient probative measure, which must be carried out with caution. It is performed as a first step in almost all infringement proceedings. It allows any claimant or potential claimant to instruct a bailiff to enter any location and write a detailed description of the alleged infringing product (with or without the taking of samples) or process. The bailiff may also be assisted by experts (for example, patent attorneys) designated by the claimant.

To perform a *saisie-contrefaçon*, the claimant must obtain an order from the president of the Paris Court of First Instance by way of an *ex parte* request. The order should specify very precisely the scope of the bailiff’s mission.¹⁶

The claimant only needs to prove that he or she is entitled to bring an infringement action (i.e., that he or she is the owner or exclusive licensee) and that the patent is in force (i.e., that annual fees have been duly paid). The Paris Court of Appeal recently recalled that it is not necessary to prove infringement to obtain permission to carry out a *saisie-contrefaçon*, because the exact purpose of the *saisie-contrefaçon* is to determine whether an infringement has occurred and to what extent.¹⁷ However, bringing ‘reasonably available evidence of infringement’ is still required.¹⁸

Challenging the validity of *saisie-contrefaçon* has become a ‘national sport’, which has given rise to a wealth of case law. Alternatives such as bailiff reports can be used, but case law around the validity of such alternatives is very strict.

Both the *ex parte* request and the order for a *saisie-contrefaçon* must be notified to the seized party before the commencement of the *saisie-contrefaçon*.

Once the *saisie-contrefaçon* has been performed, the requesting party must bring an infringement action on the merits within a month. If it fails to do so, the *saisie-contrefaçon* can be annulled, without prejudice to any compensatory damages that the seized party may claim for any losses incurred.

The seized party also has the ability to challenge or modify the order or request its withdrawal in summary proceedings. It can also seek a court order to protect the confidentiality of seized material.

To ensure that seized material is kept confidential, ‘confidentiality clubs’ may be established between the lawyers and patent attorneys of each party, subject to non-disclosure agreements being entered into by the participants.

iv Right of information

The claimant has a right to request any documents and information necessary to determine the origin and distribution networks of the alleged infringing goods or processes. This right can be exercised even if the claimant has not applied for or performed a *saisie-contrefaçon*.

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¹⁶ The question of the independence of the expert to be entrusted to assist the bailiff has been debated. It has been confirmed that a patent attorney, who has already assisted the claimant in a previous private expertise may later assist the bailiff in a *saisie-contrefaçon*. Supreme Court, 27 March 2019, 18-15005, (*Manitou/Bramford*), quashing Paris Court of Appeal, 27 March 2018, 17/18710.

¹⁷ Paris Court of Appeal, 26 May 2017, 15/10201 (*Telekom Slovenije/Orange*); Paris Court of Appeal, 16 May 2017, 15/15766 and 15/15693 (*Philips/CSI*).

¹⁸ Paris Court of First Instance, 22 December 2017, 17/14521 (*Constellium Issoire/Arconic Inc*).
The Supreme Court has ruled that the right of information could also be used in acquiring documents and information to determine the extent of the infringement and to refine claims for damages.19

In practice, this right is generally granted once a judgment ruling on infringement has been rendered and damages are then assessed through further separate proceedings before the same judge based on the information disclosed.

v Standing to sue

Standing to initiate an infringement action

Infringement proceedings must be initiated by the owner of a granted patent or patent application. In the latter case, the action will be stayed until the patent is granted.

If the patent is co-owned, each of the co-owners may initiate infringement proceedings for its own benefit but it must inform the other co-owners, unless otherwise provided in the co-ownership agreement.

If the patent has been assigned, the assignee will only be able to act if the assignment agreement has been registered at the IPO and such registration has been published. Further, unless expressly agreed upon between the parties, the assignee cannot claim damages for infringing acts that happened prior to the publication of the assignment. Such situation may be regularised until the Court has ruled.20

The beneficiary of an exclusive exploitation right (i.e., an exclusive licensee) may, unless otherwise stipulated in the licence agreement, initiate infringement proceedings if, after formal notice, the patent owner does not exercise that right. A non-exclusive licensee is entitled to intervene in the infringement proceedings to obtain compensation for its own prejudice (unfair competition).

Order No. 2018-341 of 9 May 2018 (that will enter into force together with the agreement on the Unified Patent Court) will modify those provisions, so that the exclusive licensee can initiate an infringement action unless otherwise provided for in the licence agreement, and the non-exclusive licensee can initiate an infringement action if expressly allowed in the licence agreement (both subject to prior information to the patent holder).21

Standing to initiate a nullity action

In a nullity action, the claimant must demonstrate that the patent is likely to hinder its business activities.

vi Stay of proceedings

A stay of proceedings is automatic when the action is based on a patent application but is optional in other situations. A common example of optional stay is when the validity of a patent is about to be adjudicated upon, for example, by the EPO or in a parallel nullity action.

20 Paris Court of First Instance, 10 November 2017, 15/10320 (I Do It/Alden).
A party seeking a stay must file a motion at court and attend a hearing, otherwise the application may be ruled as inadmissible. In determining whether to order a stay of proceedings, the focus must be on ensuring a sound administration of justice and must take into account:

- the seriousness of the nullity grounds invoked;
- the stage of the opposition proceedings; and
- the extent of any harmful consequences on the patentee.

vii Statutes of limitations

Infringement actions

Civil actions for infringement are confined in a five-year period. The PACTE law has modified the starting point of this period. Formerly set on the day of the infringement, the new relevant starting point is the day on which the rightholder knew or should have known the last fact allowing him or her to initiate the action. Accordingly, each infringement act does not generate an autonomous time limitation period anymore. It also means that there is a risk of dichotomy between the time for suit and the relevant period for damages.

This change could significantly reinforce the rights of the patentees as they could potentially obtain damages for acts committed prior to the five years preceding the launch of the infringement action.

In relation to criminal actions, public prosecution must occur within six years of the day on which the offence was committed.

Nullity actions

In the absence of any specific text for patent nullity action, limitation periods have been ruled by the general provisions of civil law. The limitation period for a patent nullity action was thus five years from the date on which the owner of a right knew or ought to have known the facts that enabled him or her to exercise the action.

The case law pertaining to the starting point of the five-year period has recently focused on an in concreto approach to determine, on a case-by-case basis, the date the claimant knew, or ought to have known, the facts that enabled him or her to commence the nullity action.

Statutes of limitation will no longer apply to patent nullity actions, as the PACTE law has modified the IPC to state that ‘the patent nullity action shall not be subject to any statutes of limitations’.

22 Paris Court of First Instance, 10 February 2017, 16/07227 (3M/Saint-Gobain Abrasifs); Paris Court of First Instance, 15 April 2016, 15/01377 (DSM/Novozymes).

23 A similar provision is provided for the infringement action before the Unified Patent Court.

24 Transitional aspects shall be set by the Courts.

25 Paris Court of First Instance, 16 March 2017, 16/07920 (Actelion/Icos); Paris Court of First Instance, 28 April 2017, 19/09770 (B/E Aerospace/Zodiac Aérotechnics). This could be, for instance, the date on which the patent is opposed by the patent owner in a cease-and-desist letter (Paris Court of First Instance, 6 November 2014, 13/14239, Raccords et Plastiques Nicol/Mep), the date as from which an MA can be filed (Paris Court of First Instance, 30 November 2017, 16/14666, Mylan/MSD), or the date on which an opposition was filed against a corresponding patent at the EPO.

26 Article 124 of the PACTE law providing for a new article L.615-8-1 IPC.
Preliminary relief

Overview

Any person with standing to bring an infringement action may request preliminary relief against the alleged infringer or its intermediaries in order to stop the infringement or prevent an imminent infringement. In deciding whether to grant preliminary relief, a judge will assess the likelihood of infringement and the seriousness of the invalidity arguments raised by the defendant.

The criteria for assessing the validity of a patent in hearings for preliminary relief are substantially the same as for proceedings on the merits. As such, when validity is raised, it can be difficult for a claimant to obtain preliminary relief. Further, although it is not always clearly stated in the decisions, judges in hearings for preliminary relief tend to adopt an approach that focuses on a balance of convenience and proportionality.

Nevertheless, recent cases show that judges are more inclined to grant preliminary injunctions. For instance, in the healthcare sector, originators obtained significant preliminary injunctions, sometimes even in case of extreme urgency, accompanied by recall measures and significant provisional damages.

If successful, the claimant must initiate an action on the merits within one month of obtaining an order granting preliminary relief.

In theory, such order can be granted *ex parte* in case of emergency; namely, if any delay would be likely to cause irremediable harm to the claimant. In practice, *ex parte* preliminary measures are almost never granted in patent matters. The judges consider that such measures should only be available in very extreme cases such as repeated infringement by the same infringer.

Preliminary measures may also be ordered in the course of a proceedings on the merits by the case-management judge. In such case, the defendant can only appeal the measures once a decision on the merits has been reached. This delay can be very damaging for the defendant.

Injunctions

If infringement is found, the judge generally prohibits the continuation of alleged infringing acts. The judge can submit the injunction to securities (to ensure the complainant will be compensated if the injunction is overturned on appeal) although it is rare in practice. The judge can also order the seizure of allegedly infringing products to prevent their introduction or circulation in the commercial channels.

27 Paris Court of First Instance, 31 January 2019 (JC Bamford Excavators/Manitou), 17-06462, Paris Court of First Instance, 8 February 2019, (MSD/EG Labo), Paris Court of First Instance, 8 February 2019 (MSD/Sandoz) and Paris Court of First Instance, 22 February 2019 (AH/BERA), 18/58204.

28 Paris Court of First Instance, 11 January 2019, 18-60334 (Janssen/Sandoz), preliminary injunction ordering the recall from pharmacies for an SPC expiring only 43 days later.

29 Paris Court of First Instance, 7 June 2018, 16/15196 (Teva/Novartis and al.), Paris Court of First Instance, 7 March 2019, 17/14664, (Mylan/Merck Sharp & Dohme Corp & MSD France).
Asset seizures
If the claimant is able to show that there is a risk that recovery of potential damages may be inhibited by the claimant’s behaviour, the judge may order the precautionary seizure of the defendant’s movable and immovable property. This includes the freezing of the defendant’s assets. These measures are rarely applied in practice.

ix Warning letters and risk of unfair competition
Sending a cease-and-desist letter to infringers is not required before initiating an infringement action.

The IPC distinguishes ‘direct infringers’ (manufacturers and importers) from ‘indirect infringers’ (distributors). The latter can only be liable for damages if they are aware that their activities may be infringing.

For this reason, patent owners often send warning letters to put indirect infringers on notice. However, great care must be taken while drafting such letters, as it may constitute unfair competition towards the supplier.30

Moreover, the question of being on notice regarding potential patent infringement is important in relation to damages because serving a writ of summons has been held to establish awareness for the future: as soon as a distributor receives a writ of summons, it is liable for subsequent acts until the decision on the merits.

Protective letters are not admitted, either to prevent a preliminary injunction or a saisie-contrefaçon. This is compensated by the fact that the seized party can file a motion for withdrawal of the order authorising the saisie-contrefaçon to reintroduce the adversarial principle.

IV SUBSTANTIVE LAW
i Infringement
Acts constituting infringement
The IPC broadly defines acts constituting patent infringement as:

a the manufacture, supply, placing on the market, use, importation, exportation, transshipment or holding of, for the aforementioned purposes, the product subject to the patent;

b the use of a process subject to the patent or, where the third party knows or where circumstances make it clear that the use of the process is prohibited without the consent of the owner of the patent, the offer of its use on French territory; and

c the supply, placing on the market, use, importation, exportation, transshipment or possession for the aforementioned purposes of the product obtained directly by the process subject of the patent.

Contributory infringement is also prohibited under French law.

As regards pharmaceutical patents covering an active ingredient, the fact that a generic company obtains an MA for its generic product does not indicate imminent infringement

30 Paris Court of First Instance, 16 November 2017, 14/14922 (SAS Commerce Spectacle Industrie/Philips).
for the purposes of obtaining a preliminary injunction. However, additional circumstances, for example arising from correspondence with regulatory authorities or advertising, may help prove imminent infringement. The standard of proof is nevertheless quite high.

**Doctrine of equivalents**

In principle, a patent is a self-contained title where the sole purpose of claim construction is to understand the exact scope of the monopoly right granted under the patent, taking into account description and drawings, after examination or opposition procedures.

File wrapper estoppel is not applied under French law, although a patentee’s declarations before the relevant authorities, including patent offices, in foreign jurisdictions can be taken into consideration to assess the overall credibility of the patentee’s assertions.

Construction must be true to the claims and must not change the nature of the patent, but it must also not be too literal. Under the doctrine of equivalents, a party might be held liable for patent infringement even though the infringing device or process does not fall within the literal scope of the claims of a patent, but is nevertheless equivalent to the claimed invention. The doctrine considers that two means are equivalent if, despite being of a different shape, they perform the same function in view of the same result, provided the function exercised by the patented device or process is novel.

**ii Invalidity and other defences**

**Invalidity**

A French or European patent can be revoked for:

a a lack of novelty;
b a lack of inventive step;
c a lack of industrial application;
d excluded subject matter;
e insufficiency;
f added matter beyond the content of the application as filed;
g an extension of the scope of the patent claims after limitation or amendment; or 
h if the proprietor of the patent is not the inventor nor his or her successor in title (taking into account relevant employment law).

If the grounds of invalidity affect only part of a patent, nullity is affected by limiting the relevant claims.

A trend of French case law is to consider, in the context of inventive step or insufficiency, whether the patent solves the technical problem it is supposed to and if the patent presents a plausible way of solving the technical problem at the date the patent was filed across the breadth of the claims.

In this respect, some decisions have required patents to include tests or data to show that the technical effect or effects of the patent can be reached. In the absence of any such tests, post-filing evidence should be dismissed. This case law was ambiguous and relied on the vague notion of a ‘speculative’ patent. A more classical approach of plausibility seems to have

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31 Paris Court of Appeal, 27 June 2017, 14/25023 (Vorwerk/Lacor et al); Paris Court of Appeal, 28 November 2017, 15/12176 (K Hartwakk Oy Ab c/ SAS Touraine Emballage Recyclage).
been adopted by the Paris courts since 2018. The Supreme Court has confirmed that there is no legal requirement to provide for clinical data within the description, but admitted that, in specific cases where a patent covers a new therapeutic application of a known compound, the patent application must reflect directly and unambiguously the claimed therapeutic application. How this general ruling will be applied in practice remains uncertain.

Acts that cannot infringe a patent monopoly

Patent rights cannot be infringed by:

- *a* acts done privately and for non-commercial purposes;
- *b* acts done for experimental purposes relating to the subject matter of the patented invention;
- *c* the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription, or acts concerning the medicine so prepared;
- *d* studies and tests required for the granting of an MA for a medicinal product, as well as for the acts necessary for their realisation, for obtaining said authorisation and for obtaining the required advertising (the *Bolar* exemption); and
- *e* acts related to extra-atmospheric space vessels introduced into French territory.

The French *Bolar* exemption is not limited to generic drugs, but applies to any drug, including biosimilar drugs. The *Bolar* exemption also covers the allocation of medical drugs to patients in the framework of temporary use authorisation (by name or cohort).

Personal prior possession

Any person who, in good faith on the date of filing or priority of a patent, was in possession of the invention subject of the patent, has the personal right to exploit the invention despite the existence of the patent. However, this right is limited and cannot be transferred.

Exhaustion of rights

The rights conferred by the patent do not extend to acts concerning the product covered by that patent carried out on French territory after the product has been placed on the market in France or on the territory of a state party to the Agreement on the European Economic Area by the proprietor of the patent or with his or her express consent.

Such a solution stems from the principles of free movement of merchandise, goods and services within the EU. Provided that the patent owner has agreed to the marketing of its products in the EU, he or she will not be able to rely on its patent to prevent the circulation of such goods within the EU.

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32 Paris Court of First Instance, 26 January 2018, 16/01225 (*Ethypharm/MSD*).
33 Supreme Court, Commercial Ch., 6 December 2017, No. 15-19726 (*MSD/Teva*).
34 Paris Court of First Instance, 15 March 2016, 16/51152 (*Ono Pharmaceuticals et al/MSD*).
35 Article 10 of Order No. 2018-341 of 9 May 2018 related to the European patent with unitary effect and the Unified Patent Court has changed the wording of the exhaustion of rights provision. The 'express consent' of the 'holder' (and not the proprietor) of the patent will no longer be required. Exhaustion could be avoided in case the patent holder justifies of legitimate reasons to oppose the continuation of the product commercialisation.
**Competition law**

Competition law can be used as a defence in patent litigation. In some cases, patent rights may be limited by the courts to prevent anticompetitive behaviours (such as an abuse of a dominant position). Notably, the Paris courts will take into consideration fair, reasonable, and non-discriminatory (FRAND) issues related to standard-essential patents before granting an injunction on the basis of such rights.

**Good faith is irrelevant**

Infringement will be found irrespective of any good faith on the part of the infringer. However, indirect infringers cannot be held liable for carrying out acts that they did not know infringed a third party’s patent rights.

**V"

**FINAL REMEDIES FOR INFRINGEMENT**

1. **Non-monetary remedies**

**Injunction**

Where infringement is established, an injunction is generally granted by the Paris Court of First Instance with the following exceptions:

- when the patent has expired at the date of the decision;
- when a FRAND issue prevents any injunction;
- when a compulsory licence has been granted; or
- when a national defence exploitation is at stake.36

The injunction granted by the Court will cover the acts of infringement committed by the defendant, acting on its own or through the intermediary of any third party, and should also prevent all infringing acts as defined by Articles L.613-3–L.613-6 IPC (see Section IV.i).

Injunctions are generally subject to penalties when the defendant does not comply with the decision (per day or per act of non-compliance) and provisionally enforceable (see Section V.iii).

**Recall of the infringing products from the channels of commerce**

Recall of the infringing products is allowed under French law, both on the merits and in summary proceedings. This measure is carried out at the expense of the infringer and enforced at the claimant’s own risk.

**Publication of the decision**

Upon the request of a party, the Court may, at its discretion, decide to publish the decision in full or in part in newspapers or online.

36 Article L.615-10 IPC provides that:

when an invention which is the subject matter of patent application or a granted patent, is implemented for the needs of the national defence by the state or its suppliers, its subcontractors and subsidiary suppliers, without a licence having been afforded to them, the civil proceedings shall be brought before the First Instance Court sitting in chambers. The latter cannot order the exploitation to be stopped or interrupted, nor it can order the recall provided for by Articles L.615-3 and L.615-7-1.
In practice, an extract of the judgment may be published in magazines or in the press, and also on the main page of the infringer’s website. The specifics of the publication (webpage address, font size, duration, language) should be specified by the claimant.

This measure is also carried out at the expense of the infringer.

The claimant may also publish the judgment in full or in part on its own website, and does not need an authorisation from the court for so doing. However, such publication must be done with care to avoid any grievance for unfair competition by denigration (if the judgment is appealed, it should be mentioned).³⁷

ii Monetary remedies

Under French law, the damage suffered must be repaired in full – not less, not more. As such, punitive damages are thus excluded.

In considering whether to order damages, the court must consider:

a the loss, including lost profits, that the injured party has suffered;

b any unfair profits made by the infringer; and

c where appropriate, elements other than economic factors, such as the moral prejudice caused to the rightholder by the infringement.

All those heads of damage must be documented. For this purpose, the claimant can use all available evidence tools, such as:

a the saisie-contrefaçon;

b the right of information;

c general measures of investigation allowed by the law; and

d judicial expertise.

The profits generated by the infringer cannot be confiscated but are taken into consideration when assessing the prejudice suffered.³⁸ When the defender does not provide any financial information on its sales margin, the judge can set this amount based on other public elements.³⁹ This should not lead to damages higher than the prejudice actually suffered by the rightholder, although it has been admitted by the Paris Court of First Instance on 18 May 2017 (judgment currently under appeal).⁴⁰ This would typically be the case when the margin made by the infringer on the infringing products is higher than the margin made by the claimant.

Upon request from the claimant, the damages may also be a lump sum that should be higher than the royalties the rightholder would have received if the infringer had taken a licence. The rate is determined by the judge and generally corresponds to the average rate applicable in the field at stake, generally increased by 50 per cent. This is not considered as punitive damages, but as taking into account the fact that the patentee has not been willing to grant any licence to the infringer.⁴¹

³⁷ Supreme Court, Commercial Ch, 18 October 2017, No. 15-27136 (Normalu/Newmat).
³⁸ Paris Court of Appeal, 9 February 2018, 16/23925 (Pellenc c/Extrusion de Base Normandie).
³⁹ Paris Court of First Instance, 7 June 2018, 16/15196 (SAS Teva Santé/Novartis Pharma AG, SA Novartis Pharma AG and SAS Novartis Pharma), parliamentary report indicating that generic companies’ margin is about 50 per cent.
⁴⁰ Paris Court of First Instance, 18 May 2017, 11/16313 (SEE/Rabaud).
⁴¹ Paris Court of Appeal, 27 June 2017, 15/09294 (Vorwerk/Taurus et al.).
iii Provisional enforcement

Provisional enforcement may be granted at the Court's discretion (upon request from the parties or on its own motion) for all or part of the decision. It is usually granted for patent cases. Provisional enforcement may be subject to the prior creation of a guarantee.

The rightholder must be careful when deciding to enforce the decision that is provisionally enforceable, notably by notifying it to the defendant. This is a risk where the judgment is overturned in appeal as it could trigger civil liability for damages, without the defendant having to prove any fault.

Provisional enforcement may be lifted upon request from the defendant if it is prohibited by law, or if it is likely to result in disproportionate consequences.

iv Recent noteworthy awards against infringers

The amounts of damages granted by the Paris courts have steadily increased over the past few months. The decisions below illustrate this trend:

a Paris Court of First Instance, 7 June 2018, 16/15196, SAS Teva Santé v. Novartis Pharma AG and al., grants a provisional amount of approximately €13.1 million, reduced to €10.2 million by a decision of 25 October 2018 (parties have then settled and discontinued the proceedings);

b Paris Court of First Instance, 7 March 2019, 17/14664, Mylan v. Merck Sharp & Dohme Corp. & MSD France, grants a provisional amount of approximately €4.36 million (proceedings on the merits are pending);

c Paris Court of First Instance, 18 May 2017, 11/16313, SEE v. Rabaud, grants €1.53 million to the patent-holder, confirming prior decisions from the Paris Court of First Instance and Paris Court of Appeal (additional appeal before the Supreme Court has been dismissed);

d Paris Court of Appeal, 9 February 2018, 16/23925, Pellenc v. Exbanor, grants almost €1.5 million; and

e Paris Court of First Instance, 10 June 2016, 10/05487, Time Sport v. Decathlon and D-H-G Knauer, grants €1.4 million for economical loss and €50,000 for moral loss (appeal pending).

By comparison, below is a list with the top three largest awards against infringers for the period 2010-15:

a Paris Court of Appeal, 20 March 2015, 13/00552, Eurocopter v. Bell Helicopter Textron, grants provisional amount of €3 million (definitive amount unknown);

b Paris Court of First Instance, 29 June 2012, 10/06118, ECA v. BAE Systems, grants provisional amount of €6 million and €20,000 for moral loss (aggregate around €4.1 million after expertise); and

VI OTHER TYPES OF RELIEF SOUGHT IN PATENT PROCEEDINGS

i Application for compulsory licences

Under French law, an application can be made for a compulsory licence in two circumstances, both of which are distinct from the administrative licences that may be obtained by public authorities. Compulsory licences are non-exclusive licences that can be withdrawn by the court if their terms are breached by the licensee.

A compulsory licence will be available where a patent owner has:

- failed to exploit, or seriously and effectively prepared for the exploitation of a patent in the territory of a Member State of the European Economic Community (EEC) or the EEA;
- failed to sufficiently exploit the patented product to cover the needs of the French market; or
- stopped exploiting or covering the needs of the French market for more than three years.

For these purposes, importing the patented product into the territory of a member of the World Trade Organization agreement is considered to be an exploitation of the patent.

A compulsory licence may also be available where a second patent is placed in the dependence of a first patent. In such a case, where the invention of the second patent is considered to be: a substantial technical progression from the first patent; and of significant economic interest, the court may grant the owner of the second patent a licence under the first patent to the extent necessary for the exploitation of the second patent. Where such a compulsory licence is granted, upon application to the Court, the owner of the first patent shall also be granted a cross-licence under the second patent.

This type of compulsory licence is also available for patents concerning plant-variety rights.

ii Declarations of non-infringement

A declaration can be sought from the Court that an act, or proposed act, in a territory of a member state of the EEC does not infringe a patent. Prior to commencing court proceedings, a party seeking a declaration of non-infringement (DNI) shall invite a patentee to respond to a request for a DNI.

If the party seeking a DNI is not satisfied with the patentee’s response, or if the patentee does not respond within three months, an action can be brought before the Paris Court of First Instance. In such an action, the burden of proof of non-infringement rests with the party seeking the declaration.

The judgment in DNI proceedings is handed down without prejudice to any ongoing nullity action or any subsequent infringement proceedings.

DNIs are relatively rare in France and nullity actions are preferred by claimants.
iii Entitlement claim

Where an application for a patent, utility model or SPC has been made either for an invention unlawfully taken from an inventor or his or her successors in title, or in violation of a legal contractual obligation, the injured party may claim ownership of the application or of the granted title. This may arise where a co-developer of an invention is deprived of its right of ownership, or where an employee develops an invention outside the scope of its employment.

Actions claiming ownership of such a right must be brought within five years from the publication of the grant of the right. If the rights owner has acted in bad faith, a claim can be brought as from the grant of the right until its expiry.

iv Claim for additional remuneration or fair price (employees’ inventions)

France has an employee-friendly regime. The default position is where employees have an ‘inventive job role’ (either permanent or temporary, and whether recorded by way of written employment contract or not). Their inventions belong to the employer, but the employer is required to pay the employees an ‘additional remuneration’ (ranging from €400 to €200,000 per invention). Some decisions have ruled that, to be enforceable against the employees, the means to determine the additional remuneration should be provided for in the employment agreement, a company agreement or a collective bargaining agreement, failing which the statutes of limitations cannot apply and the final amount shall be set by the courts.43 This approach is questionable and not always followed by the Paris Court of First Instance.44

Where an invention is developed by an employee who does not have an ‘inventive job role’, the invention belongs to the employee, but the employer may exercise a right of first attribution on the invention. If the employer exercises this right, it shall compensate the employee by paying him or her a ‘fair price’ for the invention (ranging from €3,000 to €500,000 per invention).

In case of a disagreement on who is entitled to the invention or the additional remuneration or what is a fair price or additional remuneration, a party may apply to the National Commission for Employees’ Inventions (CNIS) to determine the dispute. This is recommended, as the assessment made by the CNIS is often reasonable and business-oriented. If this process does not settle the dispute, the case may be brought before the Paris Court of First Instance. The case may also be brought directly before the Paris Court of First Instance without any prior CNIS step. Statutes of limitation also apply to the employee’s claim for additional remuneration (or fair price), after three (or five) years from the date on which the employee knew or ought to have known the facts that enabled him or her to exercise the action.

v Customs procedures

It is possible to prevent the entry of possibly infringing goods coming to France from outside the Regulation (EU) No. 608/2013; or coming to France from inside the EU (IPC) by filing an action before French Customs. The application must include any and all information that

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43 Paris Court of Appeal, 30 May 2017, 16/06557 (Mr Wilson/SKF France) where it was decided that an internal policy is not binding on the employee.
44 Paris Court of First Instance, 23 March 2018, 15/00961 (Mr Raynaud/Meta Systems and Mentor Graphics Corporation).
would enable Customs to identify the allegedly infringing goods and to distinguish them from genuine goods. An application granted by French Customs lasts for one year. French Customs are not able to take samples and analyse allegedly infringing products.

vi Protection of trade secrets
The Directive (EU) 2016/943 of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure has been implemented in France through Law No. 2018-670 of 30 July 2018 on the protection of trade secrets.

While trade secrets were already protected in France, this protection is now part of the commercial code, where a harmonised definition of trade secrets has been provided for.

This law sets out a number of practices that were already implemented by the Paris courts in practice, in particular closed hearings and the ability for the Court to take a confidential document into consideration while limiting its communication and adapting the wording of its judgment to preserve trade secrets.

The articulation of the protection of trade secrets with the right to perform a saisie-contrefaçon has generated some litigation. Despite being secret, a seized element that is necessary to evidence infringement should be provided to the claimant. To balance the interests at stake, the judge can order the bailiff to put the seized elements under seals, give only access to designated outside counsels or restrict access to hearings, or both45.

vii Criminal law against infringement
In criminal proceedings, infringement can result in three years’ imprisonment and a maximum fine of €300,000.

In addition, the court may make an order for the recall of the products, their destruction and the publication of the criminal sentence. An injunction is not available in criminal proceedings.

Criminal proceedings are rare because no injunction is available and there is a low cap of recoverable damages. Criminal proceedings are more likely to be brought in cases concerning pirated goods or where the claimant wants to prove criminal liability of a company’s director.

VII APPEAL
An appeal can be lodged before the Paris Court of Appeal against any judgment rendered on the merits.

The appeal stays the enforcement of the first instance judgment, but the judgment is usually provisionally enforceable. The appeal is an automatic right and is a second chance for the whole of the case – both the legal and factual elements – to be reviewed before a specialised division (Pole 5). Under a new appeal procedure of appeal, which entered into force on 1 September 2017, the appellant must file a declaration of appeal specifying the reasons of the judgment he or she seeks to overturn.

45 Paris Court of Appeal, 16 April 2019, 15/17037, Conversant Wireless Licensing SARL v. LG Electronics France SAS & LG Electronics Inc.
Additional evidence can be brought before the Court of Appeal. New claims cannot be made, unless they have a sufficient link with the initial claims (for example, if a nullity counterclaim is based on lack of novelty, it would be possible to invoke insufficiency as well).

Hearings are usually short (up to one-and-a-half days) and are held by a court composed of three judges. The judges are not patent specialists but belong to a specialised division that is composed of two chambers and to which intellectual property cases are designated.

VIII THE YEAR IN REVIEW

The following cases were brought in 2018 and 2019:

a Paris Court of Appeal, 9 Oct 2018, 17/19934, *Santen*: referral to CJEU regarding the concept of a ‘different application’ within the meaning of the judgment of 19 July 2012, *Neurim* (C-130/11, EU:C:2012:489) and whether it should be interpreted strictly, that is to say limited only to the situation where an application for human use follows a veterinary application, or more broadly;

b Paris Court of Appeal, 14 December 2018, 13/00552, *Airbus Helicopters/Bell Helicopter*: a sale offer on an international exhibition followed by a protocolary signature is an act of infringement committed in France;

c Paris Court of Appeal, 22 January 2019, 18/10532, *Merck Sharp & Dohme Corp/ Directeur Général de l’INPI*: on the refusal of SPC covering a combination of active principles where one of the active principles was already covered by two previous SPCs, alone and in combination with another active ingredient;

d Supreme Court, 27 March 2019, 18-15005, *JC Bramford Excavators Ltd/SA Manitou BF*: confirming that patent attorneys that have previously worked for a claimant can be appointed by a judge to assist a bailiff during a saisie-contrefaçon;

e Paris Court of First Instance, 7 March 2019, 17/14664, *Mylan/Merck Sharp & Dohme Corp & MSD France*: regarding the grant of a preliminary injunction against a generic drug and a significant provisional amount of damages (approximately €4.36 million);

f Paris Court of First Instance, 8 April 2019, 15/16933, *Koninklijke Philips NV/Wiko*: a person who assists a bailiff by purchasing an infringing product must be fully independent from the party instructing the bailiff to draft the official report; a trainee lawyer at the law firm advising the instructing party is not independent; and

g Paris Court of Appeal, 16 April 2019, 15/17037, *Conversant Wireless Licensing SARL v. LG Electronics France SAS & LG Electronics Inc*: the Paris Court of Appeal ruled that the two SEPs were not essential so that infringement was not established and therefore no FRAND licence rate had to be assessed.

IX OUTLOOK

i New PACTE law

The PACTE law changes the landscape of French patent law, especially by (1) introducing an opposition procedure before the IPO where some validity aspects could be debated, (2) reinforcing the examination procedure further to a French patent application, (3) modifying the statutes of limitations related to both infringement and nullity actions, and (4) strengthening the utility certificates.
ii Nullity actions

The limitation period pertaining to nullity actions has become a significant legal issue in France. Case law has confirmed that a patent nullity action is subject to a five-year limitation period, while new PACTE law now provides that statutes of limitations does not apply to patent nullity actions. Questions about the transitional period issues will probably arise in the very near future.

iii Saisie-contrefaçon

Paris Court of Appeal rulings allow for a more effective saisie-contrefaçon by limiting the amount of information needed from a claimant to obtain the requisite order. However, the courts remain wary, to prevent saisies-contrefaçon from becoming fishing expeditions. In addition, protection of trade secrets is now officially taken into account in the law as a specific regime has been implemented to allow the judge to protect the trade secrets of a seized party.

iv Bailiffs

A party can present evidence of infringement by way of official reports drafted by a bailiff. However, a Supreme Court decision provides that a person who assists the bailiff by purchasing an infringing product must be fully independent from the party instructing the bailiff to draft the report. A trainee lawyer at the law firm advising the instructing party is not independent for these purposes. The Paris Court of First Instance has taken this decision into account and it is now difficult to organise a bailiff report safely.

v Undertakings

Undertakings to grant FRAND licences, and more generally FRAND issues, are also of a significant importance in France, especially as the European Telecommunication Standard Institute policy is governed by French law. Standard-essential patents are core issues that are dealt with by the Paris Court of First Instance.

vi Unified Patent Court

The Unified Patent Court is a topic of interest in France, not least because Paris has been elected as a location of the central division for which more than 130 judges have applied. Order No. 2018-341 of 9 May 2018 modified the IPC to prepare the entry into force of the agreement on the Unified Patent Court, which remains suspended to the decision of the German government (which itself seems to be postponed until the United Kingdom leaves the European Union).

46 Paris Court of First Instance, 22 December 2017, 17/14521 (Constellium Issoire/Arconis Inc).
48 Paris Court of First Instance, 8 April 2019, 15/16933 (Koninklijke Philips NV/Wiko).
Chapter 9

GERMANY

Julia Schönbohm, Bolko Ehlgen and Natalie Ackermann-Blome¹

I OVERVIEW

Germany is one of the most prominent European jurisdictions for patent litigation and remains the most frequented one. In 2018, the German patent courts recorded almost 800 new cases, which is only slightly less than in previous years. The Regional Court Düsseldorf continues to attract the highest number of cases, followed by the courts in Mannheim and Munich. German courts are known for their technical expertise and predictability. Trials are relatively fast, and the costs are moderate. The German bifurcation system (separate trials for infringement and validity) remains attractive for patentees.

II TYPES OF PATENTS

Two types of patents are available in Germany: national patents pursuant to the German Patent Act (GPA) and German parts of European Patents according to the European Patent Convention (EPC). German law also affords protection in the form of utility models and supplementary protection certificates (SPC).

i Patents

National patents are granted for inventions in all fields of technology. The teaching must be new, involve an inventive step and needs to be industrially applicable (Section 1, Paragraph 1 GPA). The GPA provides for the typical exclusions from patent protection (e.g., violations of ordre public, inventions relating to the human body, procedures for cloning and modifying the genetic identity of human beings, plant and animal varieties). Discoveries, scientific theories, mathematical methods or business models are not considered inventions.

The German Patent and Trademark Office (GPTO) grants national patents. Following their grant, anyone can challenge the validity of a patent by filing an opposition within nine months as of the publication of the grant. Thereafter, a patent can only be challenged by filing a nullity action before the German Federal Patent Court (FPC). German opposition proceedings largely correspond to proceedings before the European Patent Office (EPO), as described in the European Patent Office chapter. The term of a German patent is 20 years, beginning with the filing date.

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Germany is a member of the EPC and the Patent Cooperation Treaty (PCT). Applicants can designate Germany in an EPC or PCT application. Once a European Patent has been granted, its German part is handled similarly to a national granted patent.

ii Utility models

Protection for inventions is also available in the form of utility models. The maximum term of a utility model is 10 years from the application date. The requirements for protectability and the rights afforded by a utility model are in principle like those of a patent. Method claims are, however, excluded from utility model protection. Novelty requirements are less strict than for patents (e.g., oral disclosures are not relevant prior art). Public prior use is only considered prior art if such use is domestic. Utility models benefit from a six months’ grace period for publications attributable to the applicant. This allows securing utility model protection when patent protection would not be available.

The GPTO will review some formal requirements before registering a utility model. It will, however, not review the substantive requirements for utility model protection. As an unexamined right, a utility model can be registered in as little as three to four months. In the absence of a presumption of validity, it is more difficult to enforce a utility model than a patent. The defendant can raise lack of validity as a defence against an infringement claim based on a utility model, in addition to filing a cancellation request before the GPTO. The infringement court must be convinced of the utility model’s validity before finding in favour of the holder.

The applicant can rely on granted foreign patents with the same scope to derive a presumption of validity. In such circumstances, the utility model can be an attractive and flexible enforcement option. Applicants can file a utility model divisional from a pending (national or European) patent application to quickly obtain an unexamined but enforceable right before the grant of the parent patent. A utility model can be enforced in a scope more limited than the scope of the registered claims. This allows ‘tailoring’ an infringement claim to the accused embodiment to reduce validity concerns.

iii Supplementary protection certificates

The term of protection for patents covering pharmaceutical or plant protection products that require a marketing authorisation can be extended for up to five years with the grant of an SPC. An SPC comes into force after the basic patent has expired. Regulation (EC) No. 469/2009 of 6 May 2009 applies to SPC protection in Germany as well, in addition to Section 16a GPA.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Competent courts

Germany has a bifurcated enforcement system. Infringement and nullity proceedings are heard at different courts. Civil courts are competent to hear infringement proceedings, and the FPC decides about nullity proceedings. Judges in infringement proceedings may determine

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2 Section 2 no. 3 German Utility Model Act. The Federal Court of Justice, ruling of 27 March 2018, X ZB 18/16 – Feldmausbekämpfung recently affirmed the constitutionality of this provision.

3 Federal Court of Justice, ruling of 13 May 2003, X ZR 226/00 – Momentanpol.
the scope of the patent for the infringement assessment. They are, however, bound by its grant and any decision of the FPC or the EPO on validity. A defendant may, therefore, not raise an invalidity defence or bring a counterclaim for invalidity in infringement proceedings. Infringement courts may merely stay the proceedings if a validity proceeding is pending.

ii Infringement

The regional courts are competent to hear infringement proceedings in the first instance, irrespective of the value of the dispute. Appeals are heard at the higher regional court, and further appeals on questions of law are, in important cases, heard at the Federal Court of Justice (FCJ). Each federal state can determine a single competent regional court to hear patent cases in its territory. The respective courts establish specialised patent chambers to ensure that experienced judges decide patent disputes. The chambers consist of three legally qualified judges and no technical judge. The same applies for the senates at the higher regional court. The FCJ decides with a panel of five legally trained judges. The most popular courts are at the regional courts of Düsseldorf, Mannheim, Munich, Frankfurt and Hamburg. The regional court where the defendant is domiciled or where the infringement took place has jurisdiction. Infringing offers on the internet amount to an infringement in all of Germany and allow the plaintiff to choose the venue.

German infringement courts prepare the trial with a fixed schedule of written submissions. The complaint should contain all relevant facts to substantiate the alleged infringement. A defendant needs to make all possible defence arguments in its statement of defence. This includes any arguments that could warrant a stay of the proceedings. The burden of proof for infringement is on the plaintiff. The plaintiff must specifically demonstrate and substantiate infringement. German procedural law has no counterpart to court-supervised fact-finding, such as discovery.

Infringement proceedings are ‘front-loaded’. They heavily depend on written submissions. Parties usually submit two rounds of briefs before the oral hearing: complaint, statement of defence, joinder and rejoinder brief. Parties often submit further briefs close to the oral hearing. Briefs after the oral hearing are rarely considered, unless the court has explicitly allowed a party to submit another brief. Oral hearings are short and focus on those issues that the chamber considers most relevant or still unclear. As a rule of thumb, hearings take between one hour in a standard case and up to three hours in more complex cases. A decision usually issues about four weeks after the oral hearing.

Infringement courts determine the scope of the patent (see Section IV.i.). The parties must present the facts and the corresponding evidence to the court. The court may then take evidence _inter alia_ by hearing witnesses or appointing neutral experts if necessary.

iii Invalidity

Invalidity proceedings are either opposition proceedings at the EPO or GPTO respectively or nullity proceedings at the FPC. For opposition proceedings please see Section II.i.

The FPC will decide nullity actions against patents in the first instance. The senate at the FPC is comprised of five judges, two fully legally qualified judges and three technical judges. Decisions of the FPC can be appealed to the FCJ. The FCJ decides with a panel of five legally trained judges.
Anybody can file a nullity action. A specific legal interest is not required unless the patent that is challenged has already expired. The nullity proceeding is not time-bound. It can, however, only be initiated after the opposition period has lapsed or a pending opposition proceeding has been concluded.

The nullity action may be based on the following reasons:

a lack of patentability;
b insufficient disclosure;
c usurpation; and
d added matter.

The FPC will investigate the facts of the case ex officio. The claimant must substantiate the grounds of invalidity. The parties usually file one or two rounds of briefs. The patentee must formally object to the nullity complaint within one month of service. To ensure timely proceedings, the FPC shall inform the parties as early as possible on the aspects that it considers relevant for its decision in a preliminary assessment. The court can order the parties to respond to its assessment within a specific timeframe. According to Section 83, Paragraph 4 GPA, the respective party may be precluded if it submits new facts or files new auxiliary requests after the deadline set by the court. Nullity proceedings are, therefore, equally front-loaded as infringement proceedings. Oral hearings are, however, much more detailed and often last a full day. The decision usually issues immediately after the oral hearing. The written grounds are only provided two to three months thereafter.

iv Requirements for establishing standing in Germany

The patentee has standing for an infringement proceeding per se. The exclusive licensee may also assert claims resulting from patent infringement as its own right. Patent ownership or a valid exclusive licence need to be established on the day of the oral hearing. Standing to sue requires that the material owner of a patent is registered in the patent register. Such registration is, however, not necessary for effectively assigning ownership.

A non-exclusive licensee has no own standing to sue. It therefore cannot claim own damages suffered because of patent infringement. Depending on the remedy sought, the non-exclusive licensee can derive a right to bring suit for patent infringement from the patentee: the patentee needs to authorise the non-exclusive licensee to bring the claim for an injunction and other claims with an injunctive character (e.g., recall and destruction). The non-exclusive licensee must furthermore have a legitimate interest to assert the claims on behalf of the patentee. Any economic interest is usually sufficient (e.g., if the infringing acts diminish sales revenue). The claims for damages, accounting and compensation can be freely assigned. The authorisation and assignment need to be completed on the day of the oral hearing.

v Stay of proceedings

Infringement courts may stay proceedings (Section 148 of the Code of Civil Procedure (CCP)) until a decision on patent validity. A stay allows aligning the infringement proceedings with the separate validity proceedings to avoid deviating decisions. The decision to stay the infringement proceedings is within the discretion of the court. It shall consider the interest of the patentee to enforce its exclusive right even before a decision on validity and the interest of the alleged infringer of not being wrongly enjoined because the patent is later found to be invalid. The patent right must not be undermined. Courts are, therefore, reluctant to stay the infringement proceedings in first instance.
Courts will stay the infringement proceeding in first instance if they believe that it is highly likely that the patent will be invalidated. The threshold is slightly lower in appeal instances. The court not only considers the likely outcome in the validity proceeding. Courts are more likely to stay infringement proceedings if the patentee merely asserts its claim for damages. Unlike the claim for injunctive relief, suspending a decision on a damages claim does not impact the right of the patentee to exclude others from making use of the patent. The case law also supports that the threshold for a stay is lower once the patentee defends the patent in the validity proceedings with only limited scope.⁴

vi Timing and cost considerations
The decision on infringement is usually issued much quicker than the decision on validity. The average duration of an infringement proceeding in the first instance ranges between 10 (for Mannheim, 12 (for Munich) and 20 (for Düsseldorf) months after the complaint was filed. The FPC currently needs at least 24 months to render a decision, often much longer. Because the FPC is more likely to invalidate a patent than an infringement court is likely to stay the case, this difference in timing often leads to provisionally enforceable first (or even second) instance infringement decisions based on patents that are subsequently invalidated.

In a litigation before a German civil court, the losing party bears the statutory costs of the litigation. These costs include court fees, statutory attorney (and patent attorney) fees and other reasonable expenses, such as travel and translation costs. The plaintiff in an infringement proceeding must advance the court fees after filing the complaint for the complaint to be served on the defendant. If the plaintiff prevails, the defendant must reimburse the court fees to the plaintiff. Statutory court and attorney fees both are calculated based on the value in dispute. The statutory limit is €30 million. If the value in dispute is, for example, €1 million, statutory court fees amount to €16,008. The court fees are higher for appeals (i.e., €21,344 at this value for the appeal to the higher regional court). A further appeal to the FCJ in such case, if admitted, would trigger court fees in the amount of €26,680.

The costs of a first instance nullity proceeding range between the costs of an appeal and a further appeal in an infringement proceeding for the same value in dispute. The FPC usually uses the value in dispute of the infringement proceeding and adds 25 per cent. The statutory fees of the nullity action are then calculated based on this increased value in dispute.

vii Preliminary injunctions
In urgent cases, a patentee may enforce its claim for injunctive relief within a few days or weeks. The courts that hear the main proceedings are also competent to issue preliminary injunctions (PI). The threshold for a PI to be issued is, however, high. The court must find, that patent validity is beyond doubt, the patent is clearly infringed, and the matter is urgent. The court considers a matter urgent if the applicant requests a PI within a month of learning the facts that constitute the alleged infringement. The Düsseldorf court applies a more flexible test that considers the actual circumstances. Petitioners may even wait until a second

⁴ Higher Regional Court Munich, ruling of 8 December 1989, 6 W 3050/89 – Regal-Ordnungssysteme; Regional Court Munich, ruling of 21 September 2017, 7 O 15820/16 – Maskensystem; see also Kühnen, Handbuch der Patentverletzung, 11th edition 2019, D. para. 731 et seqq.
instance decision on patent validity before taking action, if they have good reasons to wait.  
A reason would be if the decision on validity resolves an uncertainty as to whether the patent is infringed.

The burden of proof is with the petitioner, who must substantiate and show credibly all facts from which the infringement follows, why patent validity is beyond doubt and why the case is urgent. Unlike in main proceedings, the court does not take formal evidence, e.g. expert reports, but often relies on affidavits, which, unlike in main proceedings, are admissible in PI proceedings.

The court may issue an *ex parte* PI a couple of days after filing if the court is convinced that the patent is clearly valid and has been infringed and the matter is particularly urgent. A matter is urgent and warrants a PI to be issued *ex parte* if a further delay deprives the applicant of effective relief. This is usually the case at trade shows and for short-term sales activities. Last year, the Federal Constitutional Court (FCC) imposed stricter requirements for *ex parte* PIs to fully consider the ‘principle of procedural equality of arms’. *Ex parte* injunctions are now only permissible if the purpose of the proceedings would otherwise be defeated. The decision limits the relevance of *ex parte* PIs in German patent law to rare exceptions (i.e., trade shows). Where the circumstances permit, German courts will only consider granting a PI *ex parte*, if the applicant has sent a warning letter to the respondent to inform them about the infringement allegation and to provide the opportunity to reply. The alleged infringer should present all its arguments in detail. The applicant is required to submit such reply to the court to also inform the court about the other side of the ‘story’. If the respondent does not reply or replies only superficially, the courts assume that the respondent does not have better arguments. This may support the argument of the applicant and work against the respondent.

If an alleged infringer anticipates a PI, the infringer may also file a protective brief to present its arguments on its own initiative. The protective brief is comparable to an anticipated statement of defence. Such writ can raise doubts as to the merits of the claim and therefore prevent a PI from issuing *ex parte*. It may, however, also ‘backfire’ and enhance the chances of an *ex parte* PI if relevant details are provided. Moreover, the courts will assume that the respondent has presented its defence arguments and will be less inclined to schedule a hearing to hear the respondent’s side. It must therefore be carefully considered whether to file such brief. If the applicant has sent a warning letter first and the alleged infringer has already replied, a protective brief may no longer be necessary.

**viii Warning letter**

The patentee may alert the alleged infringer of the infringement by sending a warning letter before filing a complaint or PI application. In the letter, the patentee usually describes why the recipient infringes the patent. The patentee furthermore requests that the alleged infringer signs a cease-and-desist declaration. The description of the patent infringement needs to be specific, allowing the alleged infringer to verify the allegations and to refrain from continuing the infringing acts. The patentee usually sets a contractual penalty for each violating act. Such penalty may either be a specific amount, or the patentee may use a penalty model based on the

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5 Higher Regional Court Düsseldorf, ruling of 29 June 2017, I-15 U 4/17 – *Vakuumgestütztes Behandlungssystem*.

6 Federal Constitutional Court, ruling of 30 September 2018, 1 BvR 1783/17.
‘Hamburg custom’. According to the Hamburg custom, the patentee does not have to specify the penalty. The patentee may leave the appropriate penalty to its own discretion, allowing for a court to review, in case of dispute between the parties, if the penalty is appropriate.

An unjustified warning letter triggers liability of the patentee for damages the recipient suffers because of the unwarranted warning. Such damages are usually limited to the statutory attorney fees but may also include lost profits for lost sales, in particular if the warning letter was sent to customers of the infringer.

A warning letter also provides a reason for the alleged infringer to file a declaratory action of non-infringement. In a cross-border context, this may lead to a ‘Torpedo action’ in another EU Member State. As a result, the patentee could be hindered from filing an infringement action in Germany. Under Article 29, Paragraph 1 Brussels Ia Regulation, German courts must stay the subsequently filed infringement proceedings if proceedings are pending between the same parties on the same subject matter in another EU Member State, until jurisdiction of the first court is decided.

IV SUBSTANTIVE LAW

i Infringement

The patent claims determine the scope of protection. Under German law, patent claims must be interpreted in line with the understanding of the average skilled person in the relevant field of the art. The description and drawings must be considered in the interpretation. German courts put little to no relevance on the prosecution history of a patent when interpreting its scope.

ii Patent infringing acts

Pursuant to Section 9 GPA, the following acts directly infringe a patent:

a manufacturing, offering, putting on the market or using a patented product, or importing or possessing such product for the aforementioned purposes;

b using the patented method or offering the method for use in Germany, if the offering party knows or it is obvious from the circumstances that the use of the method is prohibited without the patentee’s consent; and

c offering, putting on the market or using a product immediately manufactured with a patented method, or importing or possessing such product for the aforementioned purposes.

Only an act in Germany can infringe a German patent. The courts are rather generous with finding domestic infringement. An offer that is directed to the German market is a domestic act regardless of where it originates. A product is put on the market in Germany if it is sent from Germany to a destination abroad or from a source abroad to a destination in Germany. The case law is stricter for method patents. Infringement either requires all process steps to be performed domestically, or the steps performed abroad must be attributable to the domestic steps. Such attribution is not possible if the results of the method are commercialised in Germany, but the final process step takes place outside of Germany. The liability for immediate products of patented methods extends beyond the territorial scope of method.

7 Higher Regional Court Düsseldorf, ruling of 23 March 2017, I-2 U 5/17 – Pränatale Diagnostik.
patents. Marketing immediate products of a patented process in Germany infringes the German patent, regardless of where the protected manufacturing method was carried out. The FCJ has, however, found that the presentation of a diagnostic result derived from a patented diagnostic process is not an immediate product of such process because it merely represents information.\(^8\)

The person that is committing the infringement is liable as infringer. Liability for infringement extends to third parties whose negligent behaviour enabled the infringement or who aided and abetted in the infringement of another person. The FCJ recently confirmed the liability for infringement in Germany of a foreign manufacturer who delivered the infringing product to a third party abroad but knew or had reason to know that the third party would later import the product to Germany.\(^9\) In addition to the company on behalf of which the infringement occurred, the management can be liable for infringement. This applies to the management personnel in whose area of responsibility the infringement occurred and to any management that knew of the infringement (or reasonably should have known) but failed to prevent it.

Mere preparatory steps do not constitute infringement. Patentees can, however, seek individual remedies for infringement even before the first infringement has occurred if there is a sufficiently high risk that an infringement will take place (Erstbegehungsgefahr). Showcasing an infringing embodiment (medical device) that is not yet marketable because a required certification has not been granted (yet) does not meet the threshold that triggers liability.\(^10\) Obtaining a marketing authorisation that allows the individual to market a pharmaceutical product does not result in liability for intended marketing of the product, at least if the allegedly infringed patent will lapse before the authorisation becomes invalid for non-use.\(^11\)

If the marketed product does not fulfil all elements of the relevant patent claim, but may do so in a subsequent manufacturing step, a third party may be liable for indirect infringement under Section 10 GPA. This applies if a third party supplies or offers to supply (in Germany) an unauthorised person with means relating to an essential element of the invention for implementation in Germany if the third party knows, or it is obvious from the circumstances that the means are suitable and intended to be used for implementation of the invention.

### iii Doctrine of equivalents

If an embodiment or method does not fall within the literal scope of a patent claim (considering also the understanding of the skilled person), it may nevertheless infringe the patent under the doctrine of equivalents. Infringement under this doctrine is subject to the following requirements:

\(a\) the embodiment solves the problem underlying the invention with modified means having objectively the same effect (Gleichwirkung);

\(b\) the person skilled in the art must have been able to come up with the modified means as having the same effect without any inventive effort (Naheliegen); and

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\(^8\) Federal Court of Justice, ruling of 27 September 2016, X ZR 124/15 – Rezeptortyrosinkinase II.

\(^9\) Federal Court of Justice, ruling of 16 May 2017, X ZR 120/15 – Abdichtsystem.

\(^10\) Regional Court Hamburg, ruling of 24 October 2013, 327 O 326/13 – Koronarstent.

\(^11\) Higher Regional Court Düsseldorf, ruling of 20 September 2012, I-2 U 44/12 – HIV-Medikament.

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c the required considerations must be based on the meaning of the technical teaching such that the skilled person considers the modification as an equivalent solution (Gleichwertigkeit).

Additionally, the accused embodiment, including the modified means, must have been new and inventive over the prior art at the priority date of the patent. This Formstein defence is an exception to the rule that validity considerations cannot be raised as defence in an infringement case.

### iv Invalidity and other defences

Outside a claim based on the doctrine of equivalents, the German bifurcation system excludes challenges of a patent’s validity as a direct defence against an infringement allegation. A defendant can only request to stay the infringement proceedings pending the outcome of a separate opposition or nullity action.

The defendant can, however, raise other substantive defences, the most important being as follows.

**Permitted use**

Section 11 GPA exempts a number of activities from patent infringement, namely private, non-commercial use, experimental use (provided that the experiment relates to the subject matter of the invention), the Roche-Bolar exemption (permits studies and trials required to obtain a pharmaceutical marketing authorisation in the EU or third countries), individual preparation of drugs in pharmacies based on a physician's prescription and use of the patent in vessels or vehicles that only temporarily enter the German territory.

**Right of prior use**

If a defendant had already begun to use the invention in Germany or had made the necessary arrangements for doing so at the date of the patent application or the relevant priority date, it is entitled to continue using the invention for purposes of its own business (Section 12 GPA). The right of prior use is specific to the respective business. The FCJ is expected to decide whether and under which circumstances a supplier of components of a patented product (who would qualify only as an indirect infringer) can later rely on its prior use for directly manufacturing the product.12

**Licence**

The patentee is precluded from enforcing its patent against a party having a valid licence in the patent.

**Exhaustion**

If the patented product is placed on the market in the EU or EEA by the patentee or with the consent of the patentee, the patentee's rights of exclusivity with respect to that product are exhausted. German law currently shows no tendency that would support a worldwide

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concept of exhaustion. The most prevalent exhaustion cases relate to whether the replacement of parts of a device that is already on the market qualifies as (exhausted) intended use or as (non-exhausted) remanufacturing of the device.\(^\text{13}\)

**Statute of limitations**

The general statute of limitations also applies to patent infringement. The remedies for infringement become time-barred after three years from the end of the year in which the claim arose and the claimant became aware (or grossly negligently did not become aware) of the identity of the defendant and the grounds giving rise to the claim. Irrespective of any knowledge about the claim, claims for patent infringement become time-barred 10 years after the claim arose. In practice, the effect of the statute of limitations is limited. If an infringement continues, each new infringement serves as recurring basis for the injunctive claim. Contrarily, damages can only be claimed for infringements that occurred within the limitation period. After the damages claim has lapsed, the patentee is still entitled to claim the unjust enrichment of the infringer as part of a ‘residual damages claim’, which itself does not become time-barred for 10 years from the infringement. This practically extends the damages claim for an overall period of 10 years.

**Laches/estoppel**

The defence of laches/estoppel applies in Germany if the claimant has remained inactive for a longer period and thereby created the impression that it will no longer assert the claim. The requirements for this defence are high. In practice it rarely applies, also given the rather long limitation periods.

**Antitrust defence**

Patents are meant to create a monopoly, which leads to the conflict between patent and antitrust law. In recent years, most disputes in the context of the antitrust defence have revolved around determining whether a patentee claiming injunctive relief based on a standard-essential patent (SEP) abuses its rights. Having a dominant market position, which does, however, not automatically follow from holding an SEP, may require the patentee to offer a licence to the infringer on fair, reasonable and non-discriminatory (FRAND) terms. Failure to offer a licence on such terms precludes remedies with injunctive character.

The leading European case on antitrust-related defences against SEP enforcement remains the European Court of Justice (ECJ) *Huawei v. ZTE* decision from 2015,\(^\text{14}\) which was based on a referral from the Regional Court Düsseldorf. German courts are still working to specify the details of the process that the ECJ requires for enforcing SEPs, namely consisting of a notification of infringement by the patentee, the implementer’s request of a licence showing its willingness to licence, a licence offer by the patentee, potentially followed by a counteroffer from the implementer. On various issues, the rulings of the prominent higher regional courts of Düsseldorf and Karlsruhe are divided. In 2019, an infringement case was finally appealed to the FCJ. It is expected to provide guidance from the highest German civil court on some FRAND issues in the foreseeable future.

Recent key developments from the first and second instance courts were as follows:

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\(^{13}\) Federal Court of Justice, ruling of 24 October 2017, X ZR 55/16 – *Trommelinheit*.

\(^{14}\) European Court of Justice, ruling of 16 July 2015, C-170/13 – *Huawei v. ZTE*.
a The Regional Court, Düsseldorf enjoined the German subsidiary of an international corporation even though the defendant had made a counteroffer for a licence. The court held that the subsidiary’s counteroffer cannot be FRAND if the patentee seeks to license the parent company, although the parent was not a party to the litigation.15

b The Higher Regional Court, Düsseldorf held that a FRAND declaration by the previous holder of the patent has a binding effect on the acquirer of the patent. The acquirer must adhere to the terms of the original FRAND declaration and cannot use the sale of the patent to claim higher royalties.16

c The ECJ’s process steps must usually be followed before filing a lawsuit. The Regional Court, Mannheim suggested some flexibility to complete omitted steps by proposing that the patentee applies for a stay of the proceedings to conclude the licence discussions (to which a defendant who is willing to license would naturally agree).17

Other key questions remain unanswered. Among these are whether only one specific offer or a range of terms can be FRAND, whether a FRAND offer requires patentees to license the SEP at a certain level in the manufacturing chain, for example, the component manufacturer as opposed to the end-product manufacturer, and whether German courts will determine royalty rates for the non-German parts of patent portfolios. Apart from litigation on patents declared standard-essential together with FRAND commitments, there is increasing attention on patents on de facto standards. The FCJ’s Orange Book decision,18 which governed the antitrust defence before Huawei v. ZTE and imposed much stricter requirements on the implementer, still seems to be good law in this context.

V FINAL REMEDIES FOR INFRINGEMENT

i Non-monetary remedies

Injunction

Once an infringing act has been committed or there is a risk of first violation, the patentee can request an injunction and require the infringer to cease and desist from further infringing activities. The statute does not set out additional requirements to secure an injunction. The injunction will remain in force until the judgment is lifted or the patent has lapsed. The injunction covers not only the infringing embodiments accused in the litigation but all other infringements that are identical at their core (i.e., that equally infringe the patent claims). For such additional embodiments, the claimants must demonstrate the infringement as part of the enforcement proceeding. Restrictions of the injunction in terms of scope or time (grace period) are hardly relevant in practice.

Recall and destruction

The patentee is entitled to require the infringer to recall infringing products from its commercial customers and to destroy infringing embodiments in its possession. The

15 Regional Court Düsseldorf, ruling of 9 November 2018, 4a O 15/17.
16 Higher Regional Court Düsseldorf, ruling of 22 March 2019, 2 U 31/16 – Improving Handovers. Further appeal pending before the FCJ.
17 Regional Court Mannheim, ruling of 10 November 2017, 7 O 28/16 – Funkstation.
destruction claim extends to materials and machines that are primarily used for manufacturing infringing products. Recall and destruction do not require negligence but are subject to a proportionality requirement.

**Information and rendering of accounts**

The patentee can seek information with a view to the infringer or with a view to third parties. Third party information relates to the origin of the infringing products and their distribution channels. This information allows the patentee to enforce its rights against suppliers or purchasers of infringing products in further proceedings. Information about the infringer includes details on the scope of the infringement and rendering of accounts. This process is intended to allow the patentee to calculate its damages claim, which the patentee cannot do without access to this information.

**Publication of judgment**

The judgment in favour of the patentee can be published at the request of the patentee and at the cost of the infringer. The decision to publish the judgment is non-discretionary but requires the patentee to demonstrate a legitimate interest in the publication. The standard for such interest is high. The publication of a judgment therefore has little practicable relevance.

ii  Monetary remedies

**Damages**

The infringer is liable for damages if the patent was intentionally or negligently infringed. The courts apply a strict negligence standard, generally requiring manufacturers (and distributors) to review the relevant patent landscape and identify patent infringements. Infringers are hardly found not at fault. The courts do, however, grant a one-month grace period after the grant before damages can be requested.

The patentee can choose between the following three methods to calculate damages. Punitive damages are not available.

a  Patentee’s lost profits: this method is rarely used. It is often difficult to prove and requires the infringer to disclose its own confidential profit structure.

b  Licence analogy: the patentee can claim the amount of reasonable licence royalties that reasonable parties would have hypothetically agreed on from an *ex ante* perspective. In practice, this will be a running royalty, not a lump-sum payment.

c  Restitution of infringer’s profit: the patentee can claim the profit that the infringer has made because of the infringement. Courts only allow deducting costs that are specifically attributable to the production of the infringing products, for which the infringer has the burden of proof. General overhead costs are not deductible.

The calculation requires information on the scope of the infringement and the infringer’s cost structure. The patentee can obtain such information through the claim to render accounts. Procedurally, patentees enforce the damages claim in two steps. The first is a request for a declaratory judgment, together with an obligation to render accounts. In most instances the court will issue the injunction at the same time. Once the calculation is made, the patentee must file a second action to claim payment of the specific amount of damages. The court has already confirmed the obligation to pay damages in the first action. Therefore, in practice many parties settle afterwards. Specific damages claims are, therefore, an exception.
Unjust enrichment
In addition to damages claims, the patentee can claim the unjust enrichment that the infringer has obtained from the infringement. In practice, the unjust enrichment claim is most relevant in the form of the residual damages claim that applies after the three-year limitation period for damages has expired but before the absolute limitation of 10 years after the infringement applies.

Adequate compensation
Use of the patented invention before the grant of the patent does not constitute infringement. The patentee can, however, claim adequate compensation for the use between the publication of the application and the grant if such use falls within the scope of the application, the defendant was at fault and (for European Patent Applications) if the application was made in German or a German translation of the claims was published by the GPTO or sent to the defendant. Compensation usually corresponds to the amount of a hypothetical licence fee.

iii Provisional enforcement
First instance judgments are provisionally enforceable pending an appeal against the provision of a security. Upon request, the courts will set separate securities for the individual remedies. Second instance judgments are provisionally enforceable without security. The defendant can request suspension of the provisional enforcement (e.g., a stay of the injunction). Such requests are, however, granted only in exceptional cases. Courts do not consider potential negative effects of the enforcement for the defendant sufficient. Courts will, however, suspend the enforcement, for example, if the patent gets revoked in a (not necessarily final) decision in a parallel validity proceeding.

If provisional enforcement turns out to be unwarranted, because the first instance decision or the appeal decision are subsequently lifted, the enforcing patentee is liable, in some cases even strictly liable for damages pursuant to Section 717 Paragraphs 2 or 3 CCP.

VI OTHER TYPES OF PATENT PROCEEDING
i Inspection proceedings
If a patentee has indications of an infringement, it can seek to gather additional information, allowing it to substantiate a complaint for patent infringement through an inspection proceeding. The information can relate to both the details of the product or method to confirm whether it falls within the scope of the patent and whether a third party commits infringing acts. After a respective court order, the patentee can conduct an onsite inspection through its attorney and patent attorney together with a bailiff and a court-appointed expert, or the patentee can demand production of documents. Orders for inspection proceedings are generally granted ex parte. The defendant’s confidentiality interests are protected by excluding the patentee from the inspection, requiring confidentiality from its counsel and only allowing

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19 Federal Court of Justice, ruling of 25 September 2018, X ZR 76/18 – Werkzeuggriff: Irreparable negative effects of disclosing information about the buyers of the infringer do not warrant suspension of enforcement even if the patent has expired and the patentee can no longer bring injunctive claims against the buyers.
the patentee access after a separate review process and redaction of sensitive information. While not as far reaching as the French *saisie-contrefaçon*, the German inspection remains a useful tool to investigate local defendants.

**ii Declarations of non-infringement**

An alleged infringer can request a declaratory judgment of non-infringement (DNI) if it can show a legitimate interest in such declaration (e.g., after it received a warning letter). Unlike in a cross-border context, a DNI in Germany does not prevent a separate infringing action before another court that has jurisdiction. A DNI becomes inadmissible once the patentee can no longer unilaterally withdraw its separate infringement action after the first oral hearing.

**iii Compulsory licences**

The GPA provides for the grant of a compulsory licence if an implementer failed to obtain a consensual licence and the public interest requires a licence. The FPC is competent to issue compulsory licences and will hear both, main actions and actions seeking the provisional grant of a licence. These licences have hardly been relevant. Between 1949 and 2016, only one compulsory licence was granted in the first instance and later revoked. With the 2016 grant of a compulsory licence for an HIV drug, which was confirmed by the FCJ, one may have thought that the practical relevance may increase. The FPC and the FCJ have, however, recently denied a request for a preliminary compulsory licence.

**iv Challenge of ownership**

Germany applies a first-to-file principle, awarding the patent to the first person who files a respective application. There is no examination of the substantive ownership of the invention. Pursuant to Section 8 GPA, if a person without title files for a patent, the entitled person can demand the assignment of the right in the patent (application). The claim must be asserted within two years of the grant of the patent, unless the applicant acted in bad faith. Typical ownership challenges relate to employees claiming rights in inventions they made but that their employer registered for patent protection. The employer is entitled to inventions of its employees under the German Act on Employee Inventions but must follow a certain process to secure ownership. In return, the employer must pay adequate remuneration for the invention in addition to the salary. Disputes on the amount of the remuneration can be adjudicated before a special arbitration board for employee inventions at the GPTO.

**v Customs seizures**

If infringing goods are imported into or exported out of Germany, patentees may apply to custom authorities to seize the infringing products at the border. Imports and exports into non-EU states are governed by European Regulation No. 608/2013. The patentee, namely the proprietor of the seized goods, can file an objection against the custom authority’s action or lack of action to seize the products. Seizures of imports and exports into the customs area

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of the EU are governed by Section 142a GPA. Such seizures require an obvious infringement of the patent. Ultimately, a court must determine whether the products infringe. A customs seizure can nevertheless be an effective tool to quickly interrupt a competitor’s marketing efforts. Some customs authorities will even conduct seizures at trade shows and remove infringing products on display. The success of a customs seizure critically depends on providing customs authorities with detailed information about the points of entry and a description of the infringing products.

VII APPEAL

i Infringement proceedings

First instance decisions of the regional courts are appealable to the higher regional courts. The appeal can be based on questions of law and questions of fact. New facts can, however, only be introduced in the second instance if admitted. The deadline for filing an appeal is one month after the written judgment of first instance has been served. The grounds for the appeal must be submitted within one additional month. The appeal procedure is equally front-loaded as the first instance proceeding. Generally, two rounds of briefs are exchanged before the oral hearing. Appeal proceedings take between one to two years, with statutory costs slightly increased over the first instance.

The decision of the appeal court can be further appealed to the FCJ. Such further appeal is limited to questions of law and requires leave to further appeal from the second instance court. In the absence of such leave, the losing party may seek permission to a further appeal from the FCJ. Most of such requests are, however, denied. The deadlines for the further appeal are like those of the appeal. The parties must be represented by attorneys that are only admitted before the FCJ.

ii Nullity proceedings

Judgments of the FPC in nullity actions can be appealed directly to the FCJ. Permission is not required. The appeal can be based on questions of law and – with certain limitations – questions of fact. The deadline for filing an appeal is one month after the written judgment of first instance was served. The grounds for the appeal must be submitted within two additional months. Parties in a nullity appeal before the FCJ can be represented by any attorney or patent attorney.

VIII THE YEAR IN REVIEW

i Infringer’s profit as part of residual damages

One of the key German decisions in the past year relates to the scope of the residual damages claim. Even though the patentee can choose between three methods to calculate the (non-time-barred) damages claim, it was previously thought that the residual damages claim is limited to a hypothetical licence fee. The FCJ now ruled that the patentee can also claim the infringer’s profit.22 The court considered that the infringer not only ‘saved’ the costs of a licence fee but also obtained its profit from the infringement at the expense of the patentee. Such profits are, therefore, covered by the residual damages claim. The claim is based on the

legal principle that an infringer shall not be allowed to retain any benefit from having acted unlawfully. Following this decision, the two most relevant calculation methods for damages will also be available under the residual damages claim. The limitation period for damages claims will, therefore, largely lose its effect. Patentees may be able to recover more substantial payments for a period of up to 10 years.

ii Recall as part of injunctive claim
In other fields of intellectual property law, the FCJ has ruled that the injunctive claim to cease and desist from further infringement includes the obligation to remove the effect of past infringements, including recalling sold products from customers. This has sparked considerable debate because it could undermine the additional requirements of the independent recall claim. It is not yet clear if this case law also applies to patent infringement. A first indication that this will not be the case comes from the Higher Regional Court, Düsseldorf. The court held that recall obligations are not part of the cease-and-desist claim. Both are governed by separate statutory provisions, subject to different requirements and must be enforced in different proceedings. It remains to be seen whether other courts, in particular the patent senate at the FCJ, will follow this approach.

iii Claim interpretation in light of cited prior art
The FCJ confirmed a patent that was challenged on the basis of prior art that was already cited in the patent specification. The court reasoned that a patent seeks to distinguish itself from the prior art that it cites. This is relevant for claim interpretation. If the description equates part of the patent claim with the cited prior art, the remaining features cannot be interpreted in a way such that they are disclosed in the very prior art from which they are intended to distinguish the subject matter. This rule of claim construction in light of cited prior art is an exception to the general rule that a patent is not necessarily interpreted to have a valid scope. While the decision will make it more difficult to invalidate patents over prior art that is already cited, it offers accused infringers a potentially powerful non-infringement argument if the accused embodiment corresponds with the cited prior art.

IX OUTLOOK
The establishment of the Unified Patent Court (UPC) is still closely followed in Germany. The constitutional complaint against the ratification of the UPC Agreement is still pending. The timeline is unclear and the outcome unknown. The ratification process is Germany is suspended pending the decision in this proceeding. After all other required jurisdictions, including the United Kingdom, have ratified the UPC Agreement, the process in Germany is the only remaining piece before the UPC can be established. The FCC announced its intention to decide in 2019. Despite the postponement of Brexit, it remains unclear whether Germany will ratify the UPC Agreement before the United Kingdom will leave the EU. Many believe this to be required for the United Kingdom to participate in the UPC following Brexit. Therefore, the future of the UPC and its territorial scope are uncertain.

23 Higher Regional Court Düsseldorf, ruling of 30 April 2018, I-15 W 9/18 – Rasierklingeneinheit.
24 Federal Court of Justice, ruling of 27 November 2018, X ZR 16/17 – Scheinwerferbelüftungssystem.
25 Federal Constitutional Court, file no. 2 BvR 739/17 – pending.
The automatic injunction, namely proportionality considerations for the grant of an injunction for patent infringement in Germany, has received the attention of policy makers in Germany. The statutory provisions do not set out additional material requirements for the grant of the injunction other than infringement. Various interested parties claim that this leads to automatic injunctions and disproportionate results in practice. Representatives of the telecommunications, electronics and automotive industries argue that this mechanism allows the patentee to leverage patents disproportionately if a patent on a small component can prevent the sale of a complex product like a car. At the same time, some companies from the healthcare sector argue that the public interest (mainly in the form of patients’ interests) is not sufficiently considered in the current injunction practice. The bifurcation system and the very different lengths of infringement and invalidity proceedings create an additional potential for patentees to enforce injunctions based on patents that are ultimately found to be invalid. The German Ministry of Justice consulted industry representatives in May 2019, and it is currently expected that German patent law will be reformed to some extent.
I OVERVIEW

The Modi government has signalled that it recognises the importance of intellectual property and expediting litigation in India’s growth map for the coming years.

With this in mind, the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act 2015 (the Commercial Courts Act) has been introduced to speed up commercial litigation in the country. All patent disputes are covered by this statute.

The hierarchy of courts in India is as follows:

- one Supreme Court – India’s Supreme Court is the highest court in the country;
- 24 High Courts – the Supreme Court is followed by High Courts in this hierarchy. India’s 29 states have 24 High Courts – some states have a common High Court; and
- over 500 district courts – each High Court exercises superintendence over district courts.

As far as patent litigation is concerned, practically speaking, there is a threefold court structure.

i Courts of first instance

A district court is the lowest court before which a patent infringement suit can be filed.

If a patent infringement lawsuit is filed before a district court and the defendant counterclaims for invalidity, then the suit is transferred to the High Court.

Only six High Courts can entertain lawsuits in the first instance. This is commonly referred to as ‘original jurisdiction’. Most patent litigation is filed before High Courts.

After the Commercial Courts Act, not all district courts can entertain ‘commercial’ lawsuits under the Commercial Courts Act. Under this Act, commercial suits can be filed only before courts designated as ‘commercial courts’ or before a High Court division designated as a ‘commercial division’.

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Where a High Court has a commercial division, no district court will be designated as a commercial court. For instance, in the state of Delhi, all commercial litigation is filed before the commercial division of the Delhi High Court.

All pre-Commercial Courts Act patent suits have been or are being transferred to the commercial court or commercial division that has territorial jurisdiction in each case.

ii Courts of first appeal

The Commercial Courts Act has reduced the kind of interlocutory orders that can be appealed. This is expected to speed up patent litigation in India.

An appeal from a district court order goes to a single judge of the High Court. An appeal from a High Court single judge's order goes to a two-judge bench of the High Court, called a division bench.

iii Appeals to the Supreme Court

Broadly speaking, appeals to the Supreme Court of India in patent matters are filed under the Supreme Court's discretionary power.

The Supreme Court is most likely to hear appeals that involve substantive questions of law. Having said that, the Supreme Court routinely interferes in matters that do not solely or directly involve such questions.

The past few years have seen a surge in pharmaceutical patents and standard-essential patents' litigation in India. The decisions in *Roche v. Cipla*\(^4\) and *Merck v. Glenmark*\(^5\) bolstered the position of pharma patent owners in India. Ericsson's and Philip's trailblazing records in standard-essential patents litigation in India have encouraged many right holders to litigate in India.

II TYPES OF PATENT

The Indian Patents Act 1970 recognises product and process patents. The Act allows the applicants to file provisional applications which are followed by non-provisional applications, convention applications under Paris Convention, national phase application pursuant to PCT international application designating India, divisional application and patent of addition application. The patent of addition applications are the applications that are filed to provide protection to the improvements or modification in the already filed or granted patent.

The Patent Rules 2003 were amended in 2016. The amended rules came into force on 16 May 2016. Some of the important changes that have been implemented by the amended rules are as follows:

- **Withdrawal of the fee paid for requesting substantive examination.** The applicants can now withdraw the application by filing a request any time before the application is referred to the examiner. Said request shall be deemed to have not been filed.
- **Time for placing the application in order under Section 21 has been reduced from 12 months to six months.** Said period is extendible by three months on request.
- **Provision for taking adjournment of hearing has been introduced.**
- **It is now possible to do hearings through video conferencing or telephonically.**

The process for expedited examination has been incorporated in Rule 24C, which provides for expedited examination of applications in certain cases. These are:

- where India has been indicated as the competent International Searching Authority or elected as an International Preliminary Examination Authority in the corresponding international application; or
- the applicant is a start-up.

A definition of start-ups has been introduced.

Patent applications are published within 18 months of the date of filing or date of priority, whichever is earlier. After publication, once a request for examination of a patent application is filed in the prescribed form and within the prescribed period, the application, specification and other related documents are referred by the Controller of Patents (Controller) to an examiner for making a report on several aspects, including the following:

- whether the application and the specification and other documents are in accordance with the Patents Act;
- whether there is any lawful objection to the grant; and
- results of the investigation for anticipation by any previous publication and prior claim.

The examiner shall make the above report within three months from the date of reference and the Controller shall ordinarily dispose of the report within one month of receipt, and issue a first statement of objections within one month from disposal of the report. An application may be put in order within six months from the date of the statement of objections.

The term of a patent is 20 years from the date of filing of the application. For international applications under the Patent Cooperation Treaty (PCT), the term is 20 years from the international filing date under the PCT.

Indian patent statutes provide both pre-grant and post-grant opposition proceedings. The pre-grant opposition can be filed under Section 25(1) of the Act any time before the examination of the application or during the prosecution of the application. The Delhi High Court in the order⁶ has held pre-grant opposition as ‘Examination-in-aid’. The post-grant proceedings are filed within one year from the date of publication of grant of patent in the Official Journal.

### III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

Patent litigation is changing rapidly with the advent of the Commercial Courts Act. For instance, this Act provides a non-extendable deadline for filing a statement of defence (called a ‘written statement’). This deadline is 120 days from the date of service. This deadline applies to the defendant in a patent infringement lawsuit as well as the defendant in a counterclaim, which is usually the plaintiff in the lawsuit. Therefore, it is extremely important to comply with procedural deadlines.

In the pre-Commercial Courts Act regime, a defendant’s delay in filing a written statement was usually condoned in the interest of justice. It was therefore not even advisable to strongly oppose condonation of delay applications because such opposition would only lead to further delay in the lawsuit.

Other important changes introduced by this Act are the introduction of ‘case management hearings’, ‘summary judgments’ and a real ‘costs’ regime.

For anyone litigating or proposing to litigate an intellectual property lawsuit in India, it may be worthwhile to go through the 22 pages of the Commercial Courts Act.

Other practical considerations in patent infringement and invalidity proceedings are as follows:

a. obtaining certified copies of patent documents from the Indian patent office because documents available on the patent office website may not be updated;

b. identifying an authorised signatory;

c. identifying an independent expert and other witnesses; and

d. certification for internet printouts.

As explained above, a patent infringement lawsuit can be brought before a commercial court or a commercial division of a High Court. If a patent infringement suit is filed before a district court, then it will be transferred to a High Court if the defendant counterclaims for invalidity of the suit patent.

The usual practice for most defendants in patent infringement lawsuits is to counterclaim for invalidity. An interim injunction may be refused if the defendant raises a credible challenge to the validity of the patent in suit. Having said that, a counterclaim may sometimes be filed only to emphasise, sometimes wrongly, the seriousness of the challenge to the validity of the patent.

Before the *Enercon* decision\(^7\) of the Supreme Court clarified the law, a defendant could not only counterclaim for invalidity in a patent infringement suit filed against it, but could also initiate revocation proceedings against the same patent before the Intellectual Property Appellate Board (IPAB). IPAB is a specialised board that hears appeals against orders of the intellectual property offices, including the patent office. This Board should have at least one technical member, among others, for hearing patent appeals. However, since 2016, the Board has been defunct after its last chairman retired. The board is likely to resume functions in 2017, once the government appoints its officials.

In 2014, the Supreme Court in *Enercon* clarified that only the first filed action between a counterclaim and a revocation will survive. Further, once a lawsuit is filed against a defendant, it can challenge validity of the patent only by way of a counterclaim.

While a High Court judge may not always have a technical background, as things stand today, proceedings before the High Court will be faster than proceedings before IPAB.

A patentee or its exclusive licensee can file a lawsuit for patent infringement. The limitation period is three years from the date of cause of action. If the cause of action is a patent infringement lawsuit, the limitation period begins when the patentee or its agent first gains knowledge of the infringement. A fresh cause of action arises each time a patent is infringed.

A defendant in a patent lawsuit can file a counterclaim in the suit to challenge the validity of the patent in suit. Revocation proceedings before IPAB can be initiated by any interested person. The term ‘any interested’ person has been interpreted by courts to include:

\[^7\] (2014) 15 SCC 360.

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make independent use of either the invention itself (which has been patented), or desires to exploit
the process (which has been patented) in his individual production activity. Therefore, the term ‘any
person interested’ is not static. 8

A revocation proceeding may be filed against a patent any time after the grant of the patent.
A patent may also be challenged by an interested person by way of a post-grant opposition under Section 25(2) of the Patents Act 1970 before the Patent Office. However, a post-grant opposition can be only filed after grant of a patent but before the expiry of one year from the date of publication of grant of a patent.

Key differences between post-grant opposition and revocation proceedings include the narrower scope of inquiry in a post-grant opposition, and the limited period in which a post-grant opposition can be filed.

The usual procedure in a patent infringement lawsuit and a counterclaim for nullity is as follows:

a Step 1 – Filing of the lawsuit and admission of the lawsuit. Once the lawsuit is admitted, summons to the defendant are issued by the court.
b Step 2 – Defendant enters appearance before the court and written pleadings are filed in court. The defendant may also file a counterclaim, in which case the plaintiff files its defence in the counterclaim.
c Step 3 – This is a procedural step called ‘admission and denial’ of documents. Parties may also seek discovery of documents.
d Step 4 – Issues in controversy are framed by the judge to narrow the controversy and the parties are sent to trial. In most patent cases, at least before the Delhi High Court, local commissioners (officers specially appointed by the court) record evidence.
e Step 5 – Trial includes examination in chief, cross examination and re-examination, if any, of witnesses. A patent infringement trial is governed by the Indian Evidence Act 1872.
f Step 6 – Final arguments before the judge.

A party to a lawsuit can also request for the appointment of a local commissioner to preserve proof of infringement.

The procedure in revocation and post-grant opposition proceedings is more relaxed. Usually, the parties file pleadings and documents, and file evidence in the form of affidavits after which the matter is put up for final arguments. These proceedings do not involve several steps explained above, including steps 3 and 4. In appropriate cases, cross-examination of witnesses may be permitted by the IPAB.

The Patent Office and the IPAB usually accept internet printouts without further proof. However, for other documents such as brochures and receipts, they may require parties to produce originals.

In a suit for patent infringement, every ground on which a patent may be revoked is available as a ground for defence. However, for a declaration of nullity of the patent in suit, a defendant will have to file a counterclaim.

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8 id. at Paragraph 21.
After the enactment of the Commercial Courts Act, the lifespan of a patent infringement lawsuit is expected to reduce to about 18 months. The timeline of proceedings before the Patent Office and the IPAB is harder to predict, but a ballpark assessment would be in the range of two to four years.

Interim reliefs in patent infringement proceedings range from interim injunctions to maintaining accounts by the defendant. Broadly, the following interim reliefs are usually granted in patent infringement proceedings:

a Interim injunctions – courts are more likely to grant interim injunctions in cases where the defendant is yet to commercially launch. It is rare for courts to direct the plaintiff to make a security deposit while granting an interim injunction in the plaintiff’s favour.

b Interim royalty arrangements – in standard-essential patents litigation, this has become the go-to remedy. Interim royalty arrangements of several kinds, including where the plaintiff receives royalty subject to its furnishing a bank guarantee for the royalty it receives, have been passed by courts in India. Another version of this remedy is where the defendant does not actually make any royalty payments to the plaintiff but furnishes a bank guarantee for the royalty due.

c Maintaining accounts – courts also direct defendants to maintain accounts of their profit from the alleged infringing activities.

d Appointment of local commissioners – courts may appoint a local commissioner to visit the defendant’s premises to preserve evidence of infringement. Such orders are usually passed in cases where the plaintiff can demonstrate to the judge that the defendant is likely to destroy evidence relevant to the proceedings.

The Patents Act empowers the recipient of groundless threats of patent infringement to move the court for a declaration that the threats are in fact groundless, and an injunction against continuance of such threats, and damages. However, this provision has not witnessed much litigation.

To the best of our knowledge, the Competition Commission of India has entertained complaints against one patentee in three cases involving standard-essential patents. The director general’s investigation report is awaited in these cases.

IV SUBSTANTIVE LAW

i Infringement

Under Section 48 of the Patents Act, the following acts constitute patent infringement:

a for a product patent, an unauthorised act of making, using, selling, offering for sale or importing for those purposes may constitute infringement of the patent; and

b for a process patent, an unauthorised act of using that process, or using, offering for sale, selling or importing for those purposes, a product directly obtained from the patented process may constitute infringement of the patent.

Indian courts recognise *quia timet* actions, namely, where there is a real and imminent apprehension of infringement. Courts have found preparatory acts, such as listing of a patented molecule on the defendant’s website, and applications filed by defendant for obtaining a manufacturing approval for the patented product, as real and imminent apprehension of infringement.
The decision of a two-judge bench of the Delhi High Court in the Roche v. Cipla\textsuperscript{9} dispute has laid down rules for claim interpretation in patent infringement lawsuits. A few key rules are reproduced below:

\begin{itemize}
  \item[a] the broad structure of a set of claims is an inverted pyramid, with the broadest at the top and the narrowest at the bottom;
  \item[b] claims are a single sentence defining an invention or an inventive concept;
  \item[c] different claims define different embodiments of the same inventive concept;
  \item[d] where claims are ‘dependent’, it incorporates by reference ‘everything in the parent claim, and adds some further statement, limitations or restrictions’;
  \item[e] at the beginning of an infringement action, courts in the United States conduct a \textit{Markman} hearing to define the scope of the claim or to throw light on certain ambiguous terms used in the claim. This is not technically done in India, but functionally most judges will resort to a similar exercise in trying to understand the scope and meaning of the claim, including its terms; and
  \item[f] a claim includes its preamble, transition phrase and body. The transition term may be open-ended or closed.
\end{itemize}

Another important principle of claim construction was set the Supreme Court in the \textit{Novartis} case,\textsuperscript{10} where it held that coverage equals disclosure in the following terms:

\begin{quote}
The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching on the other hand, seems to strike at the very root of the rationale of the law of patent…To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.
\end{quote}

In \textit{Farbewerke Hoechst v. Unichem Labs},\textsuperscript{11} a judge of the Bombay High Court held that:

\begin{quote}
[1]In an infringement action, the main function of the court is to construe the claims which are alleged to have been infringed, without reference to the body of the specification, and to refer to the body of the specification only if there is any ambiguity or difficulty in the construction of the claims in question.
\end{quote}

\section*{ii Invalidity and other defences
\textit{Bases for challenging patent validity}}

A patent may be revoked on the grounds under Section 64 of the Patents Act. These include the following:

\begin{itemize}
  \item[a] the invention was claimed in the complete specification of a earlier granted patent in India;
  \item[b] the patent was granted to a person not entitled under the Patents Act;
  \item[c] the patent was wrongfully obtained in contravention of the applicant of revocation;
  \item[d] the subject of any claim is not an invention. Section 3 of the Patents Act defines what are not inventions under the Patents Act and includes subject matter such as
\end{itemize}

\textsuperscript{9} Above at 4.
\textsuperscript{10} (2013) 6 SCC 1.
\textsuperscript{11} AIR 1969 Bom 255.
computer programs per se, invention contrary to natural laws, invention contrary to public order and morality, mere discovery of a new form of a known substance without enhanced efficacy, method of agriculture or horticulture, plants and animals, traditional knowledge, etc;
e the invention is anticipated;
f the invention is obvious;
g the invention is not useful;
h there is insufficient disclosure;
i claims are not clearly defined or are not supported by the specification;
j the patent was obtained on false suggestion or representation;
k the subject matter is not patentable under the Patents Act;
l the invention was secretly used in India prior to priority date; and
m failure to comply with Section 8, in other words, failure to disclose or disclosure of false information for corresponding foreign applications.

Every ground under which a patent may be revoked under Section 64 is available as a ground for defence in a patent infringement lawsuit.

Other defences to patent infringement
The Patents Act recognises, inter alia, the following additional defences to patent infringement:

a use merely for the purpose of experimenting or researching, including the imparting of instructions to pupils;
b making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law in India, or a foreign country, that regulates the manufacture, construction, use, sale or import of any product;
c importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product.

Further, Section 140 of the Patents Act prescribes conditions that are unlawful in a patent licence. These include conditions such as an exclusive grant back, prevention of challenges to the validity of a patent, and coercive package licensing.

V FINAL REMEDIES FOR INFRINGEMENT
A court trying a patent infringement suit may grant the following remedies:

a a permanent injunction restraining future infringement, subject to such terms as the court may deem fit;
b at the option of the plaintiff, damages or an account of the defendant’s profits; and
c litigation costs.

The damages granted by the court may include compensatory as well as punitive damages.

The court may also order delivery up, seizure, forfeiture or destruction of the infringing goods as well as materials and implements, the predominant use of which is the creation of the infringing goods.
In the *Merck v. Glenmark* case, the Delhi High Court granted a permanent injunction restraining the defendant from manufacturing the infringing drug and from otherwise infringing the plaintiff’s patent. The trial in this case was conducted on an expedited basis within a period of three months under specific orders of the Supreme Court. In the *Roche v. Cipla* case, the appellate court found that the defendant had infringed the patent and that the patent was valid. Since three months were left in the life of the patent when the decision was rendered, the court chose not to grant an injunction and instead ordered the defendant to render an account of the profits.

VI OTHER TYPES OF PATENT PROCEEDING

i **Proceedings for declaration of non-infringement**

Under Indian law, a party may file a suit for declaration that its activities with respect to a product or process, do not infringe a patent. For invoking this provision, the plaintiff must first attempt to obtain a written acknowledgment from the patentee to the effect that the plaintiff’s activities do infringe the patentee’s patent. Only if the patentee refuses or neglects to provide such an acknowledgement can the plaintiff approach the court seeking such a declaration. While seeking such an acknowledgment, the plaintiff must give full particulars of its product or process in question.

Notably, while seeking such a declaration, the plaintiff is not entitled to call the validity of the patent into question.

ii **Proceedings for restraining issuance of groundless threats regarding institution of legal proceedings**

A recipient of a threat of legal proceedings for infringement of a patent can file a suit for seeking the following reliefs:

a a declaration to the effect that the threats are unjustifiable;
b an injunction against the continuance of the threats; and
c damages, if any, for damage that he or she has sustained.

These threats may be in the form of circulars, advertisements, letters or publications, but a mere notification of the existence of a patent will not constitute a threat for institution of legal proceedings.

iii **Proceedings for issuance of compulsory licence**

The Indian Patents Act provides for compulsory licences that are granted by the Controller. A party may seek a compulsory licence, after three years of the grant of a patent, on any of the following grounds:

a the reasonable requirements of the public with respect to the patented invention have not been met;
b the patented invention has not been worked in the country; and
c the patented invention is not available to the public at a reasonably affordable price.
Prior to applying for a compulsory licence, the applicant must first seek a licence from the patentee, and only if reasonable efforts to obtain a licence fail can the applicant approach the Controller for a compulsory licence.

In 2012, the Controller granted India’s first post-Agreement on Trade-Related Aspects of Intellectual Property Rights compulsory licence to Natco Pharma Ltd, with respect to Bayer’s patented drug Sorafenib.\(^{13}\)

### iv Customs

The Intellectual Property Rights (Imported Goods) Enforcement Rules 2007 allow patentees to have their patents recorded with the Customs authorities so that authorities may suspend release of and eventually confiscate infringing goods. Recognising that the determination of patent infringement issues can be complex, the High Court of Delhi in *Ericsson v. Union of India*\(^{14}\) directed that the customs authorities would not ordinarily seize or suspend release of goods in patent cases, and would exercise these powers with extreme caution, unless the rights of the parties have been previously determined by the order of a competent court. However, in straightforward cases, where no complex issues of patent infringement or invalidity are involved, the customs authorities may proceed to suspend the release of the goods even in the absence of a court order.

### VII APPEAL

If the first instance patent infringement proceedings are instituted before the district court, an inter-court appeal by the unsuccessful party lies before the High Court; whereas, if the first-instance patent infringement proceedings are instituted before the High Court, an intra-court appeal lies before a larger bench of the High Court. An appeal against the order of the High Court lies to the Supreme Court.

Appeals can only be filed against orders that form part of a list of appealable orders. Not every order passed by the court of first instance is appealable. This list typically includes orders affecting the substantive rights of the parties, such as those granting or refusing injunctions.

First appeal against a final decision post-trial is available as a matter of right and permission to appeal is not required. While provisions for obtaining a certificate from the High Court for appealing to the Supreme Court exist, in practice, most appeals to the Supreme Court require leave to appeal to be granted by the Supreme Court for admission of the appeal.

Fresh evidence may be introduced at the appellate stage only after obtaining specific permission of the court.

First appellate courts usually consider both legal and factual issues. However, where the lower court has exercised its discretion in deciding an application for grant of an injunction, the appellate court will ordinarily not interfere in the exercise of discretion unless such exercise is perverse, capricious or arbitrary.

Under the new commercial courts regime, an appeal is to be decided within a period of six months of the date of filing of the appeal.

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VIII THE YEAR IN REVIEW

The previous year saw a lot of activity in the standard-essential patents space. Pre-suit mediation has emerged as a time- and cost-effective tool in patent disputes where there is scope for negotiation, such as in the case of fair, reasonable and non-discriminatory terms (FRAND)-encumbered patents. Post-trial judgment in India’s first standard-essential patents’ case Philips v. Rajesh Bansal and others\textsuperscript{15} was delivered in July 2018. The Court held that in view of essentiality reports in the US and EP and corresponding claims of patents, Plaintiff has proved that patent in India is also an essential patent. Further, with regard to the licence fee the Court held as follows:

> Considering that the plaintiff is seeking royalty at FRAND terms and that too at the PHILIPS ONLY option and no evidence has been led by the defendants to rebut the evidence of the plaintiff despite the onus of Issue No.(vii) being on the defendants, it is held that Manglam and Bhagirathi are required to pay royalty to the plaintiff @USD 3.175 from the date of institution of the suits till 27th May, 2010 and from 28th May, 2010 @USD 1.90 till 12th February, 2015.

An important decision in patent law handed down in 2018 was in the case of Snecma v. Union of India\textsuperscript{16} and Sphaera Pharma v. Union of India.\textsuperscript{17} In Sphaera Pharma v. Union of India, Mr Justice Bakhru of the Delhi High Court reconfirmed that the time specified in Rule 24B of the Patents Rules to file a request for examination cannot be extended by requesting the Controller to exercise his discretion under Rule 138. The Court held as follows:

> It is at once apparent that recourse to Rule 138 of the Rules is not available to extend the time prescribed under Rule 24B of the Rules. This is clear from the plain language of Rule 138 of the Rules, which expressly excludes its application to Sub-rules (1), (5) and (6) of Rule 24B of the Rules. Moreover, in terms of Rule 138(2) of the Rules, any request for extension of time prescribed has to be made before the expiry of such time as prescribed in the Rules. Therefore, even if the express language of Rule 138 of the Rules is ignored, the benefit of Rule 138 would not be available to the petitioner as no such application for extension of time was made prior to expiry of the prescribed time.

However, in Snecma v. Union of India, Justice Shakdher allowed the writ and ordered the quashing of the two patent office's communications dated 17 March 2017 and 3 April 2017. Furthermore, the Controller of patents was directed to take the petitioner’s request for examination on record and to process the same in accordance with the extant provisions. This order distinguishes a filing request for examination and the prescribed fee as two separate acts, and out of the two, the first act needs to be done on time. On 22 June 2018, Intellectual Property Rights (Imported Goods) Enforcement Amendment Rules 2018 were notified in the Official Gazette. The Amendment Rules omitted the terms ‘patent as defined in the Patents Act, 1970’ and ‘the Patents Act 1970’ from the definitions of ‘intellectual property’ in Clause 2(a) and ‘intellectual property law’ in Clause 2(b). With this amendment, custom authorities have been exempted from dealing with issues of patent infringement.

\textsuperscript{15} CS(COMM) 24/2016 and CS(COMM) 436/2017.

\textsuperscript{16} Judgment dated 19 March 2018 in WP(C) 3250/2017 & CM No. 26210/2017.

\textsuperscript{17} Judgment dated 16 February 2018 in WP(C) 1469/2018.
IX OUTLOOK

In 2015, the Supreme Court directed that the trial in the *Merck v. Glenmark*\(^{18}\) patent dispute should be concluded in five weeks. Recently, the Supreme Court has shown further interest in finding ways and means of expediting intellectual property litigation in India. The Court has asked the Delhi High Court for its recommendations in a writ petition titled ‘Re- Case Management of Original Suits’, and has observed as follows:

> The Hon’ble Judges of the Delhi High Court have to work out ways and means for effective disposal of the IPR matters before it so that a model for disposal of civil suits can be culled out from the ways and means adopted by the Delhi High Court which can form the basis of a uniform action plan for the rest of the country…

India is gearing up for fast-paced patent litigation and a setup where erring parties will be expected to bear the burden of costs for unreasonable conduct and actual damages.

In a severely fought battle last year the division bench of the Delhi High Court in *Monsanto v. Nuziveedu*\(^{19}\) declared Monsanto’s BT patent as invalid. The patent was held invalid in view of Section 3(j) of the Patents Act, which considers plants in whole or part thereof as non-patentable subject matter. However, Monsanto has been allowed to register its invention under the Plant Variety Protection and Farmer’s Rights Act 2002. Monsanto has now gone to the Supreme Court, and the matter is now *sub judice*.

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\(^{18}\) Above at 5.

I OVERVIEW

Historically, there has been comparatively little patent litigation in Ireland, in particular litigation that progressed to full trial. However, in light of a significant growth in the pharmaceutical industry, with international pharma companies basing worldwide manufacture in Ireland, in recent years there has been a significant rise in patent litigation, particularly in pharma disputes.

Patent law in Ireland is governed by the Patents Act 1992, as amended (the Irish Patents Act). The Patents Rules 1992, as amended (the Patents Rules), generally read alongside the Irish Patents Act, prescribe various procedural rules. As Ireland has a common law legal system, Irish patent law is not derived solely from the Irish Patents Act, but also from the decisions of the Irish courts, for example, interpreting various provisions of the Irish Patents Act.

The provisions of the Irish Patents Act apply equally to national Irish patents granted by the Irish Patent Office (Irish patent) and to European patents designating Ireland, granted by the European Patent Office (EPO).²

An application for a patent conferring protection in Ireland can be made either to the Irish Patents Office, for an Irish patent, or to the EPO for a European patent designating Ireland. Alternatively, in an application made to the World Intellectual Property Organization, under the Patent Cooperation Treaty, the EPO may be designated and then Ireland may be subsequently designated before the EPO.

II TYPES OF PATENTS

Irish patents can be subdivided into two categories: full-term patents (where the term of protection is 20 years from the patent filing date)³ and short-term patents (where the term of protection is 10 years from the patent filing date).⁴ They are mutually exclusive – they cannot both exist for any one invention.

Short-term patent applications are generally less costly. The distinctive features of short-term patents are set out in Part III of the Irish Patents Act.
i  Patentability
Under the Irish Patents Act, an invention shall be patentable if it is susceptible of industrial application, is new and involves an inventive step.5

The Irish Patents Act provides that an invention will be susceptible of industrial application if the invention can be made or used in any kind of industry, including agriculture.6

Further, an invention shall be novel if it does not form part of the state of the art.7 'State of the art' means everything made available to the public, anywhere in the world before the date of filing of the patent application.8

An invention will be considered to involve an inventive step if the invention would not have been obvious to a person skilled in the art, based on the entire state of the art at the date of filing.9

ii  Exclusions to patentability
A patent cannot be granted in respect of the following inventions:10

a  a discovery, scientific theory or mathematical method;
b  an aesthetic creation;
c  a scheme, rule or a method for performing a mental act, playing a game, doing business or a program for a computer;
d  the presentation of information;
e  inventions where commercial exploitation would be contrary to public order or morality;
f  a plant or animal variety or a biological process for the production of plants or animals other than microbiological processes and products thereof; or
g  a method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body.11

iii  Application – securing a patent
An application for an Irish patent must relate to one invention only or to a group of inventions so linked as to form a general inventive concept.

Every application for an Irish patent must be filed with the Irish Patents Office and must contain a request for the grant of a patent, a specification (containing a description of the invention, one or more claims and any drawing referred to in the description or claim) and an abstract.12 The claims must define the matter for which protection is sought. They must be clear and concise and must be supported by the description.13

Ireland is a party to the Paris Convention, and thus the principle of priority applies to Irish patent applications in Ireland. Once a patent application has been filed in Ireland,

5  Section 9(1) of the Irish Patents Act.
6  Section 14 of the Irish Patents Act.
7  Section 11(1) of the Irish Patents Act.
8  Section 11(2) of the Irish Patents Act.
9  Section 13 of the Irish Patents Act.
10  Sections 9 and 10 of the Irish Patents Act.
11  Section 10(2) of the Irish Patents Act, states that the exception under (vii) shall not apply to products, in particular substances or compositions for use in any such method.
12  Section 18 of the Irish Patents Act.
13  Section 20 of the Irish Patents Act.
the applicant is entitled to claim the priority date of that application in respect of all other applications for the same invention made in other states that are signatories to the Paris Convention or are members of the World Trade Organization.

iv Examination

The examination of an Irish patent is carried out by the Controller of Patents, Designs and Trade Marks (the Controller).

Once the Controller is satisfied that the invention meets the requirements of the Irish Patents Act, a patent will proceed to grant. Upon payment of the fee by the applicant, the grant becomes formalised. Once formally granted, the Controller publishes a notice of the grant and a brief specification of the patent in the Journal of the Irish Patents Office. The patent takes effect from this date of publication in the Journal of the Irish Patents Office and will continue in existence (subject to the payment of annual renewal fees) for the duration of the patent term.

In relation to Irish designated European patents, where a European patent is granted in English and designates Ireland, the patent becomes automatically validated.

v Extension of Irish patents

The Irish Patents Act does not allow for the extension of an Irish patent.

However, supplementary protection certificates (SPCs) are permissible in two sectors: agrochemicals and pharmaceuticals. SPCs can extend the period of protection to a maximum of 25 years. Importantly, the patent term is extended only in respect of the specific product, not the entire scope of the claims.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Fora for patent actions

High Court

There are no specialised patent courts in Ireland and proceedings are not heard by specialist patent judges. Patent proceedings in respect of infringement and revocation must be heard by the High Court (except in certain instances that are set out below) and may be transferred to a division of the High Court known as the Commercial Court. Cases heard by the Commercial Court are subject to efficient case management procedures, intended to provide a faster track to trial and to minimise costs.

15 Rule 1(d) of Order 63A of the Rules of the Superior Courts (as amended).
The Circuit Court
The Copyright and Other Intellectual Property Law Provisions Act 2019\(^{17}\) grants jurisdiction to the Circuit Court to hear and determine certain intellectual property claims where the damages or the value of the relief sought is not liable to exceed the sum specified to be the jurisdiction of the Circuit Court\(^{18}\) which in this case is an amount not exceeding €75,000\(^{19}\).

Patent infringement proceedings concerning short-term patents may be heard by the Circuit Court.\(^{20}\) While the Circuit Court is a court of (generally) limited and local jurisdiction, patent proceedings involving short-term patents can be brought irrespective of the value of the claim.

The District Court
Similarly, the Copyright Act 2019\(^{21}\) grants jurisdiction to the District Court to hear and determine certain intellectual property claims where the damages or the value of the other relief sought in any action is not liable to exceed the sum specified to be the jurisdiction of the District Court,\(^{22}\) which in this case is an amount not exceeding €15,000.\(^{23}\)

The Controller
While patent revocation proceedings are typically brought before the High Court, applications for revocation may also be made to the Controller.\(^{24}\) Proceedings before the Controller are governed by rules set out in Part VIII of the Patents Act 1992 and in the Patent Rules 1992.

ii Standing to bring patent infringement claims
Actions for infringement of a patent may be brought by the proprietor of a patent in respect of any act that the proprietor is entitled to prevent under Sections 40 to 43 and Section 45 of the Irish Patents Act.\(^{25}\)

Where there are two or more joint proprietors of a patent, each joint proprietor has standing to bring infringement proceedings without the concurrence of the others provided that the remaining joint proprietors are named as defendants in the proceedings.\(^{26}\)

The holder of an exclusive licence under a patent has the same standing as the proprietor to bring proceedings for acts of infringement committed from the date of the licence.\(^{27}\) Unless the proprietor is a co-plaintiff, it must be joined as a defendant in the proceedings.

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\(^{17}\) The Copyright Act 2019 was signed into law by the President on 26 June 2019 but has not yet been commenced to date.


\(^{20}\) Section 66(5) of the Patents Act 1992.

\(^{21}\) Pending commencement.


\(^{24}\) Section 57(1) of the Patents Act 1992.

\(^{25}\) Section 47(1) of the Patents Act 1992.

\(^{26}\) Section 48 of the Patents Act 1992.

\(^{27}\) Section 51 of the Patents Act 1992.
Standing to bring patent invalidity claims
Any person may apply to the High Court or to the Controller under Section 57 of the Irish Patents Act for revocation of a patent.

Limitation periods
The Irish Patents Act does not specify a limitation period within which an infringement action can be issued.

Commencing patent proceedings
Prior to commencing infringement proceedings, a cease-and-desist letter is typically issued. Such pre-action letters must be carefully drafted to avoid liability under Section 53 of the Irish Patents Act, which provides remedies for a party that receives a groundless threat of infringement proceedings. Similarly, a letter before action is often issued prior to commencing invalidity proceedings.

The initiating pleading for patent infringement proceedings is a plenary summons, which outlines the essential claim made and the remedies sought by the plaintiff. In response, the defendant delivers and files an entry of appearance that requires the plaintiff to deliver a statement of claim and confirms which lawyer will represent the defendant.

Patent invalidity proceedings are commenced by way of a petition for revocation, which must be accompanied by Particulars of Objections. At this point, an application is generally made by either party to transfer the proceedings into the Commercial Court list.

Exchange of further pleadings
In infringement proceedings, the next step is the delivery by the plaintiff of a statement of claim setting out the particulars of the alleged infringement. The defendant is then required to deliver a defence.

In invalidity proceedings, no statement of claim is delivered as the petition is accompanied by the particulars of objection. The next step is for the proprietor of the patent to deliver a defence to the petition and particulars of objection. A defendant who, under Section 57 of the Irish Patents Act, counterclaims for revocation shall deliver with his or her counterclaim the Particulars of Objection to the validity of the patent on which he or she relies in support of the counterclaim.

After the defence (or, if applicable, the reply to defence) is delivered, the pleadings are considered to be closed.

28 Order 94 RSC, Rule 3.
29 Order 94 RSC, Rule 23.
30 Order 94 RSC, Rule 4.
31 Order 94 RSC Rule 7.
Discovery and evidence

Discovery

General procedural rules regarding discovery are set out in Order 31 of the Rules of the Superior Courts (RSC). Under Irish law, either party to litigation may seek discovery of documents that are or have been in the ‘possession, power or procurement’ of the other party.

Discovery is generally agreed or ordered by reference to categories of documents, and reasons must be set out as to why each category of documents meets the criteria of relevance and necessity.

In 2016, the Court of Appeal in *Boehringer Ingelheim Pharma GmbH & CO KG v. Norton (Waterford) Limited t/a Teva Pharmaceutical Ireland* considered and summarised the legal principles applicable to discovery in patent cases.32

Expert evidence

Expert witnesses play a significant role in patent litigation. An expert witness owes a duty to the court to assist on matters within his or her field of expertise.33 This duty overrides any duty he or she has to the party instructing him or her.

The court assesses the teachings and scope of a patent through the eyes of ‘the person skilled in the art’. In considering and determining these matters, the court must ‘don the mantle’ of the skilled person ‘to arrive as closely as it can to the mental attitude of a well-instructed representative of the class to whom the specification is addressed, and no more’.34

It is the expert witnesses who assist the court in adopting the mindset of the skilled person. The skilled person has imputed to him or her the ‘common general knowledge’, which is, essentially, the standard technical background of the art in question. The expert witness must prepare an expert report or witness statement that is exchanged between the parties and ultimately submitted to the court. The expert generally provides oral testimony and can be cross-examined as to their evidence in chief.

Additionally, a person (an assessor) who is ‘specially qualified in the opinion of the court’ can be appointed by the court to assist on technical issues.35 Their function is to assist the judge in understanding the evidence before the court.

Experiments

In appropriate cases, experiments may be ordered upon the application of a party that wishes to establish a fact by experimental proof.

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33 Order 39 Rule 57.
35 Section 95(1) of the Irish Patents Act.
Pre-action disclosure – methods for obtaining evidence and information

Proceedings may be taken directly against a party to obtain discovery of documents identifying alleged infringers by way of a Norwich Pharmacal order.

Although not strictly limited to pre-action relief, a claimant alleging patent infringement may apply for an order requiring the disclosure by relevant persons (including a person found in possession of infringing goods, or found using infringing services, on a commercial scale) of information regarding the origin and distribution networks of allegedly infringing goods and services.36

The High Court and Commercial Court may also grant Anton Piller orders (preservation orders where documents and items may be seized by the moving party), where there is a serious risk that articles or documents vital to a party’s case may be imminently destroyed or otherwise disposed of.

viii Presenting and proving materials in court

Generally, materials may be presented and relied upon at a hearing on the merits only when proven (or verified). Documents are generally admitted via affidavits (sworn statements) or witness statements. The Commercial Court generally directs that written witness statements be exchanged in the lead up to the trial. These form the basis of the evidence given orally at trial and upon which the witness is cross-examined.

ix Amendment of patents in the course of proceedings

The Irish Patents Act permits the High Court (and thus the Commercial Court) or the Controller, in the course of invalidity proceedings, to allow the patent proprietor to amend a patent’s specification and claims.37

Such amendments cannot extend the subject matter of the patent,38 and are deemed to have effect from the date of grant of the patent.39 In re Norton Healthcare Ltd,40 the court exercised its discretion to grant the patentee leave to limit the claims of their patent in the event that the existing claims were found invalid.

x Challenge to the validity of the patent

Pursuant to Section 61 of the Irish Patents Act, a defendant may challenge the validity of a patent in infringement proceedings. This challenge is frequently in the form of a defence or a counterclaim to an action for infringement, or both.

Section 58 of the Irish Patents Act specifies five grounds on which an application for revocation can be grounded:

a the subject-matter of the patent is not patentable under this Act;

b the specification of the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

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36 Article 3 of the European Communities (Enforcement of Intellectual Property Rights) Regulations 2006.
37 Section 38 of the Irish Patents Act.
38 Section 38(3) of the Irish Patents Act.
39 Section 38(4) of the Irish Patents Act.
40 [2006] 3 IR 321.
the matter disclosed in the specification of the patent extends beyond that disclosed in the application as filed, or, if the patent was granted on an application which by virtue of Section 24 or 81 is deemed to have been filed on the date of filing of an earlier application, it extends beyond that disclosed in the earlier application as filed;

d the protection conferred by the patent has been extended by an amendment of the application or the specification of the patent; or

e the proprietor of the patent is not entitled thereto under Section 16(1).

If a defendant challenges a patent’s validity as a defence in infringement proceedings, the two matters will run in tandem.

xi Timing to first-instance decision for patent proceedings

One would generally expect a patent dispute (either infringement or patent invalidity proceedings) to take approximately nine to 18 months from the issuing of proceedings to the hearing of the trial, depending on the complexity of the case, the extent of discovery and where the court vacations fall. Shorter expedited timelines to trial can, however, be granted in appropriate cases and an expedited trial could begin within six months.

xii Costs of patent proceedings

Patent litigation costs awards are discretionary, but the usual rule is that costs ‘follow the event’, and are awarded to the successful party. However, orders are generally only for what are termed ‘party and party costs’. Party and party costs will cover only the main items in litigation and will not cover the entire costs. In general, somewhere between one-half and two-thirds of the total legal costs incurred are recoverable. Where the parties cannot agree on quantum, the assessment of costs can be listed before the Taxing Master, who will settle the figure to be paid.

xiii Preliminary injunctions

In an appropriate case, a preliminary injunction can be obtained by a plaintiff quickly. An interim injunction can be obtained almost immediately (within a day or so). This is applied for ex parte and lasts until an inter partes application can be heard. At the inter partes hearing, the plaintiff can apply for an interlocutory injunction that lasts until the trial. An interim injunction is only appropriate where there is extreme urgency on the part of the plaintiff and the court can be satisfied that there is good reason to grant such relief.

In most cases, the first and most common type of injunction sought is a preliminary interlocutory injunction. An application for a preliminary injunction can only be made as part of full plenary proceedings. Overall, the plaintiff must demonstrate that the matter is extremely urgent and that it cannot wait for a full trial to receive a final injunction. To obtain a preliminary interlocutory injunction, a plaintiff must show that:

a it has raised a fair question to be decided at the trial of the action;

b damages would not be an adequate remedy for it; and

c the balance of convenience favours the granting of the injunction.\(^{41}\)

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\(^{41}\) The Supreme Court in *Campus Oil v. Minister for Energy (No. 2)* [1983] IESC 2, which accepted the test laid out in *American Cyanamid v. Ethicon* [1975] UKHL 1.
An application for such an injunction is generally heard within four to six weeks.

The Irish courts had been historically slow to grant preliminary injunctions because of the general difficulty in patent matters in showing that damages would not be an adequate remedy for the applicant.

In April 2018, the High Court refused to grant a preliminary injunction in an SPC infringement case as it found that damages would be an adequate remedy for the SPC holder. The refusal of the preliminary injunction was upheld by the Court of Appeal\(^4\) in a two to one majority decision on the basis that damages would be an adequate remedy for the SPC holder. This was the first time the Court of Appeal considered the issue in Ireland. However, in July 2019, the Supreme Court unanimously held that a preliminary injunction should have been granted by the High Court\(^5\) setting out a reformulated test and holding that ‘the preferable approach is to consider the adequacy of damages as part of the balance of convenience’ assessment rather than a hurdle prior to that assessment. They held that the adequacy of damages will continue to be ‘the most important component’ of the balancing exercise but that other factors may also be considered by the court.

### Condition and security requirements for interim relief to be granted

The plaintiff must give an undertaking in damages in the event that he or she should fail at trial. This is an undertaking that, if the injunction is granted but is subsequently found to have been wrongly given, the plaintiff will compensate the defendant for any losses incurred as a result of the injunction.

### IV SUBSTANTIVE LAW

#### i Infringement

Under the Irish Patents Act, the following acts, if done without the proprietor’s consent within the territory of Ireland, amount to direct patent infringement:

- \(a\) making, offering, putting on the market or using a product which is the subject matter of the patent, or importing or stocking the product for those purposes;
- \(b\) using a process which is the subject matter of the patent, or, when the third party knows, or it is obvious to a reasonable person in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use in the state; and
- \(c\) offering, putting on the market, using or importing, or stocking for those purposes, the product obtained directly by a process which is the subject-matter of the patent.\(^4\)

Further, it is an indirect infringement of a patent for a third party, without the consent of the proprietor of the patent, to supply or offer to supply in the territory of the state a person, other than a party entitled to exploit the patented invention, with means, relating to an


\(^{44}\) Section 40 of the Patent Act.
essential element of that invention, for putting it into effect, when the third party knows, or it is obvious in the circumstances to a reasonable person, that the said means are suitable and intended for putting that invention into effect.\footnote{Section 41(1) of the Patents Act, which is subject to the caveats in Section 41(2).}

**ii  Construction**

The Irish Patents Act provides that:

\[T\]he extent of the protection conferred by a patent or a patent application shall be determined by the claims; nevertheless, the description and drawings shall be used to interpret the claims.\footnote{Section 45(1).}

Although in Ireland there is no general doctrine of equivalents, the Irish Patents Act does provide that, when interpreting this section:

\[T\]he Court shall have regard to the directions contained in the Protocol on the Interpretation of Article 69 of the European Patent Convention and set out in the Second Schedule to this Act.\footnote{Section 45(3).}

The Irish courts (both the High Court\footnote{Ranbaxy Laboratories Limited \& ors v. Warner Lambert Company [2007 IEHC 256] and Medinol Limited v. Abbott Ireland \& ors [2011 IEHC 128].} and the Supreme Court\footnote{Ranbaxy Laboratories Ltd \& ors v. Warner Lambert Company [2006] 1 IR 193.} have approved the approach taken by the UK courts in *Kirin-Amgen Inc v. Hoechst*,\footnote{[2005] 1 All ER 667. Also see *Catnic Components Ltd v. Hill \& Smith Ltd* [1982] RPC 183.} namely, a purposive construction rather than a purely literal one, giving the language of the claim the meaning that would have been understood by the notional addressee – the person skilled in the art.

The recent decision of the UK Supreme Court in *Eli Lilly v. Actavis*\footnote{[2017] UKSC 48.} may be of persuasive value to an Irish Court where issues of construction come before it.

**iii  Defences – statutory exceptions to infringement**

Under the Irish Patents Act, the rights conferred by a patent do not extend to:\footnote{Section 42 of the Irish Patents Act.}

\begin{itemize}
  \item[a] acts done privately for non-commercial purposes;
  \item[b] acts done for experimental purposes relating to the subject-matter of the relevant patented invention;
  \item[c] the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning that medicine;
  \item[d] use of the invention on board certain vessels or aircrafts that temporarily or accidentally enter the territory of the State;
  \item[e] acts specified in Article 27 of the Convention of International Civil Aviation; and
  \item[f] acts falling under the *Bolar* exemption.\footnote{Acts falling under the *Bolar* exemption exception are particularised at Section 42(g) and 42(h) of the Irish Patents Act.}
\end{itemize}
iv Other defences

In addition, a defendant may claim that the patentee has exhausted its rights. In short, the principle of exhaustion of rights provides that a patent cannot be used to prevent a third party from importing goods that have been put on the market in another Member State by the patentee or with his or her consent.

Further, a defendant may claim that it has a right to continue use that had begun before the filing or priority date, provided such acts are done in good faith.\(^{54}\)

Finally, a defendant may plead that neither damages nor an account of profits should be awarded, on the basis that he or she can prove that at the date of the infringement he or she was not aware, and had no reasonable grounds for supposing, that the infringed patent existed.\(^ {55}\)

V FINAL REMEDIES FOR INFRINGEMENT

If a patent is found to be infringed, or where a litigant’s claim is otherwise successful, a range of remedies may be available. These include the following.

i Monetary remedies

Pursuant to Section 47 of the Irish Patents Act, damages or an account of profits (but not both) can be awarded for the infringement of an Irish patent. It is ultimately at the discretion of the court to decide which is appropriate.

Damages are compensatory in nature and are predominantly calculated by way of assessing loss of profits. Alternatively, damages can be calculated based on the sum of money the infringing party would have had to pay as royalties.

An account of profits is a calculation of the profit made by an infringing party as a result of its infringing activities. An account of profits is intended to prevent unjust enrichment and to restore the patent holder to the position it would have been in had the infringement not occurred.

The court will not award either remedy against an ‘innocent infringer’, where an infringing party was not aware and had no reasonable grounds to know that the patent existed.\(^ {56}\)

ii Non-monetary remedies

Injunctions

Permanent injunctions\(^ {57}\) can be sought to restrain an infringing party from ‘any apprehended act of such infringement’. Injunctions can be prohibitory or mandatory – as was seen in Smithkline Beecham plc v. Genthon BV\(^ {58}\) – and are routinely granted at the conclusion of infringement proceedings.

The court ultimately has discretion to refuse a final injunction, and will in some instances impose a licence in lieu of a permanent injunction.

\(^ {54}\) Section 55(1) of the Irish Patents Act.
\(^ {55}\) Section 49(1) of the Irish Patents Act.
\(^ {56}\) ibid.
\(^ {57}\) Section 47(1)(a) of the Irish Patents Act.
\(^ {58}\) IEHC [2003] 623.
Delivery up or destruction

Pursuant to Section 47(1)(b) of the Irish Patents Act, the court can order the delivery up or destruction of infringing goods.

Declaration

Where a patent holder is successful in his or her infringement proceedings, the infringing party is declared to have infringed the patent. Furthermore, an order for the publication of the judgment can be made by the court at the request of the patent holder.\(^{59}\)

VI OTHER TYPES OF PATENT PROCEEDINGS

i Declarations of non-infringement

Any person may apply to the High Court for a declaration that its acts, or proposed acts, do not infringe a patent (a declaration of non-infringement: DNI).\(^{60}\) The validity of the patent cannot be challenged in proceedings for a DNI, and the making or refusal of a DNI does not imply that the patent is valid.\(^{61}\)

ii Compulsory licences

At any time after the expiration of the period of three years beginning on the date of the publication of notice of grant of a patent, any person may apply to the Controller for a licence under the patent, or for an entry in the register to the effect that licences under the patent are to be available as of right.\(^{62}\)

iii Disputes regarding entitlement to ownership of a patent

Under the Irish Patents Act any person can request that the High Court determine entitlement to ownership of a granted patent.\(^{63}\)

VII APPEAL

Decisions of the Controller can be appealed to the High Court.\(^{64}\) There is an automatic right of appeal of every decision of the High Court (including the Commercial Court) to the Court of Appeal. This is not limited to a decision on the merits and includes interlocutory decisions such as preliminary injunction orders. An appeal does not operate as an automatic stay. The court has discretion to decide whether or not to grant a stay.

To appeal against a High Court order, the appellant must lodge a notice of appeal within 10 days (for an expedited appeal)\(^{65}\) or within 28 days (for an ordinary appeal) of the date when the High Court order is perfected.

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60 Section 54(1) of the Irish Patents Act.
61 Section 54(2) of the Irish Patents Act.
62 Section 70 of the Irish Patents Act.
63 Section 81(1) of the Irish Patents Act.
64 Section 96 of the Irish Patents Act 1992.
65 Expedited appeals are described in Order 86(A), Rule 7.
In certain limited circumstances, there is a possibility of a further appeal to the Supreme Court, where (1) the decision involves a matter of general public importance; or (2) it is necessary in the interests of justice that there be an appeal to the Supreme Court.

Additionally, direct appeals (from the High Court) to the Supreme Court will be allowed where (1) the decision involves a matter of general public importance; or (2) it is necessary in the interests of justice that there be an appeal to the Supreme Court; and (3) exceptional circumstances warrant a direct appeal.

VIII THE YEAR IN REVIEW

The year 2019 has been busy for patent litigation in the Irish Courts.

The Supreme Court, in a landmark decision, adjudicated on a preliminary injunction application in respect of alleged infringement of an SPC. In granting leave to appeal, the Supreme Court found that the divergence in the application of the test between England and Ireland gave rise to an issue of law of general public importance.

Applying a reformulated test, the Supreme Court ultimately found that a preliminary injunction restraining the infringement of an SPC should have been granted by the High Court and by the Court of Appeal in 2018. Their decision, handed down in July 2019, qualifies the approach taken in many previous cases that damages would be an adequate remedy for the plaintiff and confirms the flexible nature of the remedy. Although adequacy of damages will continue to be ‘the most important component’ of the balancing exercise, the Court found that ‘the preferable approach is to consider the adequacy of damages as part of the balance of convenience’ assessment rather than as a separate and antecedent hurdle prior to that assessment.

Availability of damages will not be decisive: other factors may be considered and weighed in the balance by a court, which may include presumptive validity of intellectual property rights, a preference for preserving the status quo ante, and whether the alleged infringer could have ‘cleared the way’ by way of invalidity proceedings.

Finally, the Supreme Court found that in preliminary injunction applications, a court could consider whether the merits of the claim were likely to succeed where the strengths in the parties’ cases were apparent. For example, the Court observed that determinations of invalidity of the disputed intellectual property right in other comparable jurisdictions might weigh against granting an injunction.

In July 2018, the Irish Commercial Court heard an application for a stay and departed from the existing precedent in Merck & Co Inc v. GD Searle & Co (Merck) by refusing to suspend national patent revocation proceedings while parallel opposition proceedings were ongoing in the EPO. The applicant seeking the suspension of the Irish proceedings relied on Merck, arguing the potential waste of resources that would result from simultaneous proceedings before two separate bodies. However, the Court refused to stay the entire proceedings, and in a departure from previous Irish case law, directed that all pre-trial steps in the proceedings should go ahead, including the exchange of pleadings and any discovery but allowed the trial to be delayed until after the result of the opposition proceedings before the EPO.

IX OUTLOOK

The Supreme Court decision referred to above will have particular resonance for patent and SPC holders. Prior to this judgment, it had traditionally been difficult for rights holders to overcome the adequacy of damages threshold and the judgment may now encourage more rights holders to assert their rights by way of preliminary injunction in the Irish courts. It remains to be seen in what circumstances and to what extent the lower Courts will apply it.

Another interesting development is Regulation (EU) No. 2019/933, which amends Regulation (EC) No. 469/2009 and introduces an exception to the protection conferred by an SPC, allowing EU based manufacturers of generics or biosimilars to obtain a waiver to manufacture SPC-protected products or medicinal products containing those products in the EU, provided such manufacture is for export to non-EU countries where patent or SPC protection for those products have expired or never existed. It also permits the stockpiling of generics and biosimilars during the final six months of SPC protection to enable a ‘day 1’ launch for those products. The SPC waiver entered into force across all member states on 1 July 2019. However, importantly the Regulations provide for a three-year transition period until 2 July 2022.
Chapter 12

ISRAEL

Tal Band and Dovev Apel

I  OVERVIEW

Patent litigation in Israel is governed by the Patents Law 5727-1967 (as amended) (the Patents Law), regulations enacted thereunder, as well as by case law and decisions rendered by the courts and the Israeli Patents Registrar (the Registrar).

According to the Patents Law, patent litigation in Israel consists of three main proceedings:

a opposition, following acceptance of a patent application (pre-grant opposition);
b revocation of a patent; and
c patent infringement lawsuits.

The patentability, and hence validity of the invention may be challenged in the framework of each such proceeding.

In view of the pre-grant opposition regime, patent litigation in Israel is mostly conducted before the Registrar. According to the Israel Patent Office’s (ILPO) Annual Report 2016, approximately 50 oppositions and a few revocation applications are filed annually with the Registrar.²

Research carried out by the ILPO, relating to opposition proceedings conducted between 2012 and 2015, revealed that more than 80 per cent of the proceedings that culminated in a final decision resulted in acceptance of the opposition.³

II  TYPES OF PATENT

Patents in Israel are national, granted for a period of 20 years from the date of filing. Patents of addition remain in force throughout the duration of the main patent. The Israeli legal system does not provide protection for utility models, nor are short-term patents available in Israel.

Generally, patents are granted based on a full substantive examination. It is also possible to request abbreviated examination based on a corresponding foreign patent granted in certain jurisdictions (e.g., the European Patent Office or the US Patent Office). In addition, the

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1 Tal Band is a senior partner and Dovev Apel is a partner at S Horowitz & Co.
3 Power point presentation summarising the research, available at: www.justice.gov.il/Units/RashamHaptentim/legalinfo/Pages/Pre-grant_Oppositions.aspx.
ILPO signed several bilateral Patent Prosecution Highway (PPH) and Patent Cooperation Treaty (PCT)–PPH agreements with different national offices, which permit usage, under certain circumstances, of search and examination results of such offices.

The Registrar is empowered to extend the term of certain patents for an additional term, and subject to certain conditions the term is capped. A patent extension order may be granted only with respect to ‘basic patents’. In general, a basic patent protects either a pharmaceutical product, a substance (being an active ingredient in a pharmaceutical product), a process for the manufacture or use of such substance or product, or a medical device for which marketing authorisation is required in Israel.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

In principle, two judicial authorities cover first-instance patent enforcement and invalidity actions:

a. the Registrar, who hears mostly oppositions, revocation and amendment proceedings; and

b. the district courts that try patent infringement cases.

Defendants in a pending infringement suit may argue, *inter alia*, that the patent at issue is invalid (indirect attack) or submit an application for revocation of the patent with the Registrar (direct attack).

The question of whether the invention is patentable is the focus of most opposition proceedings conducted before the Registrar.

One should bear in mind that the burden to prove the validity of the patent during opposition proceedings rests upon the patent applicant, while in revocation and infringement proceedings, such burden lies with the revocation applicant and defendant, respectively. Hence, there is an advantage in challenging validity by opposing the patent application, rather than submitting an application for revocation of a patent.

Another important consideration that may encourage interested parties to challenge the validity of a patent as early as its acceptance is the fact that the patent cannot be enforced until it is finally granted (after appeal has been exhausted).

The Registrar usually possesses a better understanding of technological and scientific issues when compared to judges. Where necessary, the Registrar is assisted by an examiner in the relevant field.

The Patents Law provides that the court may appoint a scientific adviser. Courts usually appoint advisers in more technologically complicated cases. The scientific adviser may advise the court and assist it in collecting evidence, but should not be involved in the rendering of judgment. The scientific adviser cannot be cross-examined by the litigants.

i Patent infringement procedures

Procedure and means to obtain evidence

Infringement proceedings may be initiated by the patentee or an exclusive licensee, and are conducted before the relevant district court.

Patent infringement proceedings are similar to those employed in other civil actions. Following the pleadings phase and preliminary discovery proceedings, a pretrial hearing will usually be conducted either by the court registrar or the presiding judge to identify the disputed issues and make the trial process more efficient. During the pretrial hearing, the
judge is authorised to issue any procedural order aimed to simplify the procedure and, in particular, consider the parties’ pleas and any motions to strike out, join or remove parties, entertain discovery and interrogation requests, and rule that further and better particulars be furnished, grant interim relief and order that evidence in chief be submitted by way of affidavits.

Evidence is generally submitted by way of affidavits presenting factual evidence (including experiments) and written expert opinions, which are all subject to cross-examination during oral hearings. The standard of proof required is that of the balance of probability.

Each party to the proceedings may apply for the discovery of documents relevant to the case that are or were in the possession of the other party or a third party, provided that the discovery request was first addressed to the other party. The court may also order a party to discover specific documents or reply to questions forwarded to it by way of interrogatories. All answers must be provided in the form of an affidavit. Another possibility for obtaining and preserving evidence is by means of an *Anton Piller* order, which allows entry to the premises of the defendant, and search and seize all relevant documents and evidence, although those measures are rarely applied in patent litigation. Upon application of the plaintiff, the court may also appoint a temporary receiver over any property or order an inspection of any property or article in relation to which a question has arisen in the action.

**Limitation**

In general, like other civil claims, intellectual property matters are subject to a seven-year limitation period that begins to run on the date of establishment of the cause of action. However, as each act of infringement constitutes a new cause of action with its own period of limitation, an injunction may be filed even where the infringement commenced more than seven years beforehand. Damages, on the other hand, cannot be sought for a period exceeding seven years.

As part of the new Designs Law that entered into force on 7 August 2018, the legislator deleted a section from the Patents Law that provides that defences to a patent infringement claim (e.g., the invalidity defence) are not time-barred. Nevertheless, it was made clear that this deletion was not meant and is not expected to change the existing law that defence claims are not time-barred.

**Interim injunctions**

Often, simultaneously with the submission of a statement of claim, the plaintiff will seek an interlocutory injunction (preliminary injunction) as a form of temporary relief, in order to preserve the status quo until the court renders a decision in the main action. Only in extreme and urgent circumstances will the court be willing to grant an interlocutory injunction prior to the filing of the statement of claim.

The discretion of the court in preliminary injunction proceedings is governed by several principles and considerations. The primary consideration is whether an immediate intervention of the court is essential in order to prevent irreparable harm. In addition, the applicant must demonstrate:

- a *prima facie* case on the merits and that there is a reasonable chance of succeeding in the case (patent validity is usually not discussed by the court in interim proceedings);
- that the balance of convenience lies in his or her favour; namely, that the hardship to the applicant if a preliminary injunction is not granted will be greater than the hardship to the defendant if an injunction is granted and eventually found to be unjustified; and
‘clean hands’ in approaching the court and that the relief was sought without laches or undue delay.

Preliminary injunctions are the most common form of interim relief in patent infringement proceedings. Additional preliminary remedies that are available under Israeli law include an attachment order and a Mareva order (aimed to restrict use of an asset), an Anton Piller order and a receivership order. This list is not exhaustive and the court may grant other interim reliefs as it deems appropriate in the circumstances.

As a rule, interim relief proceedings are heard inter partes. Ex parte relief may be granted if the applicant is able to establish, through prima facie evidence, that any delay resulting from an inter partes hearing is likely to cause irreparable or severe damage, or if the court is convinced that notice to the counterparty will defeat the purpose of the order. Applications for an attachment order, a Mareva order and an Anton Piller order are usually heard ex parte. When granting ex parte relief (other than for an attachment order), the court will schedule the inter partes hearing within 14 days from the date of grant of the ex parte injunction. During preliminary injunction proceedings, the court may determine that, instead of hearing an application for a preliminary injunction, the main action will be expedited. Such determination enables plaintiffs to expedite the enforcement process.

In order for interim relief to become effective, the applicant must deposit with the court, in an amount determined by it, a personal undertaking and a third party guarantee (usually, a bank guarantee), as security in case the defendant is damaged by the action that is ultimately denied.

The practice of protective letters is not available in Israel. A third party may apply to the court seeking a declaration of non-infringement as a protective measure in proceedings that assume the patent to be valid.

In general, a bona fide attempt to enforce a patent would not impose liability on the patentee (save for costs that the court is authorised to order should the claim be dismissed). However, in a precedential decision rendered by the Central District Court at the end of 2015, it was held that misleading the Registrar, intentionally or as a result of gross negligence, in an attempt to extend the patent monopoly, constitutes abuse of a dominant position or unjust enrichment, thereby entitling the plaintiff to claim all or part of the patentee’s profits under the Unjust Enrichment Law 5739-1979. The decision, if not overturned by the Supreme Court, may also infer that a patentee may be found liable under Israeli antitrust law for threatening or commencing litigation to enforce a patent that the patentee knows is invalid, or against a defendant whom the patentee knows, is not infringing the patent.4

Interestingly, a decision taking a different approach was rendered in June 2018 by the Tel Aviv District Court in a case involving the same generic company as the plaintiff. In that case, Unipharm argued that the brand company abused its monopoly in the market of antidepressants and initiated futile proceedings (a claim based on the Unjust Enrichment Law and a preliminary injunction against the marketing of the generic version) solely for the purpose of delaying competition in the relevant market. Unipharm sought compensation and accounts.5 The court dismissed the suit, in limine, but also commented on the merits. In

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5 CC (TA) 38568-10-11 Unipharm v. Glaxo (published on Nevo, 8 June 2018).
so doing, the court held that the Israeli Antitrust Law, which prohibits abuse of monopoly power, applies to actions relating to commerce or business as opposed to actions conducted before the authorities, such as the Registrar.

The Supreme Court will probably consider and opine on the lower court’s contradicting views when rendering its anticipated decision in the Unipharm appeal.

**Amendment of specification**

Once examined and accepted, the court (or the Registrar in a case before him or her) may permit an amendment of the claims only for one of the following purposes: clarifying, removing an error in the specification or restricting the claims. The amendment may be allowed only if it does not broaden the scope of the claims or add anything to the specification that was not already included therein from the beginning.

**Duration and costs**

The duration of a patent infringement case varies significantly. The average duration is two to three years.

Costs are also difficult to estimate and may vary significantly, depending on the complexity of the case, the parties involved and the legal representation. Legal fees may range between US$400,000 and US$800,000 for the main claim and US$150,000 to US$300,000 for interim injunction proceedings.

**ii Oppositions**

Anyone can oppose a patent application within three months of publication of its acceptance.

Opposition proceedings consist of the following stages: submission of statements of arguments by both the opponent and the applicant, submission of evidence (usually in the form of affidavits and expert opinions), holding a cross-examination hearing and submission of summations.

The Registrar has an inherent authority to order discovery. However, the Registrar is usually more reluctant to exercise his or her authority in comparison to civil courts.

For details on amendment of specification, see Section III.i.

The duration of opposition proceedings may vary significantly from case to case. The average duration is two years, and six years if the proceedings ensue until a final decision is rendered. Costs are likewise difficult to estimate. In general, legal fees in opposition proceedings range between US$300,000 and US$700,000 (excluding expert fees and costs).

**iii Patent revocation**

The patentability of an invention may also be challenged in the framework of revocation proceedings, which may be initiated by any person, at any time while the patent is in force.

Revocation proceedings are essentially similar to opposition proceedings, except that in the former case, the parties are required to submit their arguments together with supporting evidence (usually by way of affidavits and expert opinions).

If a defendant in a pending infringement lawsuit files a revocation application, the Registrar will entertain it only after receiving the express permission of the court. The court may stay the infringement proceedings for a period and on conditions that it will prescribe.
If an infringement suit is filed with the court after an application for revocation has been filed with the Registrar, the Registrar will entertain the application unless otherwise ordered by the court.

The duration and costs of revocation and opposition proceedings are essentially similar. Revocation proceedings may be somewhat shorter due to the joint submission of pleadings and supporting evidence.

IV SUBSTANTIVE LAW

i Infringement

Definition of infringement

The Patents Law defines ‘infringement’ as exploitation of the invention for which a patent has been granted unlawfully or without the permission of the patentee, whether in the manner defined in the claims or in a manner similar thereto and involving the main features, as defined in the claims, of the invention that is the subject matter of the patent.

In relation to an invention that is a product, ‘exploitation of an invention’ is defined as the production, use, offer for sale, sale or import for the purpose of any of the aforesaid acts; in relation to an invention that is a process it is defined as use of the process; and, in relation to a direct product of a process, it is defined as the same activities listed with respect to an invention that is a product.

The Patents Law lists the following exemptions to patent infringement:

a activity that is not on a commercial scale, nor of a commercial nature;

b experimental use with respect to an invention, for the purpose of improving an invention or developing another invention; and

c experimental use for the purpose of obtaining registration for marketing the product after expiration of the patent if the use was done in order to obtain registration in Israel or in any other country that permits experimental use for the purpose of obtaining registration before expiration of the patent. Also, provided that all products manufactured within the framework of this exemption will not be used for any purpose other than obtaining the above registration, either during the term of the patent or thereafter (Bolar-like exemption).

While the list of acts constituting exploitation of an invention is a closed list that does not mention exportation, in one case the district court noted that activity conducted in Israel involving, or resulting in, exportation of the patented invention may be considered ‘exploitation of the invention’, if it is on a commercial scale or of a commercial nature and interferes with the exclusive right of the patentee to exploit the invention in Israel.6

The scope of the patent is defined by its claims. The claims are interpreted in light of the description in the specification. The claims must be given purposive interpretation. The applicability of file-wrapper estoppel was left open by the courts and the Registrar. However, correspondence between the patentee and the ILPO may assist the court in assessing the scope of the patent.7

6 DCA 814/05 (Jer) & CC 7076/05 (Jer) Orbotech Ltd v. Camtech Ltd (published on Nevo, 1 January 2005).

Infringement may also be found where the invention is exploited in a manner similar to that defined in the claims and making use of the essence of the invention. In this regard, the Supreme Court adopted the doctrines of equivalents or variants (or ‘pith and marrow’) and noted that a product or process that replaces components or omits immaterial components of a patent may still be considered infringing, as long as the product or process do the same work in substantially the same way, and substantially accomplish the same result.\(^8\)

### Indirect infringement

Liability may be imposed on a person who collaborated with the direct infringer in attaining the infringement. Establishing liability as joint tortfeasors requires showing direct infringement as well as concerted action between the tortfeasors towards the common goal of infringement.\(^9\) In the *Tsuk Or* case,\(^10\) the Supreme Court ruled that the company’s organs may be liable with the company as joint tortfeasors, if said requirements are fulfilled.

The contributory infringement doctrine, which was adopted by the Supreme Court in the *Rav Bariach* case,\(^11\) provides broader applicability. The Supreme Court set the following requirements for establishing contributory infringement:

- the components used by the indirect infringer constitute a material part of the invention;
- the indirect infringer knew, or should have known, that the components had been especially made or especially adapted for use in the infringement of a patent; and
- the components are not staple products that can be substantially used in a non-infringing manner.

The Supreme Court did not clarify whether direct infringement must occur within Israel, in order for liability to arise.

### ii Invalidity and other defences

Typical defences in patent infringement actions may include the following (non-exhaustive list):

- non-infringement – the defendant may argue that the product or process in dispute is not covered by the claims or that his or her activity is not included in the statutory list of activities amounting to ‘exploitation of an invention’. Sometimes the defendant may claim that his or her activity comes under the statutory exemptions to patent infringement (see Section IV.i, ‘Definition of infringement’);
- licence to exploit the patent;
- the defendant is the owner of the invention;
- right based on prior exploitation or actual preparation for exploitation in Israel in good faith on the date the application was submitted in Israel or the date of the priority application. The exploitation or preparation should be on a commercial scale and of a commercial nature; and
- invalidity, for example:
  - not a patentable subject matter;

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\(^8\) CA 345/87 *Hughes Aircraft Company v. The State of Israel* [1990] IsrSC 44(4) 45 (*Hughes*).


\(^10\) *Tsuk Or*, footnote 7, at 688.

\(^11\) See footnote 9.
• lack of novelty;
• obviousness;
• inutility;
• insufficiency of disclosure; and
• covetous claims – namely, the claims are not fairly based on the description.

The Patent Examination Guidelines published by the ILPO provide that in order to be patentable an invention must fall within a technological field, namely, it must involve a concrete technological process. Computer programs as such, are not patentable. If a computer program has the effect of changing any physical properties, or causes the computer to work in a new way, or establishes connections between system components that did not previously exist, then an indication may exist that the invention falls within a technological field. Similarly, methods of doing business are not patentable as such, since they fall within the field of commerce and are, therefore, not considered industrial. Patents will not be granted for method of therapeutic treatment of the human body or for new varieties of plants or animals, except for microbiological organisms not derived from nature.

According to the Supreme Court’s landmark judgment in the Hughes case, a novelty-destroying publication must disclose all elements of the invention. The publication may be read in light of the general common knowledge possessed by persons skilled in the art before the effective date. However, in a later decision, the Supreme Court ruled that novelty may be lost as a result of a disclosure containing the essence of the invention. Another test for assessing novelty is the infringement test (‘that which infringes if later, would anticipate it earlier’). Case law shows that the courts tend to accept the doctrine of inherency (when following a prior publication would necessarily result in the same invention).

Obviousness is assessed through the eyes of a person skilled in the art who possesses average ability, in other words, no inventive skills. Unlike novelty-destroying disclosure, inventive step may be negated based on multiple publications. However, their combination (‘mosaic’) must be obvious to a person skilled in the art. Another test applied in the context of inventive step is ‘the obvious to try’ test, assessing whether a person skilled in the art would have been motivated, based on the prior art, to undertake the route taken by the patentee with a reasonable expectation of success. Objective evidence may also give an indication on the obviousness of the invention. Such evidence (sub-tests) may include evidence of commercial success, long-felt need, failure of others and unexpected results.

The utility requirement is met if the promised result is achieved when following the information given in the specification. A credible promise of utility is usually sufficient when applying for a patent. The patentee may be required to provide evidence of utility in the framework of opposition or revocation proceedings, where the utility of a given invention is challenged.
The description must enable a person skilled in the art to perform the invention without the exercise of inventive skills. A reasonable degree of routine experiments is permissible and best mode disclosure is not required.

The claims must clearly and precisely define the claimed monopoly. In addition, the claims must reasonably be based on the description included in the specification.

In an *obiter dictum*, the Supreme Court indicated that it tends to adopt the ‘international exhaustion’ doctrine and, in any event held, that parallel import does not amount to patent infringement.\(^{17}\)

**V FINAL REMEDIES FOR INFRINGEMENT**

As in other commercial and civil litigation in Israel, the remedies granted to a successful plaintiff in an infringement case include the following.

**i Damages**

When awarding damages, the court will consider the infringing act and the plaintiff’s position in consequence of the act. The court may also consider, *inter alia*, the following:

- the direct damages caused to the plaintiff;
- the extent of the infringement;
- the profits derived by the infringer from the infringement; and
- reasonable royalties that the infringer would have had to pay had he or she been granted a licence to exploit the patent to the extent so infringed by him or her.

As mentioned above, once a patent is granted, the patentee is entitled, retroactively, to full damages for any unauthorised exploitation of the invention committed after acceptance of the patent application. The Patents Law also provides that once a patent is granted, the patentee will be retroactively entitled to damages in the form of reasonable royalties for any unauthorised exploitation of the invention that took place between the date of publication of the patent application and its date of acceptance.

Where damages are claimed, the court may order the defendant to provide an account of the extent of its infringement and the profits gained, or award compensation by way of assessment. A successful party is entitled to reimbursement of its real out-of-pocket costs. However, in practice, the level of costs determined by the courts is usually lower than the costs actually incurred.

Punitive damages may be awarded where an infringement is committed after the patentee or exclusive licensee has warned the infringer of the infringing activity. In such case, the sum of punitive damages cannot exceed the sum of the actual damages, thus amounting to double damages. In practice, the courts do not award punitive damages in infringement suits.

**ii Permanent injunctions**

If a plaintiff is successful, the court will usually grant a permanent injunction to prevent the infringer from infringing the patent in the future. As a rule, permanent injunctions remain in effect until the patent expires. The question of whether a post-expiry injunction may be

\(^{17}\) HCJ 5379/00 *Bristol-Myers Squibb Company v. Minister of Health* [2001] IsrSC 55(4) 447.
granted where the infringement was committed in order to obtain a springboard into the market after the patent’s expiry still remains open. 18 Stays are not generally granted while an appeal is pending, except where, absent the stay, the appeal may become academic and there seem to be good chances of succeeding in the appeal.

iii Delivery up of infringing material

The court may, at the request of the seizer of assets, of the receiver, or of a party, order what shall be done with the seized assets, including their return to the premises from which they were taken or to their owners, order that assets liable to spoil be sold, that assets be destroyed or transferred, or it may give any other order that is justified under the circumstances.

iv Other remedies

In general, courts adjudicating civil matters can grant declaratory judgments, prohibitive orders, orders for specific performance or any other relief, as they deem fit.

VI OTHER TYPES OF PATENT PROCEEDING

i Declaration of non-infringement

As discussed above, a third party may apply to the court for a declaration that his or her exploitation of the invention does not amount to infringement of the specific patent. The proceedings are conducted before the district court under the assumption that the patent is valid.

ii Proceedings relating to service invention

According to the Patents Law, an invention by an employee, arrived at in consequence of his or her employment and during the period of his or her employment (a service invention), shall, in the absence of an agreement to the contrary between him or her and his or her employer, become the property of the employer. An employer or employee may apply to the Registrar to determine whether a given invention constitutes a service invention.

The Patents Law further provides that in the absence of an agreement determining whether, to what extent and on what conditions an employee is entitled to remuneration for a service invention, the matter shall be decided by the Compensation and Royalties Committee (the Committee), the members of which comprise a Justice of the Supreme Court, the Registrar and an additional member from an academic institution with a scientific background. The Committee is also authorised to determine whether a certain invention constitutes a service invention prior to deciding on the matter of remuneration. 20

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19 The examples detailed below are non-exhaustive.

20 Rotem v. Teva Pharmaceutical Medical Ltd, application for remuneration for a service invention (discussing the question whether, according to Section 133 of the Patents Law, an invention that constitutes a service invention should be decided by the Registrar) (published on Nevo, 25 July 2005).
The proceedings before the Committee are held *in camera*. The Committee is authorised to prescribe its own rules of procedure, in so far as not existing under the Patents Law. Decisions of the Committee are final but may be challenged by filing a petition to the Supreme Court, sitting as the High Court of Justice.

### iii Determination of inventorship or ownership

According to the Patents Law, the owner of the invention is the inventor or whomever is entitled to the invention by operation of the Patents Law, by assignment or by agreement. In addition, the person filing a patent application is deemed the owner of the invention, until proven otherwise.

Determination of inventorship or ownership may arise ancillary to opposition, revocation and infringement proceedings, or in the framework of independent proceedings before the district court seeking a declaratory order of patent ownership or inventorship.

In a decision rendered by the National Labour Court, it was noted that the labour courts are also authorised to determine patent inventorship where such determination is required in a matter falling within the labour courts’ exclusive jurisdiction. However, it was decided that the labour court of first instance was not authorised to order the employee to sign the documents required for the registration of patents in the name of the employer, in light of the fact that the Registrar has judicial authority in such matters and may permit the employer to sign the documents himself or herself.\(^{21}\)

### iv Compulsory licences

If the Registrar is convinced that a patentee abuses his or her monopoly, he or she may grant a compulsory licence to exploit the patented invention to a person applying for that purpose, provided that the application is filed after the expiration of three years from the date of grant of the patent, or four years from the date of filing the patent application, whichever is the later. The licence will be mainly to satisfy the needs of the domestic market, and subject to royalties determined by the Registrar.

A compulsory licence may also be granted to enable exploitation of a patent that otherwise would have infringed an earlier patent, provided that the later invention demonstrates considerable progress with respect to the earlier invention. Where the invention in both patents serves the same industrial purpose, a compulsory licence will be granted only if the applicant is willing to grant a similar licence to the owner of the earlier invention.

### VII APPEAL

#### i Courts of appeal

The district courts of Jerusalem and Tel Aviv hear appeals on decisions given by the Registrar (e.g., decisions given in opposition and revocation proceedings). Appeals may be either by way of right (where the decision of the Registrar concludes the dispute) or by special leave with respect to other decisions (e.g., decisions in intermediate proceedings).

The Supreme Court hears appeals from the district courts, either by right (where the district court rendered a judgment as a court of first instance) or by special leave to appeal.

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Procedure on appeals

The losing party has a right to appeal within 45 days of delivery of the judgment.

A second appeal (where the district court sat as a court of appeal in infringement proceedings), or an appeal from a decision not being a final judgment, may only be filed if leave to appeal is granted by the court to which the appeal will be filed. An application for leave to appeal should be filed within 30 days from the date of the decision.

The notice of appeal should set out the grounds of appeal. Except with special leave of the court, the appellant is not allowed to raise any grounds of objection not specified in the notice of appeal.

As a rule, the appeal is based on the transcript of proceedings, pleadings and evidence submitted in the lower court. In exceptional cases, the court of appeal may allow new evidence. However, in the matter of Gabai, the Supreme Court noted that the court of appeal would be more inclined to allow the submission of new evidence in patent cases than in other civil cases.

Generally, the court of appeal refrains from interfering with factual findings of the first instance and focuses on legal issues.

When a date is set for the hearing of the appeal, each party should file a volume of exhibits with the court of appeal. The appellant should file a summary of his or her principal contentions at least 14 days before the hearing, and the respondent should file the same at least seven days before the hearing (unless the court instructs otherwise). When the appeal is argued orally, the appellant will argue his or her case and the respondent will then reply. The hearing is much shorter than the hearing in the lower court. The appeal may also be argued in writing (sometimes followed by short oral arguments if the court so wish, to clarify some aspects of the appeal).

The appellant must provide security for costs of the defendant, in an amount set by the court. Generally, the duration of an appeal is one to two years (until a decision is rendered).

THE YEAR IN REVIEW

Service inventions

In a precedential decision (obtained by the undersigned) that was rendered in May 2017, the Committee acknowledged the possibility of regulating the issue of compensation for service inventions, not only in the framework of individual agreements but also in the framework of collective agreements or arrangements. The Committee held that such collective agreements or arrangements similarly bereft the Committee of jurisdiction over a claim for compensation, if filed by an employee who is subject to them. The decision infers that collective agreements or arrangements may reduce the exposure of companies conducting R&D in Israel to claims by their employees for compensation for service inventions.

In another precedent-setting decision (obtained by the undersigned) that was rendered in May 2017 (but only published in December 2017), the Committee dismissed, in limine,
a suit that was filed by Dr Ruth Levy, a former R&D employee of Teva Pharmaceutical Industries Ltd (Teva), claiming entitlement to receive compensation for her contribution to the development of Azilect.\footnote{Dr Ruth Levy v. Teva Pharmaceutical Industries Ltd, application for remuneration for a service invention (motion to strike out) (published on Nevo, 25 May 2017).}

In dismissing Dr Levy’s suit, the Committee held, for the first time, that suits filed by employees for compensation for service inventions are subject to the statutes of limitation, and that suits of such nature will become time-barred seven years after the cause of action is deemed to have arisen. The Committee rejected several possibilities, raised by Dr Levy, as to when the limitation period began to be counted in her case. The Committee did not determine, however, when, in its view, the cause of action would be deemed to arise generally, in similar suits; instead, the Committee raised the following three possibilities for making this determination: (1) the cause of action arises when an invention disclosure is made by the inventor employee to the employer; (2) the cause of action arises when a patent application is filed, in respect of the service invention or when a patent is granted; or (3) the cause of action arises when the employer begins to commercialise the invention. It was held that in the present case, all three possibilities referred to above were duly met in order for a determination to be made that the seven-year time bar had indeed expired.

A petition contesting the Committee’s decision was filed with the High Court of Justice and a hearing is expected to take place in November 2018.

\section*{ii Sanctions for inadequate disclosure}

In a precedential decision that was rendered about three years ago,\footnote{See footnote 4.} and is currently under appeal, the Honourable Justice (then Judge) Prof Ofer Grosskopf established the liability of patentees for improper prosecution of a patent application and unlawful enforcement of patent rights.

The judge rendered an account of Sanofi to report its profits from selling its drug Plavix in Israel to a local generic company, Unipharm Ltd (Unipharm), within the framework of a suit claiming said profits. The judge ruled that Sanofi knowingly withheld information from the Registrar during the prosecution of its patent application, by including an incorrect example, and that the misleading application was the main reason for the delay caused in the entry of Unipharm to the relevant market and for increasing its development costs.

It was held that misleading the Registrar, intentionally or as a result of gross negligence, in an attempt to extend the patent monopoly, constitutes abuse of a dominant position or unjust enrichment on the part of the patentee, thereby entitling the plaintiff to claim all or part of the patentee’s profits under the Unjust Enrichment Law.

In the past, compensation awarded to generic companies would have probably been limited to actual losses incurred by them. The decision, if confirmed by the Supreme Court, infers that applying for a patent, while misleading and withholding information from the Registrar, in the patent application and thereafter during prosecution, may result in significant liability being attributed to the brand company, for the unjustified deterrence of potential competitors. This could also result in compensating potential competitors for the full amount of the brand company’s profits during the deterrence period.
As noted above, in June 2018, the decision in *Unipharm* was criticised by the Tel Aviv District Court, in another case involving that same plaintiff (Unipharm), and with similar factual background.\(^{26}\)

In the latter case, Unipharm claimed that Glaxo failed to properly meet its disclosure obligations by concealing a corresponding British patent application that disclosed the invention, as well as an EPO examination report that concluded that said application undermined the novelty of a corresponding EP patent application. Unipharm further argued that Glaxo conducted futile proceedings (a claim based on the Unjust Enrichment Law and a request for a preliminary injunction) solely for the purpose of deterring competition and delaying the launch of a generic drug for the antidepressant Seroxat. Moreover, Glaxo did not withdraw the appeal filed by it contesting the decision denying the infringement suit, even after its patent application was refused by the Registrar.

The court dismissed the suit as time-barred, based on its conclusion that Unipharm had been aware of all the facts relating to the claim more than seven years prior to the filing of its claim. On the merits it was held, *inter alia*, that the sanctions provided by Section 18c of the Patents Law \(^{27}\) are exhaustive and prevent the possibility of additional remedies being awarded under the Unjust Enrichment Law. In this respect, it was held that any shifting of the 'point of balance' established under the Patents Law should be made by the legislator following a comprehensive examination of the public considerations involved. The court further noted that as far as Glaxo unlawfully benefited from its failure to disclose the facts, the 'beneficiaries' entitled to the restitution are the patients who had purchased the overpriced medication.

As mentioned above, the court noted that it is doubtful whether antitrust laws applied to Glaxo's conduct as regards the Registrar. It was further held that in any case, according to the relevant provisions of the Israeli Antitrust Law and the Commercial Torts Law, the plaintiff would be entitled to compensatory damages as opposed to relief in the form of the manufacturer's profits during the alleged deterrence period.

As aforesaid, the Supreme Court would probably decide between these contradicting positions in its expected decision in the *Unipharm* appeal.

### iii Patent term extension

Patent term extension (PTE) is granted in Israel only if certain requirements are met, as set out in Section 64d of the Patents Law. One such requirement is that the marketing approval of the pharmaceutical product constitutes the first marketing approval, enabling use of the compound contained in the pharmaceutical product for medicinal purposes, in Israel ('the first marketing approval requirement'). The term 'compound' is defined in the Patents Law as the active ingredient in the pharmaceutical product, or salts, esters, hydrates or crystalline forms of said ingredient.

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26 See footnote 5.
27 Section 18c lists possible sanctions that may be imposed in the event an applicant provides the ILPO with misleading details in reply to a demand for information under Section 18, or knowingly fails to update the ILPO of any significant change in the list of publications cited against its application by foreign patent offices. The sanctions include revocation of the patent or refusing to allow it; granting a licence to third parties; and curtailing the term of the patent. The court may even impose a fine, under the Penal Law.
A particularly significant ruling in the context of the first marketing approval requirement is *Lundbeck*,\(^{28}\) where it was held that the marketing approval of a pharmaceutical product containing an enantiomeric form, would not be considered the first marketing approval enabling use of the compound contained in the pharmaceutical product for medicinal purposes in Israel, where a pharmaceutical product containing the racemic mixture (namely, a racemate comprising an equal amount of two left- and right-handed enantiomers S and R, respectively) has already been approved, since the racemate already contains the enantiomer.

In a recent decision, the Supreme Court dismissed an appeal on the district court's decision, which had dismissed the *UCB Pharma GmbH* appeal. The decision by the Registrar of Patents, subject matter of the appeal, denied UCB's request to extend its PTE.\(^{29}\)

In the appeal, UCB argued that, in light of the Israeli adoption of the European Court of Justice ruling in *Seattle Genetics*, calculation of the extension period begins from the date of notification of the grant of the marketing authorisation to the applicant (and not the date of the decision on the marketing authorisation), a further step must be taken, and the European Court of Justice ruling in the *Incyte* case should also be adopted, namely, that PTEs that were already issued should also be extended. The court rejected the appeal and concurred with the Registrar's decision.

The Supreme Court noted that, in general, it is appropriate to look overseas in order to determine a PTE term of protection that will correspond to the period granted in the reference countries. However, this does not mean that the Israeli patent will be granted the maximum protection granted in those countries. The guiding logic, when it comes to marketing corresponding pharmaceutical products, is to promote competition in the Israeli market, taking into account the period of protection in other markets as a reference point but not as a binding criterion. The linkage to the reference countries is intended to prevent a situation where other markets are competitive in relation to a particular product, while in Israel the same product is sold at a monopolistic price.

In another decision,\(^{30}\) two patent extension orders were requested, for two biological medicinal preparations. The active ingredient in the preparations is a fusion protein, which consists of two parts – one responsible for the biological activity while the other is the Fc domain of IgG1 Immunoglobulin, which has no biological activity but enhances the half-life of the active substance.

The active parts in each of the fusion proteins were known, and a number of preparations that include the active part of the digested protein were already registered. Therefore, the Examiner considered that previous preparations containing the active part of the protein should be considered as the first registration with respect to the active ingredient in the applicant’s preparations in accordance with the provisions of Section 64 (d) (3) of the Patents Law.

It has been noted that the definition of the term ‘substance’ in Section 64a does not refer to biological drugs, in particular proteins, and does not define which configurations of drugs containing biological substances will be considered the same active ingredient, even though they are not structurally identical substances. The Registrar referred to his previous

\(^{28}\) MA (Jer) 223/09 *H Lundbeck A/S v. Unipharm Ltd et al* (published on Nevo, 25 May 2009) (*Lundbeck*).

\(^{29}\) LCA 2070/19 *UCB Pharma GmbH v. Patent, Design and Trademark Registrar* (published on Nevo, 24 July 2019) (*UBC*).

\(^{30}\) Bioverative Therapeutics Inc, application for PTE No. 205802, 171779 (request for patent term extension) (published on Nevo, 4 October 2018).
decision in the *Bayer* case, where it was held that, when examining requests for extensions involving biological substances, the technical-formal test prescribed in the *Lundbeck* case is not sufficient to exhaust the comparison of registered substances with new substances, and that, with regard to medicinal products whose active ingredient is protein, it should be considered, as a preliminary test, whether the medicinal product containing the substance is considered a medicinal product containing a new active ingredient in the Ministry of Health. It was further established that, where differences exist, structural differences and their significance and impact on the molecule’s activity must be examined.

The Registrar noted that the fusion molecule, which is a product of fusion of two genes at the DNA level, should be regarded as a new molecule, not a known substance or a mixture of two substances, since it is a protein created from the beginning as one amino acid sequence, and not the two separate proteins. In order to ‘separate’ between the two parts, ‘entry’ into the molecule is required, according to the test set in the *Lundbeck* case.

**IX OUTLOOK**

**Amendment to the Patent Regulations with respect to PTE**

An amendment to the Israeli Patent Regulations with respect to PTE (the Regulations) came into force on 5 December 2017.

The principal amendments include the following:

- *a* updating the requirements for submitting a PTE application (including with respect to supporting affidavits and appropriated documentation);
- *b* clarifying that the Regulations apply, among other things, to medical devices; and
- *c* clarifying which changes in the marketing authorisation require notification.

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31 *Bayer Healthcare LLC*, application for PTE No. 124123 (appeal on the examiner’s decision pursuant to Section 161) (published on Nevo, 16 April 2018) (*Bayer*).
Chapter 13

ITALY

Licia Garotti

I OVERVIEW

With 22 civil courts specialised in intellectual property, Italy is one of the most active countries in Europe for patent litigation, including urgency proceedings.

The main legislation comprises the Italian Intellectual Property Code (IPC), which provides a comprehensive regulation of intellectual property rights, and the general rules set out in the Italian Civil Code and Civil Procedure Code. Besides the several international treaties of which Italy is a member, the community legislation should also be taken into account.

II TYPES OF PATENT

Inventions that provide a technical contribution and that are new and inventive are protected in Italy by two kinds of patents: invention patents and utility models. Both are effective in Italy and San Marino, and can be validated in the Vatican City State.

As Italy is a member of the European Patent Convention, European Patents are also effective in Italy, provided that an Italian translation is filed with the Italian Patents and Trademarks Office (IPTO).

Invention patents can protect new products, new methods or processes, as well as new uses of an already known product.

Patents applications are filed with the IPTO and, specifically, before the chambers of commerce distributed through the Italian territory, which will then submit the application to the patent office in Rome.

Italian patents have gained a higher presumption of validity since starting from July 2008, the applications are forwarded by the IPTO to the European Patent Office (EPO) for a prior art search. Should the search opinion released by the EPO contain any objection, the applicant is entitled to submit arguments to support the patent validity or to provide potential amendments to the proposed claims.

Once the application is published (i.e., after 18 months from the filing), the IPTO decides on the granting of the requested invention patent, taking into account the EPO search report and the possible following arguments submitted by the applicant.

Italian patents last for a maximum of 20 years from the relevant filing date. The duration of patents protecting any medicinal product, an active pharmaceutical ingredient

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1 Licia Garotti is partner at Gattai, Minoli, Agostinelli & Partners.
2 Legislative Decree No. 30 of 10 February 2005, and following amendments.
or an active ingredient of a plant may be extended by way of a supplementary protection certificate (SPC). The SPC can extend the life of the patent for a period not exceeding five years.\(^3\)

As mentioned above, another way to protect innovation is through utility models. Utility model patents require a minor degree of inventive steps, and are aimed at protecting new models enhancing or improving the effectiveness, in terms of ease of application or use, of machines or parts thereof or products in general. Suitable for exclusively protecting new products, utility models have a shorter life cycle, lasting only 10 years.

The filing procedure provides for no prior art search either by the EPO or by the IPTO. According to the IPC, alternative filing is possible: the applicant for an invention patent is entitled to simultaneously file an application for utility model for the same invention, to be effective if the invention patent is not granted.

The IPTO can always invite the applicant to convert an invention patent into a utility model and vice versa.

Conversion of an invention patent into a utility model is also possible within a litigation, provided that, of course, the 10-year life of the utility model has not expired yet.

### III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

#### i Competent courts

Since 2003, patent litigations are to be submitted to the exclusive jurisdiction of specialised divisions comprising judges skilled in intellectual property matters. Initially named ‘Specialised Divisions in Intellectual Property Matters’ and present in 12 Italian courts, they have been renamed as ‘Specialised Divisions in Enterprise Matters’ and the number has been increased to 22.\(^4\) However, only 11 of them have jurisdiction on cases involving a foreign defendant. Even if the specialised divisions are spread throughout the Italian territory, the most active – and most skilled – courts are in Milan and Turin, followed by Venice, Bologna and Rome.

Italian laws foresee no bifurcation of the process: in the same proceedings, both infringement and validity or invalidity of the patent can be discussed and decided.

The criteria for establishing the territorial venue of the specialised divisions are as follows:

- **a** for infringement proceedings, the domicile or the registered office of the defendant or, alternatively, the place where the infringement took place; and
- **b** for nullity actions, the place where the patentee has elected domicile for that patent.

This rule does not apply if the invalidity of the patent is brought as a counterclaim in infringement proceedings pending before another court.

In case of plurality of defendants, it is also possible to file the action for patent infringement before the specialised division where one of them is domiciled. However, Italian judges are

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\(^3\) The extended period must be equal to the period elapsed between the date on which the application for the patent was filed and the date of the first marketing authorisation.

\(^4\) Please note, however, that according to the main case law, the division between Specialised Divisions in Enterprise Matters and the Ordinary Division is a mere internal division and it does not entail a matter of the competence (see Court of Milan, decision No. 11175 of 8 November 2017).
more likely to declare the lack of territorial venue if the patentee involves a defendant that clearly has nothing to do with the case, just in order to bring the litigation before a certain court.5

ii Standing to sue

The standing to sue in proceedings aimed at obtaining patent revocation belongs to whoever has a commercial interest on the basis of competitive relationship in the sector where the patent will be effective.6 More often discussed is the standing to sue for patent infringement.

Article 131 of the IPC only quotes the owner of the enforced intellectual property right. In accordance with the main Italian case law, exclusive licensees are also acknowledged as being entitled to bring the infringement action, their rights considered equivalent to the patent owner rights. More debated is the potential entitlement of a non-exclusive licensee in the absence of the authorisation of the patent owner. With Decision No. 15350 of 4 July 2014, the Supreme Court stated that the standing to sue also belongs to other persons or entities, including a mere distributor of a patented product7, who has an interest of their own in the action since they suffered damages from the infringement8. The standing to sue for the negative ascertainment of a patent violation belongs to the accused infringer.

While infringement and invalidity actions are not subject to any time limit, damages compensation can be claimed within five years. However, some Italian case law outlines that the time limit for the restitution of the profits achieved by the infringer should be extended to 10 years, for requests that have no compensatory nature and are not linked to the ascertainment of wilful misconduct.8

iii Procedure in patent infringement and patent invalidity proceedings

As ordinary proceedings on the merits, patent infringements and patent invalidity actions are pending once the claimant serves the writ of summons to the defendant.9 The latter is entitled to file a defence statement with counterclaims and exceptions, including, inter alia, the invalidity of the enforced patent and, eventually, asking to extend the litigation to a third party allegedly involved in the matter at stake, within 20 days from the first hearing. Such hearing cannot take place before 90 days if the served defendant is based in Italy. The term is extended to 150 days for foreign defendants.

After the first hearing, the parties are allowed to exchange three defensive briefs as provided by the Civil Procedure Code, also formulating their pleadings on the basis of the adversary arguments (first brief) and bringing evidence means (documents) and evidence requests (witnesses examination) to support the formulated claims (second brief).10

Despite the high degree of specialisation in intellectual property matters11 of the judges belonging to the specialised divisions, in almost all patent litigations the court appoints a

5 See Court of Turin, Decision of 31 July 2015.
6 See, among other things, the decision issued by the Court of Milan on 11 June 2014.
7 Please note that recent case-law has denied the standing of the mere distributor of the product infringed by the patent (refer to Section VIII.iii).
8 See the decision issued by the Court of Turin on 20 February 2009.
9 Within 10 days from the service of the writ of summons, the proceeding has to be registered with the Court, either by the plaintiff or the defendant. Otherwise, the proceeding becomes ineffective.
10 The third brief is the last chance to file a replica against the adversary evidence requests.
11 The specialisation is indeed a specialisation in law, with no specific skill in technical matters.
technical expert skilled in the specific field of the patent, referring the technical question to him or her. This is commonly aimed at evaluating the validity of the patent and the technical interference of the attacked good with the existing scope of protection of the enforced patent.

In the technical debate the parties are represented by their respective technical experts, who usually exchange two technical briefs.

Partially derogating to the general evidence rule quoted above, the IPC entitles the parties to submit to the court expert new documents, even if these were not filed by the deadline for the second evidence brief, provided that such documents pertain to the technical question.

After the technical debate, the court expert issues his or her report. Even if it is not binding for the judge, such opinion often provides a sort of anticipation of the outcome of the litigation.

The parties have the option to discuss the court technical expert’s report before the judge, who will then invite the claimant and the defendant to exchange their final statement of defence and relevant replica. A final hearing to discuss the case takes place only upon the request of a party.

iv Patent’s amendment in the course of the proceeding

Article 79.3 of the IPC entitles the patentee to submit, within a nullity action, and ‘in each stage of the proceedings’, a ‘reformulation of the claims that remains within the content of the application as filed and which does not extend the protection it confers’.

Because there is no limit to the number of requests to amend the patent, there have been several cases where this possibility has been exploited by the patent owner multiple times. This option joins the already available administrative procedure for the limitation of a patent before the IPTO.

With respect to the Italian part of a European patent, the Italian Supreme Court recently affirmed that the patent limitation approved by the EPO has retroactive effects starting from the filing date of the original patent application.

v Processes for obtaining and presenting material to the court or tribunal

The burden to prove the nullity of a patent falls on whoever claims the patent revocation. The entity enforcing the patent has, on the contrary, the burden to prove the claimed infringement.

A court order for discovery can be obtained by the party that has provided serious indications to support its claims and has, in substantiating those claims, specified evidence that lies in the control of the opposing party.

Under the same conditions, for infringement committed on a commercial scale, the patentee can also obtain the disclosure of banking, financial or commercial documents under the control of the opposing party, subject to the protection of confidential information.

The right of information under Article 121 bis of the IPC was introduced through the implementation of the Enforcement Directive, which entitles the patentee to obtain from the opponent precise information on the origin of the infringing goods or services, distribution channels and the identity of any third party involved in the infringement.

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12 Provided, however, that the repeated amendments are not considered as gross abuse.
13 Decision of the Supreme Court No. 21402 of 14 August 2019.
Judicial inspection is a very common type of proceeding used in Italy to collect evidence about a suspected patent infringement, especially if the enforced patent protects a certain process, and provided that the confirmation of the infringement cannot reasonably be obtained elsewhere. In particular, this proceeding is aimed at gathering evidence to confirm:

a. the actual occurrence of the alleged infringement (typically the collection of technical information, seizure of technical documentation and samples of products where possible); and

b. the scope of infringement (seizure of accounting documentation, pricing information, invoices, volumes of stocks, etc.).

Authorisation is granted by a court order upon specific application filed by the patentee, usually submitted (and granted) ex parte, being the ‘surprise’ effect essential for the most effective execution of the obtained order.

The operations generally last between half a day and a full day, and are performed by a bailiff, usually assisted by a technical expert appointed by the court. If the judge agrees, the technical operations can also be attended by the lawyers and the patent attorney of the patentee.

If not filed when the patent infringement case is already pending, the inspection is followed by the filing of the main proceeding by the deadline imposed by the court or, in its absence, within 20 working days or 31 calendar days (if the latter is a longer period) from the obtained order.

The judge also provides specific measures aimed at preserving the confidentiality of the seized documents and obtained information, which are customarily sealed in a closed envelope kept by the court. The relevant examination could be restricted to the lawyers and technical experts of the patentee, who would in such case be bound to confidentiality towards their client.

vi  Challenge of patent validity in infringement proceedings

Stay of the infringement proceedings

As mentioned above, the challenge of the validity of the patent is the most common defence brought by the accused infringers against the patentee.

Very rarely is an infringement proceeding stayed, pending a revocation action.15

With the decision of 14 April 2016, the Italian Supreme Court16 stated, however, that infringement proceedings are necessarily suspended when, in separate proceedings between the same parties, the patent invalidity is claimed. The purpose is to avoid a decision acknowledging the patent infringement contrasting with a later decision revoking the same patent.

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15 In the same way, in accordance with the main case law, infringement proceedings concerning the Italian portion of a European patent is not stayed even if an opposition is pending against the same European patent before the EPO.

16 Court of Cassation, which is the Court for third and last instance. See also, decision of the Supreme Court No. 9500 of 4 April 2019.
Timing and cost considerations for patent infringement and patent invalidity proceedings

A first instance decision is expected about two or three years from the first hearing. It could, however, take longer for matters that are technically very complex or that require analysis and experiments.

The proceeding will certainly last longer if the patent is amended in the course of the proceedings under Article 79.3 of the IPC (see Section III.iv).

Patent litigations in Italy are not excessively expensive, especially if compared to other European jurisdictions. The costs requested by the court for filing a patent infringement or patent invalidity proceedings on the merits amount to about €1,000, while the filing of urgency proceedings amounts to about €500.

Legal fees for the defence have to be added. However, the winning party can usually recover at least part of the sustained costs. The average sums quantified by the courts for the legal fees amount to €7,000 to €15,000 for preliminary injunction proceedings and to €20,000 to €35,000 for cases on the merits, significantly increasing in certain particularly complex cases.

Urgency proceedings and available preliminary relief

The usual way to claim patent infringement in Italy is through urgency proceedings. The right holder is entitled to claim the infringement against any imminent or already existing non-authorised use of the patented invention, as well as toward any contributory infringer (see Section IV.i).

In accordance with Article 132 of the IPC, the right owner is entitled to enforce the patent even if it is still pending as application, and also when it has not been published yet. In such case, the right holder can act upon prior notification of the patent application to the infringer. Once the application is filed, a hearing for the trial is scheduled and the judge usually invites the defendant to bring its defensive arguments a few days before the scheduled hearing. For the reasons outlined in Section III.iii, as with ordinary proceedings on the merits, in urgency proceedings the judge usually appoints a technical expert. These kinds of proceedings require, by definition, the urgency to obtain the requested measures (periculum in mora) together with the likelihood of both the validity of the enforced patent and the infringement thereof (fumus boni iuris).

In principle, interim measures can also be claimed ex parte. In patent cases, however, Italian courts are quite reluctant to grant them. Should this be the case, a hearing for the confirmation, modification or revocation of the granted measure shall take place.

In general, the potentially available remedies are:

a injunction to cease and desist from any infringing act and the prohibition to advertise, manufacture, commercialise and use the infringing goods or process;
b withdrawal of the infringing goods from the market;
c penalty for any potential further infringement or non-compliance with the decision or for each day of delay in the execution of the court’s order;
d seizure of the infringing products; or
e publication of the decision.

The right of information under Article 121 bis of the IPC can be obtained, under the conditions outlined in Section III.v, in the course of preliminary injunction proceedings. The patentee can claim the discovery; however, this is rarely granted. No damages compensation can be claimed within urgency proceedings.
An injunction order does not require the following filing of ordinary proceedings on the merits, where the interim order is suitable to bring forward the effects of a decision on the merits. This applies, for instance, if the patent owner obtained the requested injunction and is not interested in pursuing the infringer for damages compensation and other remedies.

On the contrary, a granted seizure not followed by the filing of the case on the merits will lose its effectiveness.

A decision is commonly expected within two to four months, and could extend a further two to three months if the technical phase requires more time. This usually happens when the subject matter of the patented invention is particularly complex.

While preliminary injunction proceedings are managed by a single judge, the potential appeal against the first instance order will be managed by a panel of three judges of the same specialised division of the court.

The obtainment of a preliminary injunction or of a seizure is not necessarily subject to a security. It is, however, at the discretion of the judge to require the applicant to lodge an adequate security for possible damages compensation.

While in Italy the filing of protective letters aimed at reducing the risk of suffering preliminary injunctions ex parte is not allowed. In 2010, the IPC implemented a specific rule entitling the accused infringer to also claim the non-infringement through urgency proceedings, substantially conforming the already existing main case law.

iv Potential liability for threatening infringement proceedings
The threatening of infringement proceedings addressed to the alleged infringer usually raises no liability. It is a different case if the patentee sends a cease-and-desist letter to dealers or clients of the alleged infringer, where the patent owner could be considered liable under unfair competition law.

The patentee is also exposed to liability if it files a claim for patent infringement, while being aware of the nullity or the ineffectiveness of the patent, or where the claim is found to be groundless. In such case of wilful misconduct, the patentee is usually condemned to reimburse the legal costs borne by the winning party. Furthermore, it could be condemned to a damages compensation if the action was filed on the basis of a non-existing patent.

iv SUBSTANTIVE LAW
i Infringement
Any unauthorised use of a patented invention depicts a patent infringement. In particular, the patentee has the following rights:

a if the patent covers a product, the patentee can prohibit to manufacture, use, put on the market, sell or import for sale the protected product;

b if the patent covers a process or method, the patentee can use the process, as well as use, put on the market, sell or import for sale the product directly obtained with such process; and

c the patentee can prohibit third parties from supplying or offering to supply to persons or entities that are not entitled to use the patent, any means concerning an essential element of the patented invention and that are necessary for the relevant realisation of such invention within the territory of a state in which the invention is protected, when the third party knows, or should have known using the ordinary care, that those means are suitable and intended for putting that invention into effect. This provision
does not apply if the means are staple products currently on the market, unless the third party induces the supplied entity to infringe the patent. It should also be outlined that persons and entities benefitting from the limitation of the effects of the patent (for instance for private use or experimental use) are not ‘persons or entities entitled to use the patent’ for the purposes of this rule.

The right under point (c) is provided for by Article 66.2 bis of the IPC, introduced by recent Law 214/2016, which implemented the case law already existing on this topic.17

Besides the actual non-authorised use of the patent, the right owner can also challenge an ‘imminent’ infringement.

As a general rule and under certain circumstances, Italian case law includes among the infringing acts the preparatory activity, recognising that activities performed by a third party in preparation of the potential future sale of the counterfeited good (including advertisement)18 can harm the right of the patent owner, even if, in the end, the infringing product is not sold.19

The potential challenge of preparatory activity is particularly debated in the pharmaceutical sector, when these are aimed at the commercialisation of the product. Reference is made to the beginning of the necessary administrative procedures, before the expiry of the patent or of the SPC.

The case law is also not consistent with reference to preparatory acts aimed at marketing the product after the expiry of the patent.20 From a civil perspective, the company is liable for patent infringement as an entity, while its directors or commercial employees are not directly liable. The company directors could, however, be deemed liable under Law 231/2001 for patent infringement.

**Patent claims interpretation in patent infringement actions**

The scope of protection of the patent is defined by the claims, but the description and the drawings shall be used to interpret the claims. A patent infringement occurs if the patented invention is reproduced literally or by equivalence. While, in the former, all features contained

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17 See, among other things, decision of the Supreme Court No. 22495 of 19 October 2006.
18 See Court of Milan, decision of 14 January 2015 and Court of Turin, first instance order of 29 June 2018 (confirmed by the Court of Turin, appeal decision of 14 December 2018).
19 Supreme Court, decision No. 5112 of 3 April 2003.
20 With decisions of 4 November 2010 and of 8 November 2012, the Court of Milan ruled that such preparatory activity is lawful. Of the opposite opinion are the Court of Rome (decision of 11 November 2011) and the Court of Turin (decision of 11 February 2011). Recently the new EU Regulation No. 2019/33 (amending Regulation No. 469/2009 concerning the supplementary protection certificate for medicinal products), entered into force on 1 July 2019, provides that manufacturers of generic and biosimilar products established in the European Union shall, during the term of validity of the SPC, manufacture said products for the purpose of export to third-country markets where the protection does not exist or has expired. The waiver of the Reg. No. 2019/933 applies also to the stockpiling of the product in European Union territory during the last six months of the term of the SPC to allow the launch of the generic or biosimilar products on the European Union market as soon as the SPC expires.
in the patent claims are literally reproduced, in infringement by equivalence (Article 52.3 bis of the IPC), the liability is held where the challenged device or process is equivalent to the claimed invention.

Infringement by equivalence is usually assessed by applying the triple identity test: same function, same effect and same way.

Recent Decision No. 24568, issued by the Supreme Court on 2 December 2016, faced once again the debated issue of the infringement by equivalence of a pharmaceutical patent. In that case, the Court stated:

\[\text{[I]n order to assess whether the disputed embodiment can be considered equivalent to the patented one, so as to constitute an infringement thereof, it is necessary to ascertain whether, in the event of reaching the same final result, this is provided with originality, offering a non-trivial or repetitive solution to the previous one... That is to say, in order to exclude infringement by equivalence, it does not matter the variation, albeit original, of a single element of the patented invention, if the variation does not exclude the use, even partial, of the earlier patent.}\]

The infringement is also not excluded when the solution adopted by the third party modifies the earlier invention so that it constitutes an improvement (evolutionary infringement) or implies the implementation of a former patented invention, in that case being a dependent invention.22

A matter that is currently debated is the possibility to challenge the infringement by equivalence if the scope of the patent has been limited through amendments of the relevant claims, making reference to the file wrapper estoppel theory.23 This happens particularly when, applying Article 79.3 of the IPC, the patent is modified several times within proceedings when the relevant validity is challenged. In this respect, a recent decision of the Court of Milan24 affirmed that if the patent has been expressly limited within the granting process or within a proceeding, the scope of protection of the same cannot be extended by means of an interpretation by equivalence in order to cover also the cases excluded by the previous limitation.

ii Invalidity and other defences

Patent validity attacks

A patent is regarded as null for the following reasons: lack of novelty, lack of inventive step, insufficient disclosure, if it cannot be industrially implemented, for absence of lawfulness and if the subject matter extends beyond the content of the application as filed or the protection it confers has been extended. The most discussed invalidity arguments are as follows.

21 This rule was introduced in the IPC in 2010 and corresponds to Article 69 of the European Patent Convention. The previous case law did, however, already apply the principle contained therein.
22 See Court of Milan, decision of 24 January 2017.
23 The scope of protection of a patent cannot extend to features that the patentee eliminated or surrendered by limiting the patent.
25 This option rarely applies.
Italy

**Lack of novelty**

The validity of a patent requires ‘absolute novelty’, in other words, the patented invention shall not be comprised in the prior state of the art (Article 46 of the IPC). Italian courts have stressed that, for the ascertainment of the novelty requirement, it must be assessed whether the invention, as defined in the patents claims, was already described at the priority date in a single prior art document, known or disclosed, so that it can be considered to fall within the definition of state of the art. Thus, the invention meets the requirement of novelty unless it was described directly and non-ambiguously in a single prior art document. The combination of two or more prior art documents, or different parts of each of them, cannot be used for novelty attacks.

**Lack of inventive step**

A patent is inventive if it is not obvious to a person skilled in the art in respect to the prior art.

To assess the inventive step of a patent, Italian courts customarily apply the ‘problem-and-solution approach’ criterion. For such purpose, the ‘closest prior art’ has to be determined first. This identifies the most promising starting point to obtain the claimed invention, and normally has the highest number of characteristics in common with the patent (or allows at least the minimum number of modifications to obtain the claimed solution). Then, the ‘distinctive features’ have to be selected. It is also necessary to determine:

a. the ‘objective technical problem’ solved by the distinctive characteristics of the claimed solution (selecting them from that or those characteristics that are not described or suggested by the closest prior art); and

b. the expertise of the skilled person in the patent field, in order to understand whether the same, starting with the closest prior art, would (not could) solve the objective technical problem in an obvious way, possibly combining the teaching of the closest prior art with another different prior art document or with the general common knowledge of the technical sector of the patented invention.

**Sufficient disclosure**

The requirement of sufficient disclosure is met when, for the mid-level person skilled in the art of the patent field, the implementation of the invention requires no further complex investigations and experiments, but only routine activities.

Moreover, the exclusive rights conferred by a patent do not extend to:

a. private or non-commercial activities and activities having an experimental purpose;

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26 Under Article 47 of the IPC, the prior state of the art does not, however, include: (a) any disclosure of the invention occurred within six months before the filing of the patent application and resulting directly or indirectly from an evident abuse to the detriment of the applicant or his legal predecessor; (b) potential disclosures of the patented invention in an official or officially recognised exhibition as defined pursuant to the Paris convention of 22 November 1928.

27 See, in particular, Court of Milan, decision of 17 January 2017, Court of Milan, decision of 24 January 2017 and Court of Milan, decision of 31 October 2018.

28 See, in particular, Court of Milan, decision of 17 January 2017, Court of Milan, decision of 24 January 2017, Court of Milan, decision of 31 October 2018, Court of Milan, first instance order of 14 January 2019 and Court of Milan, first instance order of 4 March 2019.

29 See, in particular, Court of Milan decision of 7 March 2019.
b studies and experimental uses aimed at obtaining a marketing authorisation for a drug or medicine, comprising the ‘preparation and the use of the raw materials strictly necessary for this purpose’ (Bolar exemption); 30 and
c extemporaneous preparation of single units of medicine upon medical prescription in a pharmacy, provided that no industrially manufactured active principles are used (galenic exception).

Other defences to infringement claims
Other defences to infringement claims are detailed below.

Licence
Besides the licence that the attacked infringer can prove on the basis of an effective agreement, 31 the licence in respect to standard-essential patents (SEPs) deserves a specific mention. The implementation of an SEP is necessary in order to comply with a certain industrial standards set by the relevant standard-setting organisations. 32 There are many interests that need to be balanced: on one side, the owner of a patent is interested in obtaining the highest royalty for its patent; on the other side, any interested market player is entitled to have access to the patent at fair, reasonable and not discriminatory (FRAND) conditions.

The filing of court proceedings aimed at obtaining an injunction against any non-authorised (i.e., non-licensed) entity has been often used in order to ‘convince’ the attacked infringer to pay for play. With Decision C-170/13, the European Court of Justice stated that the holder of a SEP cannot start a legal action against the infringer before a prior notice.

The attacked infringer shall declare if it is interested in taking licence of the specific SEP at FRAND conditions. If this is the case, the patentee shall make a specific and written offer that must be accepted within a reasonable period of time.

Standardisation often raises issues under antitrust law – in particular, whether the filing of an infringement action against a non-licensed entity depicts an abuse of a dominant market position.

Exhaustion of rights
Under Article 5 of the IPC, the patentee’s rights on a given product are exhausted if such product has been marketed by the patent owner or with its consent within the European Economic Area. The exhaustion does not apply if the patentee can oppose reasonable grounds, in particular where the marketed product has been modified or altered.

Prior use
In accordance with Article 68.3 of the IPC:

30 As outlined in Section IV.i, such use is, however, not considered as authorised use for the purposes of the exclusion of the contributory infringement under Article 66.2 bis of the IPC.
31 According to the most recent case-law, the existence of a licence agreement can be proved by means of simple presumptions, based on the conduct of the patent owner (Court of Milan decision No. 10965 of 31 October 2017).
32 Reference is made, for instance, in the Information and Communications Technologies (ICT) field, to the GSM and UMTS standard.
Anyone who, during the twelve months before the filing or priority date of the patent application, has made use of the invention within their business enterprise, can continue to use it within the limits of their prior use. Said right can only be transferred together with the business where the invention is used. The burden to prove prior use and its extension belongs to the prior user.

The ‘internal business use’ excludes any public use of the invention, which would deprive the patent of the novelty requirement (see Section V.ii).

Lack of knowledge

The lack of knowledge cannot be opposed as a defence by the infringer. This can, however, be evaluated by the judge in the quantification of the damages compensation.

V FINAL REMEDIES FOR INFRINGEMENT

Besides the final remedies available in urgency proceedings (see Section III.viii), the patentee is entitled to obtain:

- definitive recall of the infringing goods from the market against the owner or anyone in possession of the infringing goods;
- destruction of the infringing goods; or
- transfer of the property of both the infringing products, as well as of the specific means univocally destined to manufacture the infringing goods, or to implement the patented method or process (contributory infringement); and
- compensation for damages suffered because of the patent infringement.

With specific reference to damages compensation, Article 125 of the IPC provides certain criteria for the relevant quantification, namely:

- loss of profits and other arising damages;
- profits achieved by the infringer (which can be claimed alternatively to the compensation of the loss of profit or to the extent exceeding such amount); or
- the reasonable royalty that the infringer should have paid having obtained a patent licence.

The burden of proof is on the patentee, who – under certain circumstances – is entitled to obtain disclosure of the adversary accounting information.

Italian courts often take into account elements such as:

- loss of value of the infringed patent;
- costs for the registration and maintenance of the patent;
- research and development costs directly relating to the patented invention; and
- costs for the promotion of the product incorporating the patented invention.

The loss of profit is often reflected in the loss of sales of the products lawfully incorporating the patent in connection with the sales made by the infringer.

When the proof is not met, the judge tends to apply the criteria set out in the second paragraph of Article 125 of the IPC, quantifying the loss of profit in a sum corresponding

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34 See, among the others, the decisions of the Court of Milan of 5 April 2016 and of 14 June 2016.
to the royalties the infringer would have paid to the owner of the infringed right had he or she obtained a licence from the patentee. Such amount is usually determined with regards to conditions set out in agreements in force with third-party licensees and industry best practice.

Lastly, upon request, in accordance with Paragraph 3 of Article 125 of the IPC, the court can provide for the restitution of the profits obtained by the infringer, which, contrarily to damage compensation, does not imply the assessment of any subjective element (fault). The infringer’s profits are often identified with ‘gross profit’ obtained by subtracting incremental costs from total revenues. On the other hand, fixed costs are usually not taken into account, as they are borne regardless of the specific production.35

Italian law does not provide for punitive damages. However, a very recent decision of the Supreme Court36 ruled in favour of enforcing in Italy foreign judgments granting the payment of punitive damages.

VI OTHER TYPES OF PATENT PROCEEDINGS

i Ownership challenge

The ownership of a patent is assumed. Article 118 of the IPC, however, entitles whoever has obtained a final decision ascertaining that the rights to the patents belongs to a different person or entity to obtain the transfer of the patent application, if still pending, or of the patent if already granted.

ii Compulsory licences

In certain cases (i.e., in case of lack of implementation of the patented invention within three years from the date of granting of the patent or for dependent patents), the interested entity is entitled to file administrative proceedings before the IPTO claiming a compulsory licence, provided that it proves:

- to have previously unsuccessfully asked the patentee for a licence;
- to be ready to pay an equitable royalty; and
- to be able to implement the patented invention in a ‘satisfactory way’.

The duration of the compulsory licence cannot exceed the life of the patent and can be transferred only with the business activity where the licensed patent is exploited. The licensee is not prevented from seeking the patent invalidity or from challenging the width of the rights deriving therefrom.

iii Customs seizure

The patentee is entitled to seek protection against its rights infringement through the Customs Authority in accordance with EU Regulation No. 608/2013. In particular, upon the filing of an application outlining the reasons of the claim, the patentee can obtain the ‘suspension of the release or detention’ of the alleged infringing goods.

If the request is granted, the Customs Authority invites all customs offices to block the goods identified by the patentee. The order becomes ineffective (and, where already seized, the infringing products are automatically released) if the patent holder does not file

35 See, in particular, Court of Appeal of Bologna, decision of 8 May 2017.
36 Supreme Court, Decision No. 16601 of 5 July 2017.
proceedings (which can consist of both a civil or a criminal action) aimed at ascertaining the infringement. As for common practice, during this 10-day period the order is not amended and the seized goods are not released.

iv Criminal proceeding
Criminal proceedings are less exploited for IP matters. However, there are many cases where the criminal action has been started in order to maintain the block of the alleged infringing goods before the Customs Authority.

VII APPEAL
A first-instance decision can be appealed for factual or legal grounds before the local court of appeals 30 days from the service of the decision or, lacking that, six months from the relevant publication.

In the appeal proceedings, the parties are not allowed to file new claims, and usually submit new evidence, unless the interested party proves that such evidence could not be filed before for independent reasons. Also, a new technical phase is very rare, unless any lack of motivation or error in the technical report of the expert appointed by the court in the first-instance proceedings is proven. Appeal proceedings are filed by serving a writ of summons on the counterpart, which is entitled to file a statement of defence, formulating a possible counter-appeal if it was only partially winning, within 20 days before the hearing scheduled by the court. If the statement of defence is filed at the hearing, no counter-appeal is admissible.

At the first hearing, the court usually schedules the hearing for the final formulation of the respective pleadings. The decision is issued after the exchange of two briefs (i.e., final statement of defence and replica) and to the possible final hearing when required by at least one of the parties. Appeal proceedings usually last between two and three years.

VIII THE YEAR IN REVIEW
Besides the recent case law quoted (see, in particular, Section V with reference to damages compensation), the following decisions deserve a dedicated comment.

i Amendment of patent claims within a proceeding: Court of Milan, Decision of 24 January 2017
Since it was introduced in 2010, the possibility to amend the patent during invalidity proceedings in accordance with Article 79.3 of the IPC has given rise to heated debates about, inter alia, methods of modifying claims. In this respect, the judge clarified that the amendment is not limited to a 'unification of the claims, but can consist of additions and specifications that draw on the content of the patent, provided that they do not extend the scope of protection and the original application'. The court added that potential additions can be drawn from the patent description, but not from an *ex post* perspective, 'treating the description as a pot'.37

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37 This position has been recently confirmed by the decision of the Court of Milan No. 11910 of 27 November 2017.
The Decision also deserves to be mentioned for the quantification of damages compensation. Indeed, the court added that the damages compensation had to be calculated from the date of the provided amendment as it is not admissible to place a disproportionate burden on the market players. It should, however, be stressed that in the case at stake, the patentee formulated several requests for amendments, picking many features from the description.

ii Software patent eligibility: Court of Appeals of Turin, Decision of 3 January 2017

The litigation concerned the validity and infringement of patents relating to the Electronic Program Guide for digital television and satellite. The attacked infringer claimed that the invention was, in reality, software and thus not eligible to gain patent protection.

At the end of a very complex litigation, the court decided that the patent was valid, outlining that a computer program is eligible for patent protection whenever there is ‘a technical effect that goes beyond the normal physical interaction generated by a program running on a computer’.

iii Counterfeiting claim against the mere distributor: Court of Milan, Decision of 18 January 2018

The litigation concerned the negative assessment of the infringement of a pharmaceutical patent.

The Court of Milan affirmed that, in such case, the proceeding cannot be brought against the mere distributor of the products covered by the patent. In fact, the quality of mere distributor does not entail the right to participate in a proceeding regarding the infringement of a patent, neither as defendant in an action aimed at the negative ascertainment of a patent violation, nor as claimant for the ascertainment of the patent infringement.

iv Coexistence between a partially void Italian patent and the Italian portion of a valid European patent having the same scope: Court of Venice, Decision of 23 May 2018

The litigation concerned the request for injunction from the manufacture of certain products infringing the Italian portion of a European Patent corresponding to an Italian patent, which had been previously declared partially null.

The judge clarified that the decision that declared the partial nullity of the Italian patent does not have any effect on the following proceedings, which are brought on the basis of the correspondent European Patent. In fact, the declaration of nullity of the Italian patent does not entail the nullity of the European Patent, which, in the meantime, has been granted.

v The retroactive effects of the patent limitation requested in the course of a proceeding also concern the calculation of compensation for damages: Court of Milan, Decision of 5 October 2018

The litigation concerned the validity and infringement of an Italian patents relating to an innovative electronic turnstile for managing the access of passengers to public transport vehicles.

The Court set the principle according to which the retroactive effects of the patent limitation requested in the course of the proceeding also concern the quantification of the damages suffered because of the patent infringement. In this way, a previous and more
restrictive case law – which excluded that the damages were due for the conduct prior to the presentation of the limitation request (see, among others, Court of Milan, Decision 24 January 2017) – was overcome.

vi The patent limitation approved by the European Patent Office has retroactive effects starting from the filing date of the original patent application: Italian Supreme Court, Decision of 14 August 2019

The Court affirmed that, according to Article 69, Paragraph 2, of the European Patent Convention, a European patent as amended in limitation proceedings shall determine retroactively the protection conferred by the application, as long as such protection is not thereby extended.

Article 56, Paragraph 1, of the IPC, stating that the scope of protection determined by the limitation is confirmed as of the date of publication of the limitation decision, shall be interpreted in accordance with Article 69, Paragraph 2. This interpretation respects the need of legal certainty and the protection of third parties. Indeed, third parties’ interests are respected by the fact that the patent as limited does not extend beyond the scope of the original patent application.

IX OUTLOOK

With Law No. 214 of 3 November 2016, Italy ratified the Unified Patent Court (UPC) Agreement, which shall have jurisdiction on infringement and validity of both Unitary Patents and European patents. Milan will be one of the local divisions of the UPC, and is competing to become the seat of the UPC central division for pharmaceuticals and life sciences, overtaking London as a consequence of Brexit.

Milan is also a candidate for hosting the European Medicines Agency.

38 On 12 March 2019 the Legislative Decree n. 18/2019 (implementing the delegation pursuant to Article 4 of Law No. 163/2017 concerning the connection between the national legislation both with the provisions of the Reg. No. 1257/2012 - regarding the implementation of an enhanced cooperation on the unitary patent protection – and with the provisions of the Agreement on the Unified Patent Court, ratified and enforced with Law No. 214/2016) has been published on the Italian Official Journal. The Legislative Decree (1) modifies Article 56 of the IPC introducing the so-called unitary patent protection, which means that ‘the European patent issued for Italy and the European patent with unitary effect provide the owner with the rights referred to in articles 25 (right to prevent the direct use of the invention) and 26 (right to prevent the indirect use of the invention) of the Agreement on a unified patent court, and is subject to the limits referred to in Article 27 of the same Agreement (limitations of the effects of a patent)’ and (2) introduces the new Article 245 bis, which provides that proceedings concerning the European patent issued for Italy and pending until the Agreement on the Unified Patent Court enters into force as well as those proceedings promoted in Italy before the Italian Court in the following seven years from the entry into force of the said Agreement will be decided according to the Italian law.
Chapter 14

JAPAN

Yasufumi Shiroyama

I  OVERVIEW

In Japan, the first instance of litigation to enforce patents is handled by the Tokyo District Court or the Osaka District Court. The number of such litigations filed in a year is around 150 to 200. The appellate proceeding is handled by the Intellectual Property High Court (IP High Court). The Supreme Court has discretion regarding whether to take appeals from the IP High Court or not, and takes no cases or only a few IP cases every year. In each of the district courts and the IP High Court, a panel of judges, consisting of career judges, hears arguments of the parties and renders judgments in writing. No United States-type discovery is available. Injunctive relief is available as long as a patent is found to be valid and infringed, and preliminary injunction is also available as an interim relief, although it takes at least several months to obtain an order of preliminary injunction. No punitive damages are available, but certain presumptions regarding the amount of the actual damages are available. Invalidity of a patent can be raised as a defence against infringement claims before the courts, although a separate proceeding to invalidate the patent is also available before the Japan Patent Office (JPO).

II  TYPES OF PATENT

There are two types of exclusive rights for protection of inventions. One is a patent and the other is a utility model right. An effective term of a patent is 20 years after a filing date, while an effective term of a utility model right is 10 years. A patent is granted for a product or process after substantive examination by an examiner of the JPO, while a utility model right is only granted for a product without substantive examination. Requirements for a utility model right, such as novelty and inventive step, are examined when a right holder tries to enforce the right because the right holder is obliged to obtain a ‘technical opinion’ of an examiner of the JPO, prior to commencement of enforcement. The level of inventive step required for a utility model right is stipulated to be lower than that required for a patent, but there appears to be little difference in practice. Chances for a post-grant claim correction of a utility model right are more limited than that of a patent. From practitioners’ point of view, a utility model right is easy to obtain, but very difficult to enforce.

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iii PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Patent enforcement actions

A patentee may enforce its right by filing a complaint with a court and obtaining an order from the court for an injunction, payment of compensation for damages, or both. Patent infringement litigation is mainly regulated by the Code of Civil Procedure (Act No. 109 of 1996), but a number of special provisions have also been included in the Patent Act. Border enforcement at a customs office is another method of enforcing a patent. Japanese courts have jurisdiction over a foreign defendant if it has an office in Japan or if the place of the alleged infringement is in Japan (Articles 3-2 and 3-3 of the Code of Civil Procedure).

An action with respect to a patent is subject to the exclusive jurisdiction of the Tokyo District Court or the Osaka District Court in the first instance and the IP High Court in the second instance (Article 6 of the Code of Civil Procedure). The IP High Court is a special branch of the Tokyo High Court established for the litigation of intellectual property rights matters. At the Tokyo District Court, Osaka District Court and the IP High Court, there are special divisions for litigation concerning intellectual property rights and many of the judges in these divisions have substantial experience in dealing with patent cases, although judges with technical backgrounds are uncommon. In the IP High Court, cases involving issues the court finds important may be heard and judged by the grand panel consisting of five judges, including the chief judges of each division. In addition to a panel of judges, a technical researcher is assigned to each case to advise the judges. The technical researchers have technical backgrounds and experience in working as patent examiners at the JPO or as patent attorneys in private practice. Further, at the time of the technical presentation session, explained below, the court may appoint technical experts.

A patentee often begins an action by sending an alleged infringer a cease-and-desist letter, but it should be noted that there is a risk that the recipient of the letter may then initiate an action for a declaratory judgment or request an invalidation trial in the JPO.

In a complaint, a patentee, as a plaintiff, has to identify the patents and their claims to be asserted by their registration numbers and claim numbers; the accused products by their trade names, model numbers, or both; and the amount of damages sought as compensation. The complaint and summons are served on the defendant, an alleged infringer, by the court, usually within a week and the first hearing is held within 30 to 50 days of the service of process.

Unlike in the United States, there is no discovery in Japan and each party has to collect its own evidence. However, Article 104-2 of the Patent Act stipulates that an alleged infringer has to disclose relevant information of the accused product or process when the alleged infringer denies the patentee’s allegation. Further, there exists a system where a court may, upon the request of a party, order the other party to submit documents. In patent infringement litigation, grounds to refuse the submission of documents, which are specifically requested by the patentee for the purpose of establishing infringement and damages, are more restricted than in general civil litigation, and therefore, the submission of documents that a court recognises as necessary cannot be rejected without justifiable grounds (Article 105 of the Patent Act). Article 105 of the Patent Act stipulates that a court may, upon the request of a party, order the other party to produce documents which the court recognises as necessary unless the party that is the subject of the request has justifiable grounds for refusal. For the purpose of determining whether there are justifiable grounds for refusing the document request or whether documents are necessary evidence, the court may cause the relevant party to bring the requested documents to the court for an in-camera inspection of the documents prior to ruling on the document request. A party that is requested to submit documents often
refuses based on the argument that it is justifiable to refuse to submit the requested documents containing trade secrets. However, in patent infringement litigation, as the protective order system is applicable and available (Article 105-4 of the Patent Act and other provisions), the fact that the requested documents contain trade secrets does not necessarily constitute a justifiable reason for refusal. A protective order prohibits the addressees from using trade secrets submitted by the counterparty for any purpose other than litigation proceedings and from disclosing trade secrets to any person other than the addressee of the protective order. A protective order is issued by the court against each natural person working as an outside or in-house counsel of the party to the litigation. Breach of a protective order may result in criminal punishment.

While the first hearing and the final hearing are held publicly, the proceedings for patent infringement litigations are often conducted by means of a non-public preparatory proceeding. A hearing or preparatory proceeding is normally concluded within 30 minutes every four to six weeks and the allegation and proof must be detailed in the documents submitted to the court in advance of the hearing or preparatory proceeding. A technical presentation session, where each party may take 30 to 60 minutes to make an oral presentation to the judges, is often held upon a party’s request once the judge feels that all of the relevant allegations and proof in relation to the infringement and validity of the patent have already been submitted to the court. In some cases, court-appointed technical experts may join the technical presentation session so that the judges know how such experts view the presentations made by both parties.

Generally, the existence of liability for infringement and the amount of damages are determined separately. The sum of the damages to be payable are determined after a preliminary assessment of the liability for infringement, only if the judges are convinced that liability for infringement exists.

It usually takes 12 to 18 months for the first instance to complete.

Proceeding with an action for preliminary injunction is substantially similar to that of a lawsuit on the merit. Even though it is a proceeding for ‘preliminary’ relief, it takes at least several months. Having said that, an order for a preliminary injunction becomes enforceable immediately, while an order of permanent injunction issued through a lawsuit on the merit becomes enforceable only after conclusion of appeal proceeding. A patentee is required to place a bond in an amount decided at the discretion of a judge in light of the estimated annual profit of an alleged infringer.

ii Patent invalidity actions

In addition to raising a defence based on patent invalidity before a court, an alleged infringer may initiate an invalidation trial before the JPO. Standing for an invalidation trial before the JPO is limited to interested parties. A case is assigned to a panel of three appeal examiners. A patentee is given an opportunity to rebut against alleged grounds for invalidation as well as correct patent claims and specification. After an exchange of arguments between the parties in writing, an oral hearing is held. A panel of appeal examiners often sends a list of questions to both parties prior to the oral hearing. If a panel of appeal examiners finds that a request for invalidation should be dismissed, then it concludes the proceeding and issues a final decision. If a panel of appeal examiners finds that a patent should be invalidated, it issues a preliminary decision in writing prior to a final decision. A patentee is given an opportunity to rebut such a preliminary decision as well as correct the patent claims and specification. It is not rare that a conclusion of a final decision is different from that of the preliminary decision.
A patent invalidation trial usually takes 10 to 15 months. A losing party may file a complaint to revoke the decision of the JPO in the IP High Court. Pendency of a patent invalidation trial before the JPO does not force the court of an infringement action to stay its proceeding. The decision of the JPO, where an action to revoke is still pending, does not have binding effect over a court of an infringement action. Nevertheless, a panel of judges in charge of an infringement action is usually interested in the progress and outcome of an invalidation trial before the JPO, and tends to avoid rendering judgment that is inconsistent with the decision of the JPO in relation to the issues regarding patent validity.

iii Potential risks associated with enforcement

Sending a cease-and-desist letter to potential purchasers or customers of an allegedly infringing product involves a risk that if, as a result of a judicial decision, no infringement is found or the patent becomes invalid, the sender of the letter may be found to have made a false statement and to have damaged the reputation of a competitor, rendering the sender liable for damages for unfair competitive acts or tortious acts. Such risk also exists when sending a cease-and-desist letter to an intermediate distributor or a retailer of the allegedly infringing product, as such parties are not only in the position of an alleged infringer as seller of the products but are also customers of the manufacturer.

Also, if an alleged infringer is forced to suspend its business due to an order of preliminary injunction, and further, if such order is cancelled thereafter due to a final decision, which finds non-infringement or invalidity of the relevant patent of the lawsuit on the merit, the patentee is liable for compensation of the damages caused by such suspension of the business.

IV SUBSTANTIVE LAW

i Infringement

Literal infringement is found if all elements of an asserted claim are satisfied by an accused product or process. Judges interpret the scope of the asserted claim based on both intrinsic evidence, such as specifications, drawings and prosecution history, and extrinsic evidence, such as dictionaries, expert opinions and prior art references.

In order to establish an infringement of a patent where the effective term was extended based on time spent obtaining marketing approval from an administrative agency, with respect to the patented pharmaceutical or agrichemical product of a patentee or its licensee, the patentee needs to argue and prove that, in addition to all elements of the asserted claim of the patent being satisfied by an accused product (i.e., a generic pharmaceutical or agrichemical product), such accused product must be almost identical to the original product of the patentee or its licensee, based on which the patent term extension was granted, in terms of components, quantity, usage, dosage, indication and efficacy.

Judges can find patent infringement not only through literal infringement, but also under the doctrine of equivalents. The Supreme Court has set forth the following conditions for finding an infringement under the doctrine of equivalents:

- a claim element, which an accused product or process does not have, is not an essential part of the claimed invention;
- the same effect is achieved if the lacking claim element is replaced with a corresponding part of the accused product or process;
c it was obvious to persons skilled in the art at the time of the acts of infringement to replace the lacking claim element with the corresponding part of the accused product or process;
d the accused product or process is not obvious from prior arts; and
e the accused product or process was not intentionally excluded from the scope of the claim in light of prosecution history (Supreme Court, 24 February 1998).

The patentee has the burden of proof regarding conditions (a) to (c), and the alleged infringer has the burden of proof regarding conditions (d) and (e).

Liability for indirect infringement is set forth in Article 101 of the Patent Act. Manufacturing, assignment or importation of an item, which is used exclusively for manufacturing patented products or using a patented process, is deemed to infringe the patent regardless of the awareness of an alleged infringer. Manufacturing, assignment or importation of an item, which is used not only for manufacturing patented products or using patented processes but also for other purposes, is deemed to infringe the patent only if all of the following conditions are met:

a the item is indispensable for exploitation of the patented invention;
b the item is not something that is generally available in Japan; and
c an alleged infringer knows both of the fact that the patent exists and the fact that the item is actually being used for manufacturing patented products or using the patented process.

ii Invalidity and other defences

Invalidity

Patent invalidity based on lack of novelty or inventive step, as well as a lack in the description requirement, such as a lack of clarity, enablement or support requirements constitutes a defence for an alleged infringer. The standard of proof for the defence based on such grounds for invalidity is the same as that for an invalidation trial before the JPO. A patentee may overcome the defence of invalidity based on the argument that the alleged grounds for invalidation is no longer applicable owing to correction to the asserted patent claims and specification.

Prosecution history estoppel

An alleged infringer often relies on this ground to argue non-infringement. Rather than applying estoppel based on prosecution history, judges tend to use prosecution history as one item of important evidence for claim construction.

Prior use

If an alleged infringer used the patented invention in its business or completed the preparation for such a business prior to the relevant priority date of the application for the patent, then the alleged infringer is vested with the statutory licence for the patent and not held liable for patent infringement (Article 79 of the Patent Act).
Licence
If an alleged infringer can establish that it was granted a licence to work the patented invention by a previous owner of the enforced patent, then the alleged infringer will not be held liable for patent infringement.

Exhaustion
Once a patentee or its licensee has sold a patented product, then the use and resale of such products do not constitute patent infringement. As for repaired or recycled patented products, such as refilled ink cartridges, the patent is enforceable only if such products are found to be new products produced by the repairing or recycling activity in light of the nature of the products, content of the patented invention, aspects of processing and replaced parts, etc. (Supreme Court, 18 November 2007).

Parallel import
The importation and distribution of products sold by a patentee or its licensee outside Japan does not generally constitute patent infringement. They do, however, constitute patent infringement if importation into Japan was prohibited as a condition of the first sale taking place outside Japan and further, if such prohibition was expressly described on such products (Supreme Court, 1 July 1997).

Experimental use
Experimental use of a patented invention is immune from liability for patent infringement (Article 69 of the Patent Act). The use of a patented invention for the purpose of clinical trials necessary for obtaining approval for generic drugs is found to fall within the scope of experimental use (Supreme Court, 16 April 1999).

Statute of limitation
Injunctive relief is not subject to a statute of limitations, or any other doctrine that prevents it from being awarded to a patentee, as long as the allegedly infringing acts or the threat of infringement exists at the time of the conclusion of the hearing proceeding. The right to seek compensation for damages for a tortious act is subject to a statute of limitations when three years have elapsed since the patentee first became aware of the infringement and the infringer. If more than three years have elapsed, proceedings may only be instituted to enforce the right to seek the return of unjust enrichment, the recoverable amount of which is limited to the reasonable royalty. The right to recover reasonable royalty, which an infringer failed to pay, as unjust enrichment is extinguished by a statute of limitations after 10 years have elapsed; however, unjust enrichment can be recovered for any unjust enrichment occurring within the 10 years preceding the date of filing a lawsuit, even if the infringement started more than 10 years prior to the filing date. In this regard, it should be noted that, under the recent revision to the Civil Code, which is supposed to become effective as of 1 April 2020, the term recoverable as unjust enrichment will be shortened to five years.
V FINAL REMEDIES FOR INFRINGEMENT

i Permanent injunction
If the court finds that the alleged infringer is actually infringing a valid patent or that there is a threat of infringement through the proceeding for litigation on the merits, the court orders an injunctive relief upon patentee’s request without examining other conditions such as public policy or the necessity for such an injunction. Nevertheless, in case of enforcement of a standard-essential patent that is subject to a fair, reasonable and non-discriminatory (FRAND) licence declaration, an injunctive relief against a willing licensee is not available as an abuse of right.

ii Damages
Compensation for damages is limited to the actual damages caused by the act of infringement taking place after the patent was granted. Punitive damages are not awarded. A patentee may rely on one of the following three methods for quantifying damages:

\[ a \quad \text{quantity of articles sold by the infringer} \times \text{marginal profit per unit of competitive products that would have been sold by the injured party;} \]
\[ b \quad \text{the marginal profits gained by the infringer through the act of infringement; and} \]
\[ c \quad \text{the amount equivalent to a reasonable royalty.} \]

Method (a) is applied if the patentee sells a product or process competing with the accused product or process in the relevant market. With respect to method (b), the court may deny its application if the patentee itself was not in a position competing with the infringer, such as a non-practising entity. Method (c) can be applied to determine the amount of compensation as damages resulting from infringement. In addition, in response to a request of the patentee, the court may appoint an expert to determine the damages and instruct said expert to inspect the financial documents of the accused infringer and submit an opinion about the amount of damages.

iii Compensation for the period before the patent is granted
If the applicant sent a letter, with a laid-open patent gazette attached, notifying an alleged infringer of the existence of the patent application and that a product or process of the alleged infringer falls within the scope of the claims prior to the registration of the patent, then the patentee may seek, after the patent is granted, reasonable royalty for the term from the notice to the registration retrospectively (Article 65 of the Patent Act).

VI OTHER TYPES OF PATENT PROCEEDING
Declaratory judgment action is available for an alleged infringer against a patentee before the courts. However, under the Code of Civil Procedure, the court cannot declare whether an allegedly infringing product or process falls within the scope of asserted claims or whether an asserted patent is valid or not; it can only declare whether a defendant, namely, a patentee, has rights to seek injunctive relief or monetary relief based on finding of such facts. One of the requirements for such an action is necessity for declaration, which is often proved by a cease-and-desist letter sent by a patentee.

Assignment of an issued patent or pending patent application can also be requested based on false inventorship before the courts. As for a pending patent application that was
not filed by a party having the right to file the patent application, a party that claims to have the right to file such an application can request declaration of the court. With the finalised declaratory judgment, the party may request that the JPO transfers the application. As for an issued patent, a party that claims to have the right to file such an application can request that the court orders assignment provided that such relief is available only for the patent, the relevant application for which was filed on or after 1 April 2012.

Border enforcement of a patent can be requested by a patentee by filing a complaint with a customs office. The customs office usually appoints three experts, consisting of practitioners and academic scholars, and relies on their opinions as to whether a patent is infringed. Detailed information is available on the customs office website at www.customs.go.jp/mizugiwa/chiteki/index_e.htm.

VII APPEAL

A losing party to a judgment by the Tokyo District Court or the Osaka District Court can appeal to the IP High Court by filing a notice of appeal within 14 days of their receipt of the judgment. The IP High Court can review not only the legal conclusion but also the fact determinations, and the parties are able to introduce new evidence during the appeal proceedings. The IP High Court conducts a review de novo, in other words, there is no legal presumption that the judgment of the first instance was correct. The period of time from the date of the appeal to the judgment of the IP High Court is approximately six to 12 months, during which a few hearings and preparatory proceedings are held. Allegations and proof must be detailed in the documents.

With respect to the judgment of the IP High Court, it is possible for a losing party to file a petition for the acceptance of a final appeal to the Supreme Court, based on the limited reasons that the judgment contains a legal conclusion that is inconsistent with precedents rendered by the Supreme Court or that it involves material matters concerning the construction of laws and regulations. The Supreme Court, in its broad discretion, may accept such a case as the final appellate court. Usually, the Supreme Court accepts no or only a few IP cases every year.

It is possible that a conclusion of the district court in respect to patent invalidity will be inconsistent with a decision of the JPO given in relation to the invalidation trial. However, both an appeal from a district court and a case for the revocation of a JPO decision will be heard and judged by the same panel of judges of the IP High Court, as long as both cases are pending simultaneously, and therefore as a practical consequence, it is to be expected that there will not be any inconsistency in decisions at an appellate court level.

VIII THE YEAR IN REVIEW

A bill to amend the Patent Act was passed by the Diet and promulgated in May 2019. The amendment introduces the system of inspection, which is supposed to help a patentee to collect evidences held by an alleged infringer. Under the amended Act, upon request of a party to a patent infringement litigation, a court may order an inspector, who is appointed by the court, to inspect the requested documents and apparatuses, etc., held by the other party for the purpose of fact finding, provided that: (1) collection of evidence through confirmation, operation, measurement, experiment, etc. in respect of such documents and apparatuses is necessary; (2) there is a reasonable ground to suspect that the inspected party infringed the
patent; (3) the inspecting party cannot collect the evidence by itself or through other means; and (4) there is no negative condition, such as that the time taken in investigating or the burden on the inspected party is too much. The inspector is entitled to do the following:

a. enter into a factory or office of the inspected party;
b. make inquiries to the inspected party;
c. request that the inspected party show the documents and apparatuses; and
d. conduct operations, measurements and experiments, etc., in respect of the documents or apparatuses, or both.

An enforcement officer of the court may assist the inspector in accordance with the court’s order. The inspected party is obliged to cooperate with the inspector and the enforcement officer. The inspector shall prepare and submit a report of inspection to the court. The report is served with the inspected party. Upon request of the inspected party made within two weeks, the court may decide not to disclose all or a part of the report to the inspecting party. Unless the court issues a decision not to disclose, the inspecting party may obtain a copy of the report. No third party is able to access the report. If the inspected party refuses to cooperate with the inspector or the enforcement officer without any justifiable reason, then the court may find the fact alleged by the inspecting party to be true.

IX OUTLOOK

On 5 June 2018, the JPO published the Guide to Licensing Negotiations involving Standard Essential Patents (https://www.jpo.go.jp/system/laws/rule/guideline/patent/document/seps-tebiki/guide-seps-en.pdf). The guide has no legally binding effect, but may be useful for practitioners’ reference purposes because it summarises updated court precedents and negotiation practices on FRAND royalty rates in not only Japan but also other major jurisdictions.
Chapter 15

MEXICO

Armando Arenas Reyes, Luz Elena Elías and Erwin Cruz

I OVERVIEW

Mexico is one of the leading countries in Latin America, and has an increasing amount of patent litigation. The Mexican market is important for many multinational organisations because it has an estimated gross domestic product of around US$2.224 trillion.

Patent litigation is handled at first stage by the Mexican Institute of Industrial Property (IMPI), which is also in charge of granting patents. The appeal stage before the Federal Court for Administrative Affairs is handled by a specialised bench on intellectual property (IP) matters. The judges only handle IP matters, but they do not need to have technical backgrounds. Circuit courts handle the final appeal stage.

Most patent litigation is related to pharmaceutical products and, recently, biotech products. The Mexican Industrial Property Law (IP Law) is pro-patents, as are the IMPI and courts. Generic efforts are usually against the patent system; fortunately, they have not had a strong influence.

Patent litigation is supposed to be an abbreviated process, but in practice it is a lengthy process as a result of Mexico’s civil law system. Strong expertise and key evidence is needed to reach a positive outcome. Damages can be pursued after reaching an infringement ruling beyond the appeal stage. Recently, few patent infringement cases have reached that point. Patent case law is still under construction in Mexico.

II TYPES OF PATENT

Products and processes can be the subject of patent protection under the IP Law and its regulations, provided that they meet patentability standards – mainly novelty, inventiveness and utility.

Utility models are also the subject of protection under the IP Law, provided that they meet novelty and utility standards.

The IMPI grants patent protection. Where pharmaceutical products, compounds are concerned, formulations, uses and manufacturing processes of medicines are the subject of patent protection.

Article 19 of the IP Law excludes medical procedures from being the subject matter of an invention. However, a patent can be obtained for a therapeutic method by drafting the claims in the EPC2000 or Swiss-style format.
i  Obtaining protection

Applications must be filed before the IMPI. The average time for obtaining a Mexican patent varies, depending on the field of technology. Generally, it takes from three to six years to obtain a patent.

The IMPI conducts a formal examination of the documentation and may order clarifications or further details, or that an omission be remedied. If so, an official communication requests the outstanding documents (that is, a power of attorney and an assignment of rights). This communication is usually issued four to six months after filing.

The abstract is published in the Official Gazette. This step normally occurs 18 months after the filing of the priority claim or, if no priority is claimed, 18 months from the filing date.

Examination on the merits of the invention begins automatically after the corresponding fees are paid, concurrent with filing the application.

An official action is issued between two and three years after the filing date either requesting amendments to the claims (for example, due to disapproval or clarification regarding novelty), or granting the protection sought and requesting payment of the final IMPI fees together with the payment of the first five annuities.

Maintenance fees are due every five years until the end of the patent term.

ii  Patent Prosecution Highway programmes

The IMPI has implemented Patent Prosecution Highway (PPH) pilot programmes to accept examinations by foreign patent offices, such as the United States Patent and Trademark Office, the European Patent Office, the Japanese Patent Office, the National Intellectual Property Administration of China, Pacific Alliance (Colombia, Chile and Peru), the Spain Patent Office, the Singapore Patent Office, the Canada Patent Office, the Portugal Office, the Austria Patent Office and the Korean Intellectual Property Office. In general, PPH is a mechanism that enables applicants to request accelerated substantive examination, based on the search and examination results from an office of first filing, who have already determined one or more claims to be allowable.

The request for examination under PPH should be filed after the publication of the patent application in the Industrial Property Gazette and prior to the issuance of the first official action.

III  PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

The only venue to enforce and to contest validity of a patent is through administrative proceedings (an infringement action or an invalidity action) before the IMPI. The IMPI is an administrative authority that has exclusive jurisdiction to hear all patent infringement and invalidity cases at first stage. There is no judge or jury participation in patent infringement actions.

i  Evidence

Proving patent infringement in Mexico is a difficult task, because the jurisdiction follows a strict civil law system that has formalistic rules for both evidence and proceedings.

The IP Law does not regulate the manner in which an invalidity or infringement is to be proven. The Federal Code of Civil Procedure is applied supplementary to the IP Law.
Expert testimony can be filed as documentary evidence or as a report given during the proceeding. The IMPI also requires a technical report from its Patents Department to determine the grounds of an invalidity or infringement action.

The IMPI rejects depositions and testimonial evidence unless they are included with an affidavit. Affidavits will not be considered a primary source of evidence. Mexican law does not allow live testimony or cross-examination of witnesses. However, in accordance with recent case law issued by the federal courts, IMPI has been ordered to admit this evidence for isolated cases. Actually, it is under discussion as a part of draft of the reform to the IP Law to permit this type of evidence.

ii Obtaining evidence from defendant and third parties

In Mexico, there is no pretrial stage or discovery. However, the plaintiff in an infringement action is entitled to request from the defendant all the documentation necessary to help to prove the infringement that should be in the defendant’s possession. The plaintiff must request from the IMPI the issuance of an order addressed to the defendant requesting this documentation and data, pointing out exactly what documents he or she is pursuing, and the importance and relevance of them to the prosecution of the infringement case. In case of lack of compliance with this order, a fine will be imposed on the defendant and the facts that plaintiff were seeking to prove with the documentation requested will be considered proved.

iii Structure of the main proceeding

Basically, the Mexican enforcement of a patent starts with an infringement claim filed before the IMPI. The claim is served on the alleged infringer, who then has 10 working days to respond and, if applicable, bring a counterclaim. That response is then served on the claimant to refute it. All the evidence is analysed, and finally a decision is issued.

At first sight, the proceeding seems abbreviated. In practice, depending on the evidence submitted by parties and the backlog at the IMPI, the proceeding becomes lengthy. A decision by the IMPI usually takes between 18 and 24 months. However, there are cases where the decision has taken up to five years.

iv Defences

An accused infringer may assert that the patent that is the subject matter of the infringement action is void, and hence subject to nullity.

This defence should be alleged when answering the plaintiff’s claim, but by means of a counterclaim. The IMPI will give notification of the counterclaim to the party that filed the original complaint. In practice, both the infringement claim and the counterclaim are decided simultaneously to preclude the possibility of contradictory resolutions. Conversely, the IP Law is silent in this regard and establishes that invalidity challenges provide a basis for staying proceedings for infringement.

For our comments on invalidity and other defences, please see Section IV.iii.

v Preliminary injunctions

The provisional injunctions established by the IP Law are essentially:

- ordering the recall or impeding circulation of the infringing merchandise;
- ordering the following materials to be withdrawn from circulation: 
  - illegally manufactured or used articles;
• articles, packaging, wrapping, stationery, advertising material and other similar items that infringe upon any of the rights protected by law;
• advertisements, signs, posters, stationery and other similar articles that infringe any of the rights protected by law; and
• utensils or instruments destined for or used in the manufacture, production or obtainment of any of the concepts indicated in the above bullet points;

c immediately prohibiting the marketing or use of the products with which any rights protected by the law are violated;
d ordering the attachment of the commodities of the products (pursuant to Articles 211–212 bis (2) of the IP Law);
e ordering the alleged transgressor or third parties to suspend or cease all acts that constitute a violation to the provisions of the law; and
f ordering a suspension of service or the closure of the establishment when the measures indicated above are insufficient to prevent or avoid the violation of rights protected by the law.

The same obligation is imposed on producers, manufacturers, importers and their distributors, who will be responsible for immediately recalling the products that are found in trade.

vi Requirements for getting preliminary injunctions
In order to grant preliminary injunctions, the IMPI requires the petitioner to comply with the following:

a provide evidence showing that he or she is the holder of the right, proving any one of the following hypotheses:
• the existence of a violation of his or her right;
• that the violation of his or her right is imminent;
• the existence of the possibility of suffering an irreparable damage; and
• the existence of a grounded fear that the evidence may be destroyed, concealed, lost or altered;

b post a bond in a sufficient amount to respond to harm and damages that may be caused to the person against whom the measure has been requested. (The main problem with this is that the law and regulations are silent about the rules and parameters for the IMPI to fix the amount of the bonds and eventual counterbonds to lift the preliminary injunctions.) (The full discretion of the IMPI in this regard has caused certain inequities that have provoked the continuation of the infringing activity rather than discouraging the infringer due to the contingency); and
c provide necessary information to identify the products, services or establishments with which or where the violation of industrial property rights is committed.

The IMPI will take into account the seriousness of the infringement and the nature of the requested measure to determine the amount of the bond and the counter-bond.
vii Structure of the preliminary injunctions proceeding
If a plaintiff chooses to ask the IMPI for a preliminary injunction, a bond will be fixed to warrant possible damages to the defendant. This injunction should be petitioned in writing, and within a term of 20 days from its execution the plaintiff is required to file a formal written claim of infringement. Failure to do so will cause the plaintiff to lose the bond in favour of the defendant.

Once the injunctions are imposed, the IMPI may request to broaden the amount of the bond, if necessary. The main problem with setting this amount is that the law and the regulations are silent about the rules and parameters for the IMPI to fix such amounts. The IMPI’s faculty of discretion in this regard has caused certain inequities that have also caused the continuance of the infringing activity rather than discouraging infringers.

Injunctions must be requested by means of a writ. The defendant has the right to place a counter-bond to stop the effects of the provisional injunction, which amount will have to be 40 per cent higher than the amount of the bond posted by the plaintiff. Defendants have the right to allege whatever they deem pertinent with respect to the provisional injunctions within a term of 10 days from the date of execution.

viii Costs
IMPI fees are very low, and there are no government fees for appeals before the courts.

ix Invalidity actions and post-grant amendments
The IP Law states that amendments or changes in the text or drawings of a letter patent may be allowed only to correct any obvious or formal errors, or to narrow the scope of the claims. The IP Law is silent about post-grant amendments for those patents under litigation, and there are few court precedents in this regard to rely on.

Olivares has pioneered a method of handling cases where a post-grant amendment petition is submitted as a strategy in response to an invalidity action. This strategy has achieved positive outcomes, but those cases wherein the strategy has been implemented are pending decisions on the merits of the cases and have not reached final decisions yet.

IV SUBSTANTIVE LAW
i Infringement
The IP Law grants patentees the right to the exclusive exploitation of the patented invention. Therefore, a patent grants the right to exclude others from making, using, offering for sale or importing the patented invention.

The IP Law sets forth, essentially, that the following acts are causes of patent infringement:

- manufacturing or producing products covered by a patent without the consent of the holder or without the respective licence;
- offering for sale or placing into circulation products covered by a patent, knowing that they were manufactured or produced without the consent of the patent holder or without the respective licence;
- using patented processes without the consent of the patent holder or without the respective licence; and
offering for sale or placing into circulation products that are the result of putting into practice patented processes, knowing that they were put into practice without the consent of the patent holder or the person who had a licence for their working.

The IP Law establishes direct infringement over the manufacturer. Infringement against sellers requires evidence of prior notice of the alleged infringement.

When a plaintiff claims infringement of a patented process, the defendant has the burden of proving the use of a different process other than the patented process.

The IP Law recognises literal infringement. The IP Law does not directly establish contributory infringement, but some cases for inducing infringement are under test.

### ii Standard

The IP Law is silent on the matter of a statute of limitations. Thus, the patentee may bring a patent infringement suit with the IMPI at any time while the patent is in force.

The plaintiff must prove that the wording of the patent’s claim or claims cover the alleged infringing product or process. First, the plaintiff must define the scope of the approved claims. The IP Law provides that the span of the claims is determined by its wording, aided by the description and drawings.

The interpretation of the claims and the use of the patented invention on the infringing product or process are technical issues. Therefore, infringement actions usually require expert evidence even though a technical report from the Patents Department may be rendered by a request from the Contentious Department, which handles IP litigation, both of the IMPI.

### iii Invalidity and other defences

#### Invalidity action

The IP law establishes several grounds upon which a patent can be invalidated:

- **a** when the patent was granted in contravention of the provisions on requirements and conditions for the grant of patents, Articles 16, 19, 27, 31 and 47 of the IP Law, which essentially include:
  - lack of novelty (anticipation, prior public use, prior sale and prior disclosure);
  - lack of inventive step;
  - lack of industrial applicability;
  - non-patentable subject matter;
  - lack of clarity (indefiniteness);
  - unsupported claims (added subject matter); and
  - non-enablement;

- **b** when the patent was granted in contravention of the provisions of the law in force at the time when granting. Actions based on this cause of invalidity cannot challenge the legal representation of the applicant when prosecuting and obtaining a patent;

- **c** when the patent application was abandoned while prosecuted; and

- **d** when the patent is granted by error or serious oversight, or when it is granted to someone not entitled to obtain it (ownership errors and inventorship errors).

The Contentious Department has issued some decisions allowing arguments against claims to priority inserted into grounds of invalidity of lack of novelty or inventiveness. However, such decisions are under appeal.
Other defences
A prior use defence would be also available as a cause for non-infringement. Additionally, the Mexican patent system operates on a first-to-file basis.

No laches defence is recognised by the IP Law.

The usual exceptions by importers are experimental use and Roche-Bolar exceptions; however, neither of them apply to commercial activities and such activities that will eventually end in the commercialisation of the generics would be considered commercial.

The experimental use defence
This is established in the IP Law, Article 22(I). Although the terms and conditions for this exception are not expressly detailed in the law, it is considered as the use of a patented invention for pure experimental and non-commercial purposes. The burden of the proof of the experimental use is on the defendant.

The Roche-Bolar exception
It is established in the Linkage Regulations, which in general terms state that during the three years before the expiration date of the patent related to chemical APIs, and the eight years before the expiration of the patent related to biologic APIs, anyone can use the patented product only for the purposes to obtain the corresponding marketing authorisation. The marketing authorisation, however, will be granted after the corresponding patent expires.

Currently, there is no jurisprudence or binding decisions regarding the parameters over these two exceptions, and they are still the subject of debate before the Courts.

Conversely, Olivares have handled the enforcement of patents against the importation of patented APIs that exceeded amounts for experimental use or Roche-Bolar exceptions with great success against infringing manufacturers and brokers. For example, we have obtained decisions stating that broker companies importing patented APIs were subject of infringement because their activities did not qualify for the Roche-Bolar exception.

Standard
Patent invalidity decisions are relatively difficult to obtain. The plaintiff must prove that the invalidity cause occurred. These actions usually require conclusive evidence even though a technical report from the Patent Department may be rendered by request of the Contentious Department, both of the IMPI.

V FINAL REMEDIES FOR INFRINGEMENT

i Sanctions
Several administrative sanctions can be imposed on a person found to have infringed a patent, ranging from a fine of up to 20,000 units (approximately US$105,000) to a definitive closure of the establishment (Article 214, IP Law). Repeated infringement activity is also considered a criminal offence (Article 223, IP Law).

ii Damages
The affected party may bring an additional claim for damages and lost profit in a civil law action. Damages and lost profits start accruing from the date on which the existence of an infringement can be proven.
Likewise, the IP provides a rule, applicable in all type of patent, trademark and copyright infringement actions, imposing on the civil courts the obligation to declare monetary damages of at least a 40 per cent of the commercial value of the infringing products. This minimum standard provision is known as the 40 per cent rule.

For cases related to trademarks and patents, the civil action can be claimed once the decision regarding the infringement is final; for copyright the civil action can be claimed at any time.

Recently, the Mexican Supreme Court issued a non-binding decision establishing that getting a final IP infringement decision does not meant the IP rightholder automatically suffered damages. Thus, IP rightholder should demonstrate actual damages. We observe this decision has some flaws in its reasoning and, fortunately, it is non-binding. There will be other cases to properly address why an IP right infringement directly causes collectable damages and why the 40 per cent rule should directly apply.

Attorney fees are very hard to obtain, and in any event, would be discretion to the judge. The civil laws do recognise attorney fees, but without expressly stating how judges can make them applicable.

A civil action claiming damages must be filed within two years of the infringing ruling being ineligible for appeal.

First ruling in Mexico awarding patent holder with damages higher than the 40 per cent rule

Olivares devised an action that allowed a patent holder of a blockbuster product to collect close to 63 per cent of sales of infringing products.

A generic company achieved two marketing authorisations to sell a pharmaceutical product with a patented compound while the patent was in force. Further to patent infringement actions, the patent holder pursued actions against the generic’s marketing authorisations. These actions ended before the District Courts, which granted the generic with injunctions to keep such marketing authorisations in force while the court actions were pending of a final decision as to the merits.

The patent holder was able to revert to the granted injunctions and to reach a final decision before the Circuit Courts invalidated the generic’s marketing authorisation. Conversely, during the few weeks that such injunctions were in force the generic gained several million peso’s worth of sales.

Through innovative actions before the District Courts, the patent holder claimed damages and lost profits from the generic’s sales under injunctions. Among other damages, the patent holder claimed its exclusive right to receive all sales of pharmaceutical products with the patented compound. It also claimed lost profits derived from the fact that the infringing products were sold under patentee’s product prices. The plaintiff had to submit proof of experts to demonstrate the amount of sales. The generic used this chance to argue costs such as manufacturing should be discounted. After years of litigation, the patent holder reached a final decision awarding it around 55 per cent of claimed sales (which is, of course, higher than the 40 per cent provided by the IP Law).

In view of the generic’s reluctance to pay, the patent holder had to additionally pursue a civil action to execute the awarding ruling. After further years of litigation, the patent holder was awarded not only around 55 per cent of generic’s sales, but also an additional 17 per cent of main claimed amount as interests and legal expenses. The patent holder had a high burden...
of effort and time, but prevailed and collected close to 63 per cent of generic’s sales at the end. No other case like this has been litigated in Mexico before, even after the Supreme Court’s non-binding ruling commented above.

We consider this case provides patent holders with a clear vision over those challenges involved in collecting damages from infringers, taking advantage of expertise that is beyond that of the case recently decided by the Supreme Court.

VI OTHER TYPES OF PATENT PROCEEDING

i Linkage regulations

Pursuant to Article 167 bis of the Health Law Regulations, on filing the application, the applicant has to prove that he or she is the owner or licensee of the patent of the active ingredient of the product (recorded before the IMPI), or state under oath that their application does not violate the list of products published in the Linkage Gazette, and observes patent law.

Before granting a marketing authorisation to third parties other than the patent holder, the Mexican Healthcare Products Regulatory Agency (COFEPRIS) must check the listed patents, first by compound and then by the list of patented products issued by the IMPI in the Linkage Gazette, which is organised according to the active ingredient’s generic name. Therefore, COFEPRIS and the IMPI have the burden of analysing whether an MA application invades a listed patent.

As mentioned, COFEPRIS may request additional information from the MA applicant. If COFEPRIS suspects that patent rights may be violated, it can request technical assistance from the IMPI regarding the scope of third patent rights.

If COFEPRIS requests technical assistance, the IMPI then has 10 days to produce an opinion on the scope of the patent and whether the product for which MA is sought falls within patent protection.

If the IMPI is of the opinion that the product in question falls within the scope of a published patent, in practice, COFEPRIS may give the applicant the opportunity to show that it has a right to make and sell that product.

If an applicant does not convince COFEPRIS, the application may either be suspended until the expiration date of the patent, or rejected. In the first scenario, the application may stay in abeyance until the patent term expires if this was filed three years prior to such term for chemical products, and eight years for biotechnological products, under the Roche-Bolar exception.

VII APPEAL

A decision by the IMPI can be appealed either before the IMPI through a review recourse within a term of 15 working days, or before a specialised IP section of the Federal Court for Administrative Affairs (FCAA) within a term of 30 working days.

Review recourses usually take around seven to 10 months for decision, which can be further appealed before the FCAA.

Appeals before the FCAA usually take around 12 to 15 months. A final stage of appeal before a Federal Circuit Court usually takes between six and 10 months.
In Mexico City, there are 20 federal circuit courts to deal with administrative matters; however, each case is chosen randomly by a computer system. By territorial jurisdiction, IP matters are mainly decided in Mexico City.

VIII THE YEAR IN REVIEW

i First final ruling about post-grant amendments related to a patent invalidity action

A Federal Circuit Court ordered approval of post-grant amendments of a patent under invalidity action for the first time ever in Mexico.

In 2015, a generic company filed an invalidity action against a formulation patent before the IMPI, arguing, among other issues, that the claimed scope was broad and without support on patent specification. In reply to the invalidity action, the patentee filed a post-grant amendments petition narrowing the scope of their claims, which is an innovative action in Mexico because the IP Law is silent about post-grant amendments for those patents under litigation and there were no court precedents in this regard to rely on. Moreover, the IMPI usually invalidates patent claims rather than narrowing their scope.

While the invalidity action was ongoing, the IMPI refused the post-grant amendments petition alleging they were against the essence of the invention. The patentee appealed this decision before a higher rank officer than the one that issued such refusal, but were again refused the amendments, stating this time that by eliminating claims the patentee was broadening the scope of the patent rather than narrowing it.

The patentee had to appeal such refusal before the Federal Court for Administrative Affairs. Importantly, in this stage, the patentee filed an injunction ordering the IMPI to avoid any act that may impact the letter’s patent while the appeal is decided in the merits. Moreover, the generic company attempted to allege the amendments refusal should be upheld, without success. The Court reversed the amendments’ refusal in part but not in full. Therefore, the patentee had to appeal such reversal before the Circuit Court to reach a full reversal.

After almost four years of litigation, the Circuit Court reversed the amendments rejection, ordering the IMPI to approve the amendments petition in full. The Circuit Court established that the patentee was allowed to amend its patent and that eliminating claims does not broaden the scope of the patent. They found such elimination reduced the subject matter protected by this patent.

This ruling is final and it is pending compliance. Although it is not binding for other cases, the ruling provides a way for patentees to redefine and narrow the scope of their patents under invalidity actions in Mexico. To prevent this, the IMPI tries to invalidate them under improper assessments, since they usually invalidate claims rather than narrowing their scope.

ii IP owners may be awarded with more than the minimum rule of 40 per cent of infringing products’ sales

A Circuit Court recently observed that industrial property owners can be awarded with actual damages plus 40 per cent of infringing products sales as punitive damages.

The Mexican IP Law, Article 221 bis, provides that damages awarded to the claimant shall be no less than 40 per cent of the sales of the infringing product at the price of sale to consumers (the 40 per cent rule).

The Mexican Supreme Court essentially ruled that to be entitled to damages, further to demonstrating an IP infringement beyond shadow of appeal, claimants must demonstrate suffered harm and a causal nexus between the IP infringement and such suffered harm.
Based on an analysis of punitive damages in the US legal system, the Circuit Court reasoned that the 40 per cent rule seems to apply the principle of punitive damages in the Mexican legal framework. Therefore, the Circuit Court commented that judges can impose both compensatory damages for loss suffered, provided that the requirements established by the Supreme Court are met, and the 40 per cent rule as punitive damages.

At first sight, this may seem like a more favourable interpretation of the IP Law for claimants. Conversely, the text of the ruling is ambiguous, and the proposed interpretation of the Law may mean that the court has unlimited discretion to determine the amount of compensatory damages, further to imposing the 40 per cent rule.

According to the Mexican legal system, this Circuit Court precedent is not binding and, thus, we consider that the application of the 40 per cent rule continues. This reassures any claimant that it is guaranteed to this minimum, as long as it meets the test above. Nonetheless, extensive expertise to claim damages in Mexico is always advisable, since navigating the rules and venues to claim damages derived from the violation of IP rights in Mexico has been a problem for many years.

In light of this decision and the recent approval of the USMCA that provides minimum standards to claim damages, we consider that the IP Law requires urgent amendments to provide better guidelines, including the definition, nature, origin and types of damages that can be claimed and recovered and the methods for doing so. This is to avoid loose interpretations by the courts, which would require lengthy and strenuous civil litigation to be contested.

IX OUTLOOK

i New Health Law Proposal Would Limit Mexican Patent Linkage System

Mexico’s Senate published in its official gazette a proposal to modify the Mexican Health Law to reduce the scope of the linkage system with respect to certain pharmaceutical patents.

In summary, the proposal includes the following changes to the linkage system:

a An applicant for an innovative drug must post a copy of the patent covering the active ingredient of the medicine to be approved with COFEPRIS and prove that the applicant is the owner or licensee of said patent.

b COFEPRIS will integrate and publish a list of approved innovative products, citing only one patent per product covering the active ingredient and its expiration date.

c Only one patent can be listed for each innovative chemical synthesis drug.

d If the patent is granted after the authorisation of the innovative drug, it should be included in the list issued by COFEPRIS no later than one month after issuance of the patent.

e The generic applicant must include a statement under oath that the sanitary registration of a generic medicine does not infringe the active ingredient patent rights along with a corresponding analysis of why it does not infringe.

f The generic applicant can request that generic registration is granted immediately after the expiration of the active ingredient patent term related with the innovative drug.

g The information provided by the applicant for a generic marketing authorisation to COFEPRIS should be sent to the IMPI for an analysis limited to the active ingredient patent related to the product; the IMPI should provide a response to COFEPRIS within a term of 10 working days. If the IMPI does not respond within that time period, the generic application is assumed to have a green light to proceed, and COFEPRIS can authorise the generic product.
b Patents for biologics will not be considered.
i Generally, the Health Law proposal contradicts what is established in Article 28 of the Constitution and other articles of the Industrial Property Law, which recognise exclusive rights for all inventions, without creating exceptions for certain categories.

The proposal disregards the jurisprudence of the Mexican Supreme Court, which, after many years of discrimination against formulation patents, ruled that formulation patents should be part of the patent linkage system.

The legislative proposal also contradicts definitions provided by the Health Law itself and international treaties, such as the text of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, which establishes a linkage system contemplating protection of patents for approved pharmaceutical products. It would also violate the US-Mexico-Canada Agreement (USMCA), which calls for a linkage system without discrimination, including for patents covering pharmaceutical products.

The IMPI does not welcome this proposal and it seems that it does not have much acceptance within legislators. Olivares is closely following it.

ii Proposal to Modify IP Law to Empower IMPI

Mexico's Senate recently published in its Official Gazette a proposal to modify several provisions of the Mexican Industrial Property Law (IP Law). In summary, the proposal includes the following additions to the IP Law:

a The IMPI, as the administrative authority in IP matters, would be empowered to carry out the following actions:

b The IMPI may seize goods to be imported, exported, or that are in transit, in accordance with the Customs Law.

c The Office may issue decisions, including compensation for damages, caused by the violation of IP rights.

Currently, a claim of damages derived from a finding of infringement of a patent or trademark can be initiated only in a civil court, and only once the decision issued in the administrative infringement action is final beyond the shadow of appeal.

There is no doubt that it is necessary to improve the enforcement system in Mexico by avoiding multiple independent and consecutive proceedings to obtain an award of damages.

However, the proposal may be questionable because under the Mexican Constitution, administrative authorities such as the IMPI arguably cannot determine awards nor enforce damages, as the IMPI is not considered a court of law.

If the purpose of this proposal is to provide the IMPI with the ability to award damages, other bodies of law should be modified as well.

It is our view that Mexico's IP enforcement system should be reviewed in its entirety, and the power to decide IP conflicts trusted to certain established courts of law. Under this system, a single proceeding could result in a ruling on infringement and any applicable damages award.
I OVERVIEW

Together with Germany, the United Kingdom and France, the Netherlands is one of the most popular European venues for patent litigation. Although the Netherlands is only a small European country of around 17 million people, the Dutch market is important for many multinationals, as an entrance gate to Europe from which their products are distributed to other European countries. Getting an injunction in the Netherlands could, therefore, effectively block the European distribution of an infringing product.

Another important reason why the Netherlands is considered a good venue for patent litigation is that there is a specialist patents court in The Hague, which has exclusive jurisdiction to pass judgment in patent infringement and invalidity cases. Dutch patent judges are experienced, and the majority of the judges also started their careers in private practice as intellectual property lawyers. Some even have a technical background or were experienced patent litigators or patent attorneys before they moved to the bench.

This year's patent litigation landscape is dominated by cross-border biotech and electronics/telecom cases. There have been significant patent litigation proceedings in these two technical fields, which have led to (appeal) judgments in the past year, and many biotech cases have been settled just before judgment. It is estimated that every year around 40-50 patent cases are pending before the courts of The Hague. In recent years the number of complicated cross-border patent cases has increased considerably. Since there is no bifurcation in the Netherlands, it is also safe to assume that in almost all of these cases the validity of the patent or patents in suit was also disputed, which makes the judgments in these cases of higher value for other jurisdictions as well.

Although the patents court has adopted an accelerated regime for patent cases that should lead to a judgment on infringement and validity in 12 months, the current heavy workload of the court has led to delays in passing judgments. In the last year the patents court has done everything in their power to find a solution to deal with this workload, for instance, by recruiting newly qualified judges with expertise in the field of intellectual property. This has already had a positive effect on the judgments in patent cases in accelerated regime.

Finally, a specific trend in the past years patent litigation is that there were several very important judgments in standard-essential patent cases in which a fair, reasonable and non-discriminatory (FRAND) defence was raised.2

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II TYPES OF PATENT

There are several ways to obtain patent protection in the Netherlands, of which filing a patent application with the Dutch Patent Office is the first. Second, the protection of patents in the Netherlands can ensue from a European application before the European Patent Office (EPO). In addition, the Netherlands is a member of the Patent Cooperation Treaty (PCT). Whether it be via a national application or an international treaty (European Patent Convention (EPC) or PCT), a patent that is issued for the region of the Netherlands will be governed by the Dutch Patents Act (DPA).

i National Dutch patent application

National Dutch patents are granted through a patent application procedure before the Dutch Patent Office. Several requirements must be met before patent protection is granted: the invention must be novel, must involve an inventive step and must be capable of industrial application. The term ‘unexamined’ is often used when referring to Dutch national patents. Even though patent application procedures always involve a search into the prior art (national or international, depending on the choice of the applicant), the actual grant of the Dutch national patent will not be affected by the results of such a search. Hence, the results of the search into documents that destroy novelty or are prejudicial to inventive step never prevent applications for Dutch national patents from being granted. The underlying idea is that this would allow smaller companies to obtain patent protection as it limits prosecution costs. Subsequent enforcement proceedings will then address the issue of the patent’s validity.

ii European patents

A European patent will be valid in the Netherlands once the corresponding patent application that designates the Netherlands is granted. The rules of the DPA will govern the Dutch part of that European patent. The DPA distinguishes, in some respects, between Dutch patents granted via a European application and those granted following a Dutch national application. The distinction in their respective treatments relates primarily to the unexamined nature of Dutch national patents. However, the remedies are the same for both types of patents.

Most of the patents valid in the Netherlands are issued following application procedures with either the EPC or the PCT.

iii Obtaining protection

The Dutch Patents Act provides that patent protection can be obtained for inventions that meet three conditions: they must be new, must involve an inventive step and must be capable of industrial application. In addition, the invention has to be sufficiently disclosed in the patent and needs to be described clearly therein. These requirements reflect those stated in the EPC. As is the case in the EPC, certain subjects are not considered to be inventions under the Dutch Patents Act. These subjects include scientific theories and mathematical methods, aesthetical shapes, computer programs and business methods. The DPA also describes inventions that cannot be patented, such as the human body in the various stages of development, and the discovery of parts of it that include sequences or partial sequences of the genome, plants and animal races, methods that are predominantly biological in nature and methods for the treatment of the human or animal body. To be more specific, the DPA provides that certain methods would be contrary to public policy and, therefore, cannot be patented. Such methods include human cloning, methods whereby the genetic identity of
humans can be changed, using human embryos, methods changing the genetic identity of animals that would cause suffering without any medical use, and methods that could damage the health of humans, animals or plants or lead to significant damage to the environment.

In the Netherlands, patent protection can be obtained by filing a patent application with the Dutch Patent Office. After 18 months have passed since the date on which the application was filed, the application will be recorded in the patent register at the earliest opportunity. The patent application is made public at that time. The patentee will then have to apply for a novelty search within a period of 13 months after the filing or the priority date. While the search may bring to light documents that could destroy the novelty of the invention or be prejudicial to its inventive step, the results of the search have no impact on the actual grant of the patent. The patent will be registered at least two months after the publication of the search and is thereby granted, affording it a protection period of 20 years. After learning the results of the novelty search, the patentee can amend the patent application if need be.

While Dutch national patents are not examined per se, the validity of the patent will become the issue at the heart of any enforcement action initiated by the patentee.

It bears noting that most of the patents enforced in the Netherlands are actually Dutch parts of European patents that have been issued by the EPO after a thorough examination of the European patent application.

The wording of the patent claims determines the scope of protection of a Dutch patent. Such patent claims must be interpreted in light of the descriptions and the drawings accompanying the patent. In Dutch case law, reference is often made to Article 69 EPC and the protocol belonging thereto. In some cases, the prosecution file may carry relevance for the scope of protection of patents in the Netherlands.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

In the Netherlands, patents can be enforced through the regular system of civil proceedings. The EU Enforcement Directive (No. 2004/48) has been implemented in the Dutch Code for Civil Procedure (DCCP), which includes such measures as ex parte injunctions, seizure of evidence and full cost orders for losing parties.

Typically, the Dutch enforcement of a patent starts with a letter to the alleged infringer, stating the details of the infringement, the patent that is invoked and the steps that the infringer is requested to take. If no settlement is reached, the patentee will typically start preliminary injunction proceedings or proceedings on the merits.

The majority of all Dutch patent cases are brought before the District Court in The Hague since this court has exclusive jurisdiction to hear all patent infringement and invalidity cases. However, some patent disputes start with pretrial measures, such as a seizure that does not fall within the exclusive jurisdiction of the court of The Hague, but in practice, other courts will request assistance of the The Hague judges to render a decision in these cases.

i  Requirements for jurisdiction and venue
If the defendant has its place of business in the Netherlands, or if the actual patent infringement takes place on Dutch territory, Dutch courts can assume international jurisdiction to take cognisance of disputes. Once international jurisdiction has been established, to the extent necessary, the jurisdiction of the relevant district court is determined in much the same way. The court of the district in which the defendant has its office, or in which the infringement actually takes place, will have local jurisdiction. These rules allow the possibility of multiple district courts having jurisdiction within the Netherlands. However, as already mentioned above, relating to patent infringement and the validity of patents, exclusive jurisdiction lies with the district court in The Hague.

ii  Obtaining relevant evidence of infringement and discovery
Dutch procedural law does not provide for a general concept of discovery or disclosure of documents. In principle, the parties are free to collect the evidence that they require in the proceedings and the Dutch courts are free to weigh that evidence as they deem appropriate.

The implementation of the Enforcement Directive has led to the implementation of certain possibilities to seize and safeguard information into the DCCP. These rules allow the patentee to request the district court in preliminary relief proceedings to grant permission to seize evidence that is in the possession or under the control of the infringer. The preliminary relief judge will assess such requests for permission, mostly on an _ex parte_ basis. The requests must explain and elaborate why a legitimate fear of infringement exists. After permission for a seizure has been granted, the patentee may direct a bailiff to inspect the premises of the infringer. Accordingly, the bailiff will do so with the help of the necessary experts, such as IT specialists or technical experts. Any information collected by the bailiff will not, however, be handed over to the patentee directly. The information will initially be held by a custodian who has been appointed for this purpose when the leave for seizure was granted. The patentee will then have to institute separate proceedings, requesting the court for disclosure of the relevant documents that were seized. The patentee will not be able to access the seized documents until the court grants the request for such disclosure.

iii  Trial decision-maker
The District Court employs specialised judges to adjudicate patent cases, all of whom are seasoned experts. Some of the specialised patent judges on this court’s payroll can boast technical acumen as well. Proceedings on the merits are typically heard by a three-judge division. Preliminary relief proceedings, in which patentees have an urgent interest in relief, are adjudicated by a single judge, who is referred to as the preliminary relief judge.

Although the procedural rules that apply in the Netherlands allow courts to appoint independent experts who specialise in a particular technical field or to request the parties to produce additional evidence to support the facts they are relying on, parties rarely ask for such an appointment. Instead, in patent cases, the parties to the proceedings are usually assisted by technical experts of their own choosing, who will file written expert statements on behalf of the party that engaged them. These experts often show up at the hearing as well.

The examination and cross-examination of party witnesses, be they experts or not, has no place in the proceedings, as litigation advances primarily through the exchange of written briefs (see subsection.iv).
iv  Structure of the trial

Dutch proceedings on the merits are conducted mainly by the exchange of written briefs in which the parties set out their arguments and defences. This exchange is often followed by a court hearing during which the parties will have the opportunity to present further arguments. Proceedings are initiated with a writ of summons, in which the claimant describes the patent that it invokes, the infringement against which the action is brought, and the relief that is requested. In setting out the particulars of the case, the claimant has to be as complete as possible. Also, the claimant is required to substantiate its claims in the writ of summons with evidence. Writs of summons in patent cases typically provide a technical background to the technical field at the heart of the dispute.

Being served a writ of summons, the defendant will be given the opportunity to file a statement of defence. This statement of defence enables the defendant to raise defences and file exhibits that support its position. With the statement of defence, the defendant can furthermore avail itself of the opportunity to bring a counterclaim against the claimant. It can do so, for example, to claim the invalidity of the patent in question. The course of events to follow hinges on the proceedings themselves. The court will either schedule a hearing after the statement of defence, and after the claimant has had the opportunity to respond to the counterclaim, or it will allow the parties to continue the exchange of written arguments, after which a court hearing usually follows.

During the hearing, the parties will be able to argue their case before the court. Court sessions in patent cases generally last around four or five hours. The court may take longer to hear the parties if the complexity of the patent matter at hand merits it. For reasons of judicial efficiency, however, Dutch courts do not allow full elaboration on every single part of the arguments exchanged between the parties, thereby preventing needless repetition of what has already been argued in the written statements.

Patent cases in which the validity of a patent is challenged offer the patentee the opportunity to file auxiliary requests. Pursuant to such requests, the court may decide to uphold the patent in its present form or in amended form.

In the Netherlands, evidence in proceedings is usually presented by the production of documents. Similarly, witness testimony is usually produced by filing written statements. District courts have to schedule separate sessions if they want to hear witnesses. While this is certainly an option, it rarely happens in patent cases.

v  Infringement

In their adjudication of patent cases, the Dutch courts will interpret the claims in conformity with Article 69 of the EPC and the protocol belonging thereto. Dutch case law provides a number of criteria applicable to that Article (see Section III). Besides literal infringement, the Dutch courts can also establish infringement by equivalence.

In consonance with Supreme Court case law, the patentee's actions during the patent's prosecution can be a relevant factor in the assessment of the scope of patent protection.

vi  Time to first-level decision

In general patent cases, proceedings on the merits usually take around 12–16 months from the moment that the writ initiating the proceedings is filed until the court renders a decision in the first instance. The District Court of The Hague has established an accelerated regime for patent cases, which is known as the ‘VRO-regime’. This regime can be used for (non)-infringement claims and revocation actions. On the basis of this regime, the dates on which
the substantive documents must be filed and on which the hearing will take place are set out in a fixed schedule before the proceedings are set to commence. Because the parties are bound to this schedule, a first instance decision can typically be handed down within 12 months from the date on which the writ of summons is filed. Decisions in preliminary relief proceedings can be rendered within a few weeks, and even sooner in cases of extreme urgency.

In cases involving a manifest infringement, causing irreparable harm to the rights holder, the Dutch system also allows for an *ex parte* injunction. Injunctions such as these can be issued without hearing the defendant, and can be obtained in days.

vii  **Protective letters**

In the Netherlands, it is not common practice to protect against *ex parte* preliminary relief by filing protective letters. The only court that facilitates the filing of protective letters is the court of The Hague. Although this court is the exclusive court for patent infringement and invalidity cases, seizure requests do not fall within this exclusive jurisdiction of this court and are, therefore, filed with other district courts that do not hold a register for such letters. If such a court involves a judge from the The Hague court – which is allowed, but certainly not mandatory under Dutch procedural law – this judge will most probably check the The Hague register of protective letters.

A protective letter does not protect against an *ex parte* request per se, but the judge will weigh these counter arguments in his or her decision-making process. The preliminary relief judge could also decide to hear the alleged infringing party before he or she decides upon the request, but only after he or she gave the opportunity to the patentee to withdraw the request. It is also possible that the judge will only grant the *ex parte* preliminary relief under certain additional conditions to safeguard the interests of the alleged infringer, for instance by obliging the patentee to file a bond, a deposit or some sort of other monetary guarantee.

viii  **Liability for enforcing a patent**

Under Dutch law, it is, in principle, possible to exercise patent rights against alleged infringers, even when these infringement claims are later dismissed by a court. A patentee cannot be found liable in such cases. The only exception is when the patentee should have reasonably known at the time he or she enforced the patent against alleged infringers, often by way of a warning letter or summons, that the patent was invalid or not infringed. For instance, if he or she already knew of certain prior art that would invalidate his or her patent, enforcing the patent anyway would be regarded as an unlawful against the alleged infringer.

Enforcing an injunction or other relief granted by the court against an infringer can also amount to liability of the patentee if a (higher) court later (in appeal) lifts the injunction or the relief and rules in favour of the alleged infringer.

Sending warning letters to, inter alia, customers or trading partners of an alleged infringer is often considered as an unlawful act against the alleged infringer, albeit based on general tort law, unfair competition or misleading advertising, if the infringement claims are later dismissed in court. In those cases, the court often orders a patentee to cease and desist from making the unfounded allegations and send a rectification letter to all parties that have received the warning letter.
ix Costs
In the majority of patent cases, the court fees in the Netherlands are very low compared to other countries, and are therefore not a cost factor to take into account before initiating a patent case in the Netherlands. The only significant costs are those of the lawyers, supporting patent attorney, experts and translations. The fees of the lawyers will be the highest cost factor to consider. Although it highly depends on, inter alia, the complexity of the case and the technology involved and the amount of patents invoked, the lawyers’ fees involved with patent cases will generally be €75,000 to €250,000. The costs of a patent attorney offering trial support is often a smaller percentage of the lawyer's fees – often around 20 to 25 per cent.

The cost regime in patent cases often accounts for a full compensation of all costs involved (such as lawyer’s fees, patent attorney’s fees, expert costs, translation costs, etc). This means that the losing party is ordered to pay the costs of the prevailing party. If the costs for which compensation has been requested are not reasonable and fair in light of the complexity of the case, it is possible to raise a substantiated objection against these costs. However, in many patent cases parties reach a cost agreement before the oral hearing, which the court will accordingly execute in its final judgment.

IV SUBSTANTIVE LAW
This section provides an analysis of the main substantive law aspects relating to patent infringement and validity in the Netherlands, referring wherever possible to recent noteworthy developments in the legislation, case law or court practice.

i Infringement
In the Netherlands, there are two types of infringement. Article 53 of the Dutch Patent Act deals with direct infringement (which can be literal infringement or infringement by way of equivalence). The patentee has the exclusive right to do the following:

a make, use, put on the market or resell, hire out or deliver the patented product, or otherwise utilise it as part of his or her business, or to offer, import or stock it for any of those purposes; or

b use the patented process in or for his or her business or to use, put on the market, or resell, hire out or deliver the product obtained directly as a result of the use of the patented process, or otherwise utilise it as part of his or her business, or to offer, import or stock it for any of those purposes.

Article 73 of the Dutch Patent Act also forbids indirect or contributory infringement. The patentee may institute the claims at his or her disposal in enforcing his or her patent against any person who, in the Netherlands or Netherlands Antilles offers or delivers, in or for his or her business, means relating to an essential element of the invention for the application of the patented invention in the Netherlands or Netherlands Antilles, to persons other than those who are entitled to apply the patented invention (for instance, by way of a licence), provided that that person knows, or that it is evident considering the circumstances, that those means are suitable and intended for that application. However, if the means delivered or offered are products that are generally available in commerce, there will not be contributory infringement.
It is possible under certain conditions to also hold liable other persons (e.g., directors of infringing companies, foreign suppliers, accessories, etc) involved with the infringement, but this is dealt with under the general law of tort. This is, however, not common practice in Dutch patent cases.

ii Invalidity and other defences

In patent infringement proceedings, the most important defences are those directed at the invalidity of the patent. The district court can deal with these defences in the same proceedings that involve the actual infringement. In preliminary relief proceedings, the preliminary relief court will make a provisional assessment of the validity of the patent in question. Although the right cannot be invalidated for the Netherlands in these proceedings, infringement claims will be denied if the court considers it likely that the patent will be found invalid in proceedings on the merits. Claims on the grounds of inequitable conduct or similar defences are not recognised within the Dutch system.

In patent cases, the validity of patents can be challenged on account of non-patentable subject matter (inter alia, lack of novelty or inventive step), insufficiency of disclosure (lack of enablement), and extension of subject matter beyond the content of the application as originally filed (added matter). This can be done in much the same way such challenges would be lodged with the European Patent Office.

The Dutch court also recognises a Gilette defence, which is a hybrid defence between an inventive step defence and an infringement defence. If an alleged infringer applies a product or a process that was already known in the prior art, or an obvious variant thereof, it cannot be an infringement or otherwise the patent would be invalid as not novel or not inventive.4

The court accepts the problem solution approach as a test to substantiate an inventive step defence. However, the court also recognises that the problem solution approach is only a test and that is not mandatory to apply it. In the end, the only real test is whether or not a defendant is able to substantiate the obviousness of an invention, and he or she can do so with all evidence available as long as he or she shows that the evidence is not tainted with hindsight.5

Other defences against infringement can be that there is a licence in place, exhaustion of patent rights, other competition law defences, such as a FRAND defence, or experimental use exceptions. Lack of knowledge is never a defence against infringement. It could, however, be a relevant defence against a damages claim.

V FINAL REMEDIES FOR INFRINGEMENT

Remedies that are most often sought in Dutch patent cases are:

a injunctions;

b accountability relating to the trade and infringing products (prices, quantity of products, customers, suppliers, etc.);


destruction of the products;
damages or the surrender of profits; and
compensation of legal fees.

The above-mentioned remedies are easily obtained by a patentee if infringement has been found by the court. In practice it does not require any further substantiation, although in theory a defendant could argue for all remedies, except for the injunction and the damages or surrendering of profits that are always ‘automatically’ granted in the Netherlands, that there is a lack of interest. The defendant will then have to substantiate these arguments to convince the court of this alleged lack of interest, because in practice a court will automatically grant these remedies if requested as it follows from the Dutch Patent Act and DCCP that a patentee is entitled to these remedies as well in case of infringement.

A rectification can also be requested as an additional remedy, but if disputed the patentee has to show its legal interest in why a rectification letter is required.

As already mentioned, in the Netherlands, the court will always grant an injunction if infringement has been found. The wording of the injunction consists of general terms – inter alia, ‘the defendant is ordered to cease and desist infringement of the patent in suit’, on pain of a penalty sum. The duration of the injunction is indefinite and will last until it has been lifted in appeal or in proceedings on the merits (in case of preliminary injunction). If the injunction is not lifted, it will last until the patent expires, unless the parties reach an agreement.

The territorial scope of an injunction is typically only for the Netherlands. However, the Dutch patent court has shown that it is not reluctant to grant cross-border injunctions in preliminary injunction proceedings. In theory, a cross-border injunction is also available in proceedings on the merits, but in practice this does not really work because the court will then have to stay the proceedings until a decision on the validity of the patent has been rendered in the other countries for which an injunction was sought. In practice, this would lead to an almost indefinite stay of the infringement case for those countries.

Relief by the court will typically be granted notwithstanding appeal, meaning that the decision will be enforceable immediately once it has been served on the defendant and before a decision on appeal is available. If the first-instance decision should be set aside on appeal, the party enforcing the first-instance decision will generally be liable to bear the damage it thereby causes.

VI OTHER TYPES OF PATENT PROCEEDING

Except for patent proceedings relating to infringement or invalidity, it is also possible to start proceedings in the Netherlands for, inter alia, declarations of non-infringement, a compulsory licence and challenges of ownership of a patent. A special trend in biotech cases seems to be asking for an Arrow declaration, which under certain conditions is possible in the Netherlands. An Arrow declaration is a declaratory judgment of the court that a certain product was already known in the prior art. This offers the opportunity to a party to already acquire more certainty about the infringing nature of its own product before entering the market, even though the patents of the patentee are not (all) granted in their final form yet.

Criminal court proceedings cannot be initiated by a civil party. Only the Public Prosecution Service can start criminal proceedings. If the OM decide not prosecute an infringer, the patentee, if he or she has filed a criminal complaint, could start an ‘Article 12
of the Dutch Code of Criminal Procedure’ procedure before the competent Court of Appeal. In practice, however, patent infringement in the Netherlands is rarely dealt with in criminal proceedings.

VII APPEAL

Dutch law provides that decisions in the first instance are open to appeal. The Court of Appeal in The Hague has exclusive jurisdiction to hear appeals of patent cases. Under the Dutch system, appeals are de novo. The Court of Appeal has complete jurisdiction to decide on both the main claim (e.g., infringement) and the counterclaim (invalidity or revocation), subject to the parts of the decision that the parties take issue with. In such appeal proceedings, parties are free to adopt new positions and adduce new evidence.

As is the case in first-instance proceedings, most proceedings are conducted through the exchange of written briefs between the parties, after which the case will be heard by the Court of Appeal. Defendants on appeal also have the opportunity to file a counter-appeal, in which they can advance their own grievances to the decision rendered in the first instance. Appeal cases are typically handled by a panel of three judges, taking anywhere between 16 and 20 months from the moment the appeal is filed until an appeal decision is reached.

It is difficult to predict the likelihood of overturning a decision. As appeals are de novo, one could argue that a party has the same chance of overturning the decision as he or she had winning the first-instance case. However, since the first-instance court is also a very experienced court, one could also assume that to win in appeal, a new line of reasoning, or at least a different emphasis on the arguments as brought forward in first instance, will be required to be successful in appeal. However, in almost all bigger patent litigation cases, the losing parties files an appeal against the decision in first instance, and these appeals are regularly successful.

The costs of an appeal are quite similar to the costs in first instance. In 2017, the appeal court fee for the majority of the patent cases was only €717. Depending on, inter alia, the complexity of the technology, the facts of the case, the amount of patents in suit and pretrial remedies sought, lawyers’ fees are around €75,000 to €250,000.

VIII THE YEAR IN REVIEW

A specific trend in the past years patent litigation is that there were several very important judgments in standard-essential patent (SEP) cases in which a FRAND defence was raised. The Court of Appeal of The Hague has shown itself to be very strict if an implementer of a SEP does not act swiftly enough in taking a FRAND licence. I expect that SEP-holders who believe their counterparties apply hold-out strategies will now certainly consider filing infringement suits at the Dutch patent court in trying to force these counterparties to come to the negotiation table by threat of an (in the Netherlands: still) automatic injunction.

I have also seen a lot of activity in the biotech and pharma field. For instance, many biosimilar cases have been initiated in the last few years, but the majority of these cases are settled just before judgment. The Dutch patent court – like the UK High Court – also

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expressed a willingness to hear Arrow declarations. The court ruled that it had a discretionary power to grant a declaration (an Arrow declaration) that a generic pharmaceutical was known or obvious at the priority date. The availability in principle of Arrow declarations is very useful for generic pharmaceutical companies confronted with delaying tactics of the innovator company effectively preventing the usual remedy of revocation proceedings in respect of granted patents.

IX OUTLOOK

I expect that more holders of SEPs will choose the Netherlands as a venue to sue non-willing licensees. The activity in pharma patent cases will probably stay the same as in the previous years.

7 The name originates from an English case: Arrow Generics Ltd v. Merek & Co Inc.
Chapter 17

NIGERIA

Fred Onuobia, Solomon Ezike and Ayodele Kadiri

I OVERVIEW

There has been very little litigation activity relating to patents in the past year. Currently, we are representing a leading telecommunications networks and service provider (Telco) in Nigeria at the Court of Appeal to defend an appeal arising from a patent infringement proceeding at the Federal High Court (the High Court). In 2017 the High Court dismissed a 100 billion naira patent infringement claim against Telco on the ground, among others, that the claimants in that action were neither the patentees nor licensees of the patent in issue. The claimants appealed this decision and there has been no decision as yet on the appeal. Issues submitted for determination in the appeal include a determination as to who a patentee is, and who can sue for an alleged patent infringement, whether multiple patents can be granted in respect of the same invention, and whether a non-natural and an unincorporated entity can apply for and be granted a patent.

II TYPES OF PATENT

Patents are regulated in Nigeria by the Patent and Design Act 1970 (PDA), Nigeria’s patent legislation. A patent granted under the PDA provides protection only in Nigeria. Under the PDA, a patent is granted in relation to an invention for a product or process that is:

a new or constitutes an improvement on a patented activity and results from inventive activity; and

b capable of industrial application.4

These requirements are conjunctive. An invention must satisfy the requirements of novelty and industrial applicability.

Under the PDA, the following are unpatentable:

a plants and animal varieties or biological processes for the production of plants and animals;

b inventions whose publication or exploitation would be contrary to public order or morality; and

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1 Fred Onuobia is a managing partner, Solomon Ezike is a senior associate and Ayodele Kadiri is an associate at G Elias & Co.
2 This is the federal commercial court that, among others, adjudicates intellectual property disputes.
3 Approximately USD$274,898,970.
4 PDA Section 1(1).
Although the PDA stipulates the conditions that must be satisfied before an invention can be the subject of a patent grant, the Nigerian Patent Registry (the Patent Registry) does not, in practice, insist on a strict satisfaction of the conditions. Inventions are merely examined by the Patent Registry for compliance with the following formal requirements:

- the application for the patent must be made in the prescribed form;
- there must be a description of the invention with any drawings and plans;
- the applicant must make a claim or claims in relation to the invention;
- there must be a declaration by the true inventor (where required);
- a power of attorney (where required); and
- the payment of the prescribed fee.

Where these requirements are met, the Patent Registry will grant a patent to the inventor without subjecting the invention to a substantive examination for compliance with the patentability requirements of Section 1 of the PDA. The absence of a substantive examination regime has encouraged the grant of patents for inventions that are normally not patentable, thereby resulting in a high volume of patent litigation.

A patent grant subsists for 20 years from the date of filing of the application. Thereafter, it goes into the public domain. However, a patent may lapse at any time before the expiration of 20 years where the patentee fails to renew it by paying the prescribed annual fees. In practice, the Patent Registry has not been known to allow a patent to lapse for non-payment of annual fees. Instead, the Patent Registry charges a penalty fee for late payment of the annual fees.

Nigeria is a party to the Patent Cooperation Treaty of 1970 (PCT). Thus, a resident or citizen of any other state party to the PCT may file an international application for the grant of a patent in Nigeria. However, such an application may be approved or rejected by the Patent Registry as it deems fit.

Residents and citizens of other state parties to the PCT may also make priority applications for patents that have been granted earlier by another state party to the PCT. A priority application, if approved by the Patent Registry, would give the applicant a right to the patent commencing on the date the earlier application was granted. International and priority applications, if approved by the Patent Registry afford the same protection as applications filed directly under the PDA.

### III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

The High Court is conferred with exclusive jurisdiction to hear and determine disputes arising under the PDA. The High Court is established by the Constitution with powers to hear and determine disputes on several matters, including disputes arising from any federal enactment relating to patents. The High Court is properly constituted when it is composed of a single
judge. There is no jury system in Nigeria. Although the High Court is not a specialised court, a fair amount of expertise can be expected from the High Court because it is the only court of first instance with jurisdiction to adjudicate patent disputes. In determining patent disputes, the High Court is empowered to sit with and be advised by experts having knowledge of the issues involved. The Rules9 (defined below) empower the High Court to appoint an expert with or without the application of the parties before it. The Rules provide for the procedure that will be adopted by the expert in producing his or her report in relation to such matter.

It is noteworthy that the Patent Registry does not have any dispute resolution mechanism for resolving oppositions to the grant of a patent. Opposition or protests to the grant of a patent are resolved by the High Court.

Border control agencies also play a role in enforcing patent rights. The Nigerian Customs Service (NCS) is empowered to search for, seize, detain and destroy counterfeit goods brought into Nigeria.10 A patent owner may take advantage of this provision by writing a petition to the Comptroller General of the NCS. In practice, patent owners collaborate with the NCS to enforce their rights against infringers. The role of the NCS in such collaborations includes following up on any information from the owner of a patent on the possible entry of counterfeit goods into Nigeria, seizing such counterfeit goods and alerting rights owners of any suspected counterfeit brands that might be of interest to such right owners, discovered in the course of a routine check on goods entering or leaving Nigeria.

The patentee has the legal right to bring a patent infringement suit. A registered licensee may also institute an action for patent infringement if:

a. the licensee notifies the patentee of the infringement;

b. the patentee unreasonably refuses or neglects to institute an action; and

c. the licensee files a copy of his or her notice to the patentee with the Registrar of Patents.

However, the patentee has a right to intervene in proceedings brought by a licensee.

Patent infringement and patent nullification proceedings are governed by the civil procedure rules of the High Court. The plaintiff commences a patent infringement proceeding by filing at the registry of the High Court a writ of summons,11 together with:

a. a statement of claim setting out the particulars of the infringement;

b. a list of witnesses the plaintiff intends to call at trial (including expert witnesses) and their written testimonies; and

c. copies of all the documents the plaintiff intends to rely on at the trial.

The defendant is required to respond within 30 days of receipt of the plaintiff’s papers by filing a statement of defence together with a list of its witnesses and their written testimonies, and the documents it intends to rely on at the trial. The defendant may also file a counterclaim. Upon receipt of the defendant’s filings, the plaintiff may file a reply within 14 days.

The plaintiff commences a patent nullification proceeding by a petition,12 which is accompanied by particulars of the objections to the validity of the patent. The particulars must (1) include every ground on which the validity is questioned and (2) define every issue

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9 Order 53 Rule 11; Order 41.
10 Customs and Excise Management Act Sections 24 and 46; Nigerian Customs Service Prohibition List: https://www.customs.gov.ng/ProhibitionList/import_2.php.
12 The Rules, Order 53 Rule 8.
the petition will raise. After these filings, the plaintiff or petitioner is required to take out a summons for directions as to the place and mode of trial. The summons is returnable in no less than 21 days. Where the plaintiff or petitioner fails to do so, the defendant or respondent is required to take out the summons. An action will only be set down for hearing where a summons is taken out and directions given thereunder by the High Court have been carried out or the period fixed for carrying out such directions has expired. A patent cannot be amended in the course of infringement proceedings.

The trial comprises of the examination, cross-examination and re-examination (if need be) of witnesses by the plaintiff and the defendant. The plaintiff’s witnesses start, followed by the defendant’s witnesses. Documentary, oral or electronic evidence may be produced during trial. Evidence can only be given on facts that are set out in the pleadings. At the conclusion of trial, the parties are required to file final written addresses in support of the claim or defence (as the case may be). Judgment is delivered within 90 days of the adoption of final written addresses.

As in other civil cases, the legal burden of proof is always on the plaintiff. During trial, however, the evidential burden of proof may shift between the parties. A defendant may also be required to prove its defence. Thus, absent any presumptions of law, the plaintiff in a patent infringement proceedings will need to establish that:

- it is the grantee of the patent; and
- the defendant has infringed the grantee’s rights without consent or licence.

The plaintiff is required to positively prove its claims, and not simply rely on the weaknesses of the defendant’s case. If, for instance, the defendant’s defence is that the patent is invalid, the defendant must prove that:

- the subject of the patent is not patentable;
- the patent fails to conform to the requirement for clarity and completeness; or
- there was an existing prior application or grant of a patent in respect of that same invention.

A party may be compelled to disclose relevant documents or materials to an adversary through procedures called ‘interrogatories’ (to provide information) and ‘discoveries’ (to provide documents). Interrogatories are to be delivered within seven days of close of pleadings. Where an interrogated party fails to answer or answers insufficiently, the judge can, on application, order the defaulting party to answer or to answer sufficiently (as the case may be). Discoveries are made in writing, and require another party to make discovery on oath of the documents that are or have been in its possession, custody, power or control, relating to any issue in question in the action.

The High Court may, upon the application of a party, issue a subpoena duces tecum or subpoena ad testificandum, compelling a third party to produce certain documents in its possession or give oral testimony or do both. Also useful in obtaining evidence against a defendant is the Anton Piller order that, when granted by the High Court, entitles the plaintiff to enter the premises of the defendant and recover the infringing items. An application for an Anton Piller order can be made ex parte and is granted sparingly. The plaintiff must show that:

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13 See generally Order 53 Rule 10(6) of the Federal High Court (Civil Procedure) Rules, 2019 (the Rules).
15 Order 43 of the Rules.
A defendant to a claim for patent infringement may challenge the validity of a patent as a defence to the suit. The defendant may also file a counterclaim in the same suit, requesting the High Court to nullify such a patent. It is also a defence to a patent infringement suit that the acts said to constitute the infringement took place before the patent was granted or that the defendant was granted a licence (by the patentee, the High Court or the Minister of Trade, Industry and Investments) to exploit the patent, or that the patent has expired or lapsed. When raising the invalidity of a patent as a defence, the defendant must ensure that the patentee (not a mere licensee) is a party to the action. Thus, where the defendant is sued by a licensee and the defendant intends to validly challenge the validity of the patent, the defendant must apply to the High Court for leave to have the patentee joined as a party to the suit.

A defendant to a patent infringement action can rely on the existence of a concurrent action challenging the validity of the patent to apply for and obtain an order for stay of proceedings in a patent infringement action. Under Nigerian law, an order for stay of proceedings in respect of concurrent or cross-action will be granted where:

a. the parties in the concurrent proceedings are the same;
b. the subject matter in the action sought to be stayed is substantially similar to that of the action already pending between the parties; and
c. there is no other consideration against granting the relief for stay of proceedings; for example, unreasonable delay, acquiescence or abuse of court process.

Further, a party prosecuting an interlocutory appeal may apply for and obtain a stay of proceedings in the substantive suit pending the determination of the interlocutory appeal. Where a defendant satisfies the foregoing requirements, the High Court may grant an order for stay of proceedings pending when the question regarding the validity of the plaintiffs’ patent is determined. The High Court may also consolidate both actions, hear and determine them together.

Proceedings for patent infringements could take 12 to 18 months at the trial court, and a final appeal to the Supreme Court of Nigeria could take four to six years. The usual costs are:

a. court filing fees, which are assessed on the amount of claim;
b. fees of expert witnesses; and
c. attorneys’ fees.

Costs are usually awarded in favour of a successful party. The quantum of costs recoverable is usually at the discretion of the High Court. However, a specific amount may be recovered where specifically proven (e.g., filing fees).

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17 Ojora v. AGIP (2014) 1 NWLR (Part 1387) 150.
18 That is, an appeal against a decision not determinative of the final rights and obligations of the parties.
A plaintiff in a patent infringement action may apply to the High Court for an order of interim or interlocutory injunction, requiring the defendant to desist from further infringement of the patent. An application for interim injunction can be made *ex parte*. Interim injunctions are only granted in situations of extreme urgency. As such, the High Court will grant an order of interim injunction only where the plaintiff shows that it will suffer irreparable damage if the order is refused. An interim order subsists for a short period, usually pending the hearing of an application for interlocutory injunction (with the defendant being put on notice).

An order of interlocutory injunction, on the other hand, subsists until the final determination of the action, unless vacated earlier by the High Court. A plaintiff requesting an order of interlocutory injunction from the High Court must establish that:

- it has a legal right that has been infringed and requires protection;
- there is a serious question to be tried in the action;
- damages will not be an adequate remedy for the injury it has suffered by reason of the infringement of the patent;
- the balance of convenience is on its side, and that more justice will result in the grant of the application than in refusing it; and
- it has not acted reprehensibly.

When applying for an interim or interlocutory order of injunction, the plaintiff must make an undertaking (and file a letter of undertaking) to the High Court to pay damages to the defendant if it is discovered that the order ought not to have been made.

Patentees cannot face liability for threatening patent infringement proceedings. However, where a patentee institutes patent infringement proceedings, and it is found in the course of the proceedings that the plaintiff’s claims lack merit, the action will be dismissed and costs may be awarded against the plaintiff.

**IV SUBSTANTIVE LAW**

**i Infringement**

A patent confers on the patentee the right to preclude any other person the following:

- where the patent has been granted in respect of a product, from making, importing, selling or using the product, or stocking it for sale and use; and
- where the patent has been granted in respect of a process, from applying the process or doing, in respect of a product obtained directly by the process, any of the acts in (a).

Thus, an infringement is committed where a person other than the patentee, in the case of a patented product, makes, imports, sells, uses such product, and in the case of a patented process, applies the process or imports, sells, makes or uses the product of the process, without the licence of the patentee. An actual infringement of the patent must occur before the cause of action can accrue. However, where there is a threat of infringement, a patentee

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20 *Pharma Deko Plc v. FDC Ltd* (supra).
21 PDA Section 6.
22 PDA Section 25(1).
may apply to the High Court for a quia timet injunction, which prevents a threatened infringement of the patentee’s right. There is no time limit for commencing an action for patent infringement.23

Nigerian patent law does not have extraterritorial effect. As such, patent infringements that take place outside Nigeria cannot be enforced by Nigerian courts. For an infringement to be actionable, the alleged infringement of the patent must have been committed in Nigeria.

The directors of a company cannot be held personally liable for the wrongful acts of the company. A company acts through its directors and its shareholders, and the acts of the members in general meeting or its directors in the ordinary course of business are taken to be the acts of the company itself.24 Thus, directors will not be liable for patent infringements committed by a company. However, a company will be vicariously liable for infringements committed by its employees acting within the scope of their employment.25

The doctrines of equivalents and file wrapper estoppel do not apply in Nigeria. Similarly, Nigerian patent law is silent on exhaustion of rights. However, in practice, a defendant can assert that the patentee cannot claim the exclusivity conferred by the patent in order to oppose further commercialisation of genuine products protected by such rights once those products have been brought to the market by the patentee or with its consent. In determining an allegation of infringement, the High Court is required to interpret the patent in question and determine the scope of protection conferred in terms of its claims and specifications. In doing so, the description (and the plans and drawings, if any) included in the patent are used to interpret the claims.26

ii Invalidity and other defences

A patent may be challenged on the ground that the subject of the patent is unpatentable; for example:

- the patent is not new, does not result from inventive activity and is not capable of industrial application;
- the patent is in respect of a plant or animal variety or biological process; or
- the application or exploitation of the patent is contrary to public order or morality.

A patent can also be challenged on the basis that the description of the invention is not sufficiently clear and complete for the invention to be put into effect by a person skilled in the art or field of knowledge to which the invention relates, or that a patent has been granted in Nigeria for the same invention that is the subject of a prior application or an application benefitting from an earlier foreign priority.

A defendant to a claim for patent infringement may challenge the validity of a patent as a defence to the suit.27 The defendant may also file a counterclaim in the same suit, requesting the High Court to nullify such a patent. It is also a defence to a patent infringement suit that the acts said to constitute the infringement took place before the patent was granted,28 or that the defendant was granted a licence by the patentee to exploit the patent (by the patentee,

24 Companies and Allied Matters Act 1990 (CAMA) Section 65.
25 CAMA Section 66(3).
26 PDA Section 6(2).
28 PDA Sections 6(3)(b) and 6(4); Uwemedimo v. MP (Nig) Unltd (2011) 4 NWLR (Part 1236) 80.
the High Court, or the Minister of Trade, Industry and Investments), or that the patent has expired or lapsed. When raising the invalidity of a patent as a defence, the defendant must ensure that the patentee (not a mere licensee) is a party to the action. Thus, where the defendant is sued by a licensee and the defendant intends to validly challenge the validity of the patent, the defendant must apply to the High Court for leave to have the patentee joined as a party to the suit. Lack of knowledge is not a defence to a patent infringement claim.

V FINAL REMEDIES FOR INFRINGEMENT

Where a plaintiff succeeds in a patent infringement action, the High Court may award monetary damages against the defendant, or make an order of mandatory injunction requiring the defendant to desist from further infringement of the patent. The High Court may also order the defendant to account for profits made from the infringement of the patented invention, or to deliver up the infringing items for destruction.29 Damages can be nominal, general, punitive or special. The plaintiff is required to prove its entitlement to damages claimed and can do so by an estimation of the loss it incurred as a direct result of the infringement.

Mandatory injunctions are granted where a plaintiff succeeds in establishing an actual or threatened infringement of its patented invention. The injunction will usually restrain the doing of all the activities that constituted the infringement or threatened infringement, and will last as long as the patent subsists or until the injunction is set aside by an appellate court. A mandatory injunction may also be stayed pending the determination of an appeal against the decision.

VI OTHER TYPES OF PATENT PROCEEDING

i Declaration of invalidity

In addition to an action for infringement of patent, the High Court has exclusive jurisdiction to adjudicate an application challenging the validity of a patent. The High Court is properly constituted when it is composed of a single judge. The High Court may also sit with and be advised by experts where the High Court considers it necessary.

An action to challenge the validity of a patent can be brought by any person, including a public officer in the execution of his or her public duty. However, any person, other than a public officer, who files an application challenging the validity of a patent must satisfy the High Court that he or she has a material interest in bringing the application. Failure to satisfy the High Court that he or she has a material interest in the subject matter of the application will result in a dismissal of the application. The patentee must be made a party to the action. The High Court cannot determine the validity of the patent where the patentee is not a party to the action.30

An action to challenge the validity of a patent is commenced by filing a petition. The petition must set out the particulars of the petitioner’s objections to the validity of the patent and specify in clear terms every ground on which the validity of the patent is being challenged. If the grounds include want of novelty or inventive step, the particulars must

29 PDA Section 25(2).
30 PDA Section 9(5)(a); Arewa Textiles Plc v Finetex Ltd (see footnote 27).
state the manner, time and place of every prior publication or user relied upon among others. Except with leave of the High Court, no evidence is admissible in proof of any objection to the validity of a patent, if the objection was not raised in the particulars of objection. A respondent to such an action is required to file an answer to the petition within 21 days of receipt of the petition.

The petitioner is required, within one month of receipt of the respondent’s answer or after the expiration of the time fixed for service of the answer, to apply to the High Court by a summons for directions as to the place and mode of trial. The respondent is empowered to take the foregoing steps if the petitioner fails to do so. The petition will not be set down for trial unless and until the summons for directions has been taken out and the directions given and complied with. Where the High Court directs that evidence is to be given by affidavit, the deponents or witnesses (expert witnesses inclusive) will be cross-examined, unless with the permission of the High Court the parties agree otherwise. In addition to oral evidence, the petitioner and the respondent may also provide documentary and electronic evidence during the trial.

As in a patent infringement action, a party may be compelled to disclose relevant documents or materials to an adversary through procedures called ‘interrogatories’ (to provide information) and ‘discoveries’ (to provide documents). Interrogatories shall be delivered within seven days of close of pleadings. Where an interrogated party fails to answer or answers insufficiently, the judge shall, on application, order him or her to answer or to answer sufficiently. Discoveries are also made in writing requiring another party to make discovery on oath of the documents that are or have been in his or her possession, custody, power or control, relating to any issue in question in the suit.

Upon the application of any party, the High Court may issue a subpoena duces tecum or subpoena ad testificandum compelling a third party to produce certain documents in its possession or give oral testimony or both. The plaintiff may apply to the High Court for an Anton Piller order to enable it to enter the premises of the defendant and recover the infringing items.

As in all civil cases, the onus lies on the challenger to prove that the patent is invalid. The standard of proof is on the balance of probabilities. The application may take between 12 and 18 months before it is heard and determined. Where the application fails, the patentee may recover the costs of the action from the challenger. Costs are usually awarded at the discretion of the High Court, taking into account the fact and circumstances of each case.

ii Proceedings for compulsory licence

Court-sanctioned

The High Court also has the power to hear applications for and to grant compulsory licences in respect of patents.31 An application for compulsory licence may be brought on several grounds. These grounds include that:

a the patented invention, being capable of being worked in Nigeria, has not been so worked;

b the existing degree of working the patented invention in Nigeria does not meet, on reasonable terms, the demand for the product;

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31 PDA Section 11.
the working of the patented invention in Nigeria is being hindered by the importation of the patented article; or
by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced.

An application for a compulsory licence on any of these grounds can be brought by any person at any time after the expiration of a period of four years after the filing of a patent application or three years after the grant of the patent – whichever is later.

In addition to the above, a person who intends to exploit an invention protected by a patent, but cannot do so without infringing the patent, may obtain a compulsory licence in respect of the patent to the extent necessary for the working of the later invention, provided that a later invention:

serves industrial purposes different from those served by the invention that is the subject of the earlier patent; and

constitutes substantial technical progress in relation to earlier invention.

Where both inventions serve the same industrial purpose, the High Court may grant compulsory licences in respect of both patents to the patentees.

A compulsory licence will not be granted unless the applicant satisfies the High Court that he or she has asked the patentee for a contractual licence but has been unable to obtain a licence on reasonable terms and within a reasonable time, and guarantees to the High Court to work the invention sufficiently to remedy the deficiencies that gave rise to its application. Where the High Court grants the compulsory licence, it may also make an order as to the terms of the licence, including royalties. A compulsory licence entitles the licensee to make, sell, import the product or apply the process covered by the licence, but does not entitle the licensee to issue licences. A compulsory licence is non-exclusive.

After the grant of a compulsory licence, a patentee or licensee may apply to the High Court to vary the licence where reasonable grounds exist for doing so (e.g., the patentee has granted contractual licences on more favourable terms). The patentee may also bring an application to cancel a compulsory licence if the licensee does not comply with the terms of the licence, or the conditions that justified the grant of the licence have ceased to exist.

**Government agencies**

The Minister of Industry, Trade and Investment may, if satisfied that it is in the public interest to do so, authorise any person to purchase, make, exercise or vend any patented article or invention for the service of a government agency in Nigeria. Such authority may be granted to any person, whether or not he or she is authorised by the patentee to exploit the relevant patent. The Minister may grant such authority before or after the relevant patent has been granted, or before or after the doing of the acts in respect of which the authority was given. The grantee of such an authority is exempted from liability for infringement of the patentee’s rights.

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32 PDA Section 11.
VII APPEAL

Appeals against the decisions of the High Court are heard in the first instance by the Court of Appeal and finally by the Supreme Court. Thus, parties to a patent infringement and patent invalidity actions may file an appeal as of right to the Court of Appeal, against the final decision of the High Court. Interlocutory decisions of the High Court are also appealable to the Court of Appeal either with leave or as of right. Appeal lies with the leave of the High Court or the Court of Appeal on interlocutory decisions of the High Court where the grounds of appeal involve only questions of facts or a mixture of facts and law.

The Court of Appeal generally re-examines or reviews the decisions of the High Court with a view to deciding whether, on proper consideration of the facts and the applicable law, the High Court arrived at a correct decision or conclusion. Appeals are determined on briefs of argument filed by both parties. Only in exceptional circumstances does the Court of Appeal consider new evidence. A party that seeks to introduce new evidence on appeal must satisfy the appellate court that the evidence:

- could not have been obtained for use at the trial with reasonable diligence;
- if admitted, the evidence would have an important, not necessarily crucial effect on the whole case; and
- must be credible in the sense that it is capable of being believed and it need not be incontrovertible.

An appeal can take between 12 and 36 months at the Court of Appeal, and up to five years at the Supreme Court. The typical appeal costs are court filing fees and attorneys’ fees. Costs are usually awarded in favour of a successful party. This is, however, at the discretion of the appellate court.

VIII THE YEAR IN REVIEW

There has been very little patent litigation activity in the past year. Proceedings in which we are currently involved at the Court of Appeal seek to resolve, among others, questions as to who a patentee is, who can apply for and be granted a patent and whether you can have multiple patentees in respect of the same invention.

IX OUTLOOK

There is currently a draft bill to establish the Industrial Property Commission (the IPCOM Bill). The objective of the IPCOM Bill is to harmonise all intellectual property legislation and intellectual property administering agencies, such that IPCOM will be the sole agency responsible for the administration of intellectual property in Nigeria.

In addition, the IPCOM Bill seeks to provide for the protection of trademarks, patents, designs, plant varieties, animal breeders and farmers’ rights. Consultations on the IPCOM Bill are continuing.

33 The Constitution Sections 241(1)(a) and 243(a).
34 The Constitution Sections 241, 242(1) and 243(a).
35 The current situation admits both the Nigerian Copyright Commission (the agency responsible for the administration of copyrights) and the Patents and Trademarks Registry (for patents and trademarks).
I OVERVIEW

The Portuguese patent litigation system has some particularities that make it a rather unique system.

In Portugal, patent litigation generally takes place before the Intellectual Property Court (the Court). This specialised state court, with jurisdiction at a national level, has been operating in Portugal since 30 March 2012 and is competent to handle all actions concerning industrial property in all forms as provided in law, including both patent enforcement and invalidation proceedings.

However, in the field of pharmaceutical patents, special attention must be given to the patent enforcement system put in place by Law No. 62/2011 of 12 December 2011 (Law 62/2011).

Law 62/2011, which came into force on 19 December 2011, originally established a mandatory arbitration regime for the settlement of disputes arising from industrial property rights whenever reference medicinal products (that correspond to patent rights) and generic medicinal products were at stake.

However, after seven years in force, significant changes to Law 62/2011 were approved by Decree-Law No. 110/2018 of 10 December 2018 (Decree-Law 110/2018). Those changes came into force on 9 January 2019.

A special pharmaceutical patent enforcement system was maintained but the nature of the arbitration changed from mandatory to voluntary. In case the parties do not agree to submit the dispute to arbitration (which is likely to be the most common scenario), it is now established that the enforcement action shall be brought before the Court. This unique pharmaceutical patent enforcement system has been playing – and still plays – a decisive role in the patent litigation landscape in Portugal, as it has provided – and is expected to continue to provide – a stage for the most relevant patent case law in Portugal.

Criminal proceedings and voluntary alternative dispute resolution means are also available to interested parties to deal with patent disputes but are rarely used in Portugal.

Finally, the above-mentioned Decree-Law 110/2018 also put into force the new Industrial Property Code (IPC), which is the most significant piece of national legislation regarding the protection of industrial property.
II TYPES OF PATENT

Inventions can be protected by two types of industrial property rights: patent and utility models. Patents can be granted to any type of invention in any field of technology, whether it is a product or a process, as well as for new processes for obtaining products, substances or compounds that already exist.

Apart from applying for a national patent through a national route in accordance with the Portuguese IPC, it is also possible to apply for protection at both European and international levels under the European Patent Convention and under the Patent Cooperation Treaty, respectively.

The duration of a patent is 20 years from the date of application, and the invention must have novelty, inventiveness and industrial applicability. At the European level, an extension may be granted to specific pharmaceutical and plant protection products that have been authorised by regulatory authorities by means of a supplementary protection certificate (SPC). An SPC can extend a patent right for a maximum of five years. Furthermore, a six-month additional extension is also available in Portugal if the SPC relates to a medicinal product for children for which data has been submitted according to a paediatric investigation plan.

Applications for patents must always be examined, such examination being a crucial part of the patent grant. New inventions involving an inventive step can also be protected as utility models, if they have an industrial application.

Apart from applying for a utility model through a national route in accordance with the IPC, it is also possible to apply for protection at international level under the Patent Cooperation Treaty. The duration of a utility model is six years from the date of application and can be renewed for up to 10 years.

Although the requirements for protection are similar for both types of protection of inventions, utility models are not available for inventions dealing with biological material or chemical and pharmaceutical substances or processes. The main difference between a patent and a utility model is that in the latter a mere technical advantage will suffice for the respective protection, provided that it has novelty, inventiveness and industrial applicability.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

As a rule, patent rights shall be enforced and invalidated before the Court. Furthermore, according to Article 34 of the IPC, the declaration of nullity or annulment may only result from a judicial decision – that is, one rendered by the Court.

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3 See also Regulation (EC) No. 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.


5 Following the entry into force of the new IPC, the Portuguese Patent Office is now entitled to declare ex officio the nullity of an SPC if the basic patent lapsed before its expiry date or if it was annulled (see Article 118(11) of the IPC).
A special legal system of enforcement of industrial property rights was created by Law 62/2011 applicable to all disputes, including preliminary injunctions, related to reference medicines and generic medicines, regardless of whether they involved process, product or utilisation patents, or SPCs.

Until January 2019, mandatory arbitration proceedings should be initiated within 30 days of the Portuguese Authority of Medicines and Health Products’ (INFARMED) publication, on its official website, of the marketing authorisation application, or from the date of the registration application, in case of centralised marketing authorisation.

Decree-Law 110/2018, which amended Law 62/2011, maintained the same enforcement system for pharmaceutical patents and generic medicines but revoked the mandatory arbitration route. Since 9 January 2019, the interested party who seeks to enforce an industrial property right, in light of the publication of a marketing authorisation application for generics medicines, still needs to do so within a 30-day deadline, but the nature of the arbitration for generic medicines is now voluntary rather than mandatory. If the parties do not agree to submit the dispute to arbitration, the enforcement action shall be brought before the Court.

The establishment of an Intellectual Property Court could lead to the conclusion that the judges of said Court would be highly specialised in intellectual property law. However, given the relatively recent establishment of this Court and also the competence of arbitral tribunals to handle pharmaceutical patent cases until recently, the expertise in this field is not yet sufficiently developed. The Court is now expected to deal with a growing number of patent cases, in light of the recent changes in Law 62/2011.

Finally, since patent infringement is considered a criminal offence, punishable with imprisonment for up to three years or a penalty up to a maximum of 360 days, the injured parties may also resort to criminal courts. However, the resort to criminal proceedings in Portugal is mainly reserved for the most blatant cases of trademark infringement – counterfeiting – and is not usual for patent enforcement cases.

It must be noted that, where the cases demand specific technical skills and expertise that the judges and arbitrators do not possess, the court or tribunal may be assisted by an expert (a technical advisor).

Industrial property has guarantees established by law for property in general and enjoys special protection under the IPC and other legislation and conventions in force. Therefore, a patent holder or a licensee or sub-licensee (if this is contemplated in the respective licence or sub-licence contract) has standing to sue.

The enforcement of patent rights can be made through actions aiming at preventing or putting an end to the infringement of those patent rights. In relation to invalidity claims, the Public Prosecutor’s Office or any interested party are entitled to bring a suit to annul or declare the nullity of a patent against any holder of registered patent rights. Nullity can be invoked at any time by any interested party. Annulment actions, following the enactment of the new IPC, must now be filed within five years as from the decision of the respective grant.

Arbitration, as well as the procedural rules of the arbitration adopted in each case. Patent infringement proceedings before the criminal courts will follow the procedural rules set out in the Portuguese Criminal Procedural Code.

In any case, as a rule, the parties will submit their pleadings with evidence, thus being given the opportunity to present their case in writing and to file their requests in relation to further evidence to be presented. The evidence generally includes documentary evidence and testimonial evidence, but may also include written depositions, legal opinions and expert opinions.

The IPC contemplates measures and procedures to ensure the enforcement of the industrial property rights, including specific rules for obtaining relevant evidence of infringement and discovery and also for interim measures or preliminary injunctions. In this context, whenever evidence is in the possession of, held by or under the control of the opposing or a third party, the interested party may request of the Court that it be presented, provided that, to justify its intentions, it presents sufficient indication of a violation of industrial property rights.

Concerning acts carried out on a commercial scale, the applicant may also ask the Court for the presentation of banking, financial, accounting or commercial documents that are in the possession of, accessible to or under the control of the opposing or third party.

Whenever industrial property rights are violated, or there are grounds to believe a third party may cause serious, difficult-to-repair harm to these rights, the interested party may request urgent and effective provisional measures aimed at preserving evidence of the alleged violation. This legal provision gives rise to a great amount of discussion in doctrine and case law in relation to the interpretation of ‘damage to an industrial property right that is serious and difficult to repair’, in other words, irreparable harm.

Finally, the interested party may also request the submission of detailed information (from the alleged violator or from third parties) on the origin and distribution networks of the goods or services it suspects infringe industrial property rights.

In invalidation proceedings before the Court, a patentee may limit the scope of protection of an invention by altering the claims both via the administrative route (before the Patent Office) and the judicial route (before the Court).

Separately or within the scope of a counterclaim in infringement proceedings, it is usual – especially as regards pharmaceutical patents – for the defendant to request the declaration of nullity of the patent, usually claiming that the patent did not meet, at the time of its grant, the patentability requirements.

This was a hot topic in the context of mandatory arbitrations under Law 62/2011 as the case law of the arbitral tribunals has been very torn concerning the arbitral tribunals’ own competence to assess the validity of patents (or SPCs) even if raised as a defence with mere inter partes effects. The courts of appeal have been strongly divided about this topic, despite the fact that none of the decisions rendered had a generally binding force.

Decree-Law 110/2018 inserted a new provision in Law 62/2011, allowing the invalidity objection to be assessed and declared with mere effects inter partes in the context of voluntary arbitration proceedings.

However, this new provision does not settle at all the previous discussions on this topic. It is therefore likely that this controversy will maintain pertinence, now in the context of voluntary arbitration and also in the context of judicial proceedings.

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A typical patent infringement or invalidation case in the Court may take a couple of years or more, depending on the complexity of the matters involved therein. A preliminary injunction may take between three and eight months.

As regards the voluntary arbitration proceedings under Law 62/2011 as amended by Decree-Law 110/2018, said law establishes that the final hearing must take place 60 days following the filing of the defence, although this deadline was already provided for in the context of mandatory arbitration and it was rarely complied with. In the context of potential voluntary arbitrations, the applicable Law on Voluntary Arbitration establishes a 12-month period for the arbitration award, which may nevertheless be extended by agreement of the parties. This deadline to give a final award was often extended in the context of mandatory arbitrations, in particular in more complex cases.

As to the costs of the proceedings, court fees are calculated based on the value of the dispute, as fixed by the court on the basis of the worth of the interest of the parties in dispute. Arbitration costs include the arbitrators’ fees (in the context of mandatory arbitrations, usually around €60,000 for the arbitral panel, in cases where the arbitration reached its end with a final merit award) and the administrative costs (secretary and other administrative expenses).

Added to this, the parties must consider the attorney’s fees and possibly the experts’ fees. It is possible to apply for an interim injunction seeking a provisional decision that prevents or puts an end to the infringement of an industrial property right, including the seizure of the infringing products.

With regard to preliminary injunctions, the IPC provides (Article 345) that whenever there is violation of, or justified fear that, another party may cause serious and difficult-to-repair harm to an industrial property right, the court may, if the interested party so requests:

a) order the appropriate measures to rule out any imminent violation; or
b) prohibit continuation of the violation.

The injunction can be effective against the infringer’s suppliers or customers if these are also parties in the injunction proceedings and therefore specifically covered by the court’s injunction decision.

As mentioned before, preliminary injunctions related to pharmaceutical patents may also be filed before the arbitral tribunals, currently in the context of voluntary arbitration. Ex parte decisions are not common in patent matters in Portugal. Likewise, there is neither regulation nor tradition in Portugal on protective letters used as means of reducing risk in ex parte preliminary relief. In this sense, a protective letter would not reduce the risk of ex parte preliminary relief, notably because of the mentioned lack of regulation on those protective letters.

Article 343 of the IPC foresees the applicant’s liability in provisional and precautionary measure and it was recently amended in order to now include, as a ground for possible damages, the measure being ‘abusively applied for or in bad faith’. It also provides that the damages can be claimed by the defendant as well as by ‘any injured third party’.
IV  SUBSTANTIVE LAW

i  Infringement

Former Articles 101(1) and 101(2) of the IPC already provided that the patent confers upon the holder the exclusive right to use the invention anywhere in the Portuguese territory, which translates into the right to prevent others from manufacturing, offering, storing, marketing or using the patented product, or importing or possessing it, for any of the mentioned purposes, without his or her consent.

Current Article 102 of the IPC specifically lists the following prohibited conduct:

a  the use of a protected process (or the offer to use such process, if the third party knew or should know that the unauthorised use is prohibited);

b  the offer, stockpiling, marketing, use and the importation for any of the previous conducts, of the products directly obtained by the process that is the subject of the patent; and

c  the indirect infringement (very similar to Article 26 of the Agreement on a Unified Patent Court).

Proceedings can be brought for preparatory acts, although difficulties may occur in relation to the evidence of those acts.

In civil proceedings – before the judicial courts and arbitral tribunals – the liability for infringement relies on the civil liability of the infringer, namely, the company that performed the infringement. The liability of foreign suppliers is difficult to discuss and prove in civil proceedings and is not usually a topic in such actions.

In criminal proceedings – before the criminal courts – the criminal liability relies on the company that infringed IP rights, but can also rely on the directors of infringing companies.

In accordance with Article 98 of the IPC, 7 ‘the scope of protection conferred by the patent shall be determined by the contents of the claims and the description and drawings shall serve for the interpretation thereof’. This means that patent claims are commonly interpreted under this legal criterion.

Neither this provision nor other provisions of the Portuguese law foresee equivalents for determining the extent of protection by a patent. However, the doctrine of equivalents is regularly invoked in patent litigation cases and is also regularly considered and applied by the courts and arbitral tribunals. 8

Furthermore, considering the fact that Portugal is a member of the European Patent Convention (EPC), even though the Protocol on the Interpretation of Article 69 European Patent Convention of 5 October 1973, as revised on 29 November 2000, has no equivalent under Portuguese Law, it should be applied by the Portuguese courts and tribunals as legal framework for the interpretation of the patent claims and determination of their scope of protection, regardless of being European or Portuguese patents, for reasons of equality and legal certainty.

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7  Clearly based on Article 69 of the European Patent Convention (EPC), which states that ‘the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims’.

8  The doctrine of equivalents was first introduced by the Portuguese Courts with two judgments rendered by the Appeal Court of Lisbon on 1974, in the framework of the IPC of 1940.
The prosecution history may also play an important role in determining the scope of patent protection, notably whenever the doctrine of equivalents is argued before a Portuguese court.

The contents of an opposition, a reply, an amendment or any submitted document filed by the parties, subject to the previous analysis of the Patent Office, will also certainly play an important role in determining the scope of a patent. There is no estoppel defence or estoppel effect under the Portuguese civil procedural rules, and no precedent rule.

ii Invalidity and other defences

Under Article 32 of the IPC, patents, utility models and registrations shall be totally or partially null if:

\( a \) their object cannot be protected;
\( b \) when granted, procedures or formalities essential to the grant of the right have been omitted; or
\( c \) public rules have been violated.

In addition, under Article 114 of the IPC, a patent shall be null and void if:

\( a \) its object does not meet the requirements of novelty, inventive step and industrial application;
\( b \) its object cannot be protected according to the applicable provisions of the IPC;
\( c \) it is recognised that the title or heading given to the invention covers a different object; or
\( d \) its object has not been described in such a way that anyone skilled in the art can carry it out.

Under Article 33 of the IPC, patents, utility models and registrations shall be totally or partially annulable if the holders are not entitled to them, namely, if:

\( a \) the right does not belong to them; or
\( b \) they were granted with disregard for the rights set forth in the procedural rules set out in the IPC.

One or more claims may be declared null and void or annulled, but partial nullity may not be declared, nor may a claim be partially annulled. The typical grounds for an invalidity action are the lack of novelty or inventiveness, or industrial applicability (industrial use). ‘Insufficiency’ has also been raised in recent cases.

The legal and technical discussions on those grounds are not different from any of the EU countries – and the EPC states – being that jurisprudence from the European Patent Office (EPO) is the most relevant basis for the same discussions.

In relation to the obviousness or inventiveness test, the EPO’s jurisprudence on this matter is generally followed – notably, the ‘could/would’ approach in order to determine whether a patent is ‘obvious’ or ‘inventive’ in view of the prior art. Also, consideration of the person skilled in the art in each case is defined under the EPO’s case law. For the insufficiency argument, the plausibility test is normally considered.

In relation to other defences, although rarely applied in practice, the interested parties can object to patent infringement by invoking:

\( a \) legal limitations of the rights conferred by a patent (for instance, acts performed in private and not for commercial purposes or only performed exclusively for trial or experimental purposes – Bolar exemption);
exhaustion of rights (as the rights conferred by a patent do not allow its holder to forbid acts related to the products protected by it after its sale by the patentee or with his consent, in the European economic area);

non-opposability (as, in general, rights conferred by a patent are not opposable in Portuguese territory before the date of the application or of priority, if it is claimed against someone who, in good faith, has learned of the invention by his or her own means and used it or made effective, serious preparations to use it); or

d the existence of a licence.

V FINAL REMEDIES FOR INFRINGEMENT

Under Article 347 of the IPC, whoever illegally violates the industrial property rights of another person, be it with criminal intent or by mere blame, must pay compensation to the injured party for the damages resulting from the violation.

First, the IP right holder has to prove the causality of the infringement for the damages calculation.

In determining the amount of compensation for losses and damages, the court shall take into account, in particular, the profit obtained by the violator and the resulting damages and lost profits suffered by the injured party. It shall also take into consideration the costs borne with the protection of the right in question, and the investigation and termination of the harmful conduct.

Also, in calculating the compensation to be paid to the injured party, the revenue resulting from the violator’s unlawful conduct shall be taken into account. Normally, the evidence in this regard is produced by means of expert evidence with the necessary inspection of the parties’ commercial accounts. If the mentioned damages aspects fail to be evidenced, there is also the possibility of calculating damages based on the licence analogy criteria.

In the absence of specific evidence for the purpose of calculating the damages or regarding the total extent thereof, the decision may also determine that the damages be ascertained during the phase of execution against the infringer.

The Court may also decide on additional measures relating to:

- the fate of the goods that have violated the industrial property rights;
- the prevention of the continuation of the proven infraction; or
- the publication of the judicial decision.

VI OTHER TYPES OF PATENT PROCEEDING

Apart from the proceedings already mentioned, in the context of infringement proceedings, declaratory judgment suits are also available to obtain a decision of non-infringement of an industrial property right, usually in anticipation – on the part of whoever intends to use or market what is protected by that right – of enforcement actions that the owner of that right may initiate. The competent court is the Intellectual Property Court.

It must be also noted that patent infringement is considered a criminal offence, punishable with imprisonment for up to three years or a penalty up to a maximum of 360 days. Therefore, the injured parties may also resort to criminal courts or district courts with general competence, including criminal cases, although this route is rarely used.

The parties are also entitled to seek alternative means of dispute resolution such as mediation or voluntary arbitration, provided that the parties agree to such alternative
dispute resolution. As already mentioned, Law 62/2011 now expressly foresees the voluntary arbitration route to resolve pharmaceutical patent disputes related to reference medicines and generic medicines.

However, this route was almost never used in relation to patent disputes and it is not likely that it will be often used in the context of Law 62/2011.

Yet it must be said that often the parties manage to reach an alternative solution to litigation by executing an agreement either before or during pending proceedings.

Finally, there are also mechanisms to obtain a compulsory licence to a patent. A patent holder who, without a good reason or legal basis, does not exploit an invention, directly or under licence, or does not do so in such a way as to meet national needs, may be obliged to grant a licence for its exploitation.

Compulsory licences must be requested from the Patent Office, and the interested parties – the applicant and the patent holder – are allowed to file their arguments on the request. If the Patent Office decides in favour of the granting of the compulsory licence, it shall give both parties one month to appoint an expert who, together with the expert appointed by the Patent Office, shall agree, within two months, on the conditions of the compulsory licence and the compensation to be paid to the patent holder.

Customs proceedings – under the relevant EU Regulations – are significantly growing as another and supplementary route for preventing patent infringement.

VII APPEAL

A first-instance decision can be appealed to the second-instance court (court of appeal) both on matters of fact and of law. The decision under appeal is assessed by a panel of three judges, one of whom is the reporting judge. In particular circumstances, decisions from the second instance courts can be appealed to the Supreme Court of Justice, which decides only on matters of law. Generally, new evidence is not allowed at the appeal stage and is not also usual to have hearings at this stage, the appeal process being basically a written proceeding.

In relation to the decisions given by arbitral tribunals constituted under Law 62/2011, the arbitral award may be appealed to the second instance court.

In the previous mandatory arbitration system, this provision has been often construed as preventing the decision of the second instance court to be appealed to the Supreme Court of Justice. Although, in most cases, the Supreme Court rejects ordinary appeals, it has been recently admitting appeals in cases where, according to the procedural law, the decision is always appealable.9

Usually decisions on the appeals – both at second and last instance – may take from four to eight months, and the appeal court fees are not significantly high.

9 Namely, in case of the contradiction of decisions rendered by the Lisbon Court of Appeal or based in violation of certain rules related to court jurisdiction or res judicata.
VIII THE YEAR IN REVIEW

i Arbitration award of 14 December 2018 – Novartis v. Normon (Imatinib)

In the context of mandatory arbitration proceedings under Law 62/2011 (in its original version), the Arbitral Tribunal granted several claims put forward by the claimants aiming at the enforcement of second medical use claims.

This was an interesting decision, since the Portuguese case law is not significant and gives contradictory signs about what can be understood as a conduct that infringes a second medical use claim.

The Tribunal acknowledged that a preventive award against the defendant was justified and that the generic company should take additional steps deemed appropriate and necessary to prevent or deter the use of products, once supplied, for the therapeutic purposes protected by the patent claims at stake.

In brief, the defendant was ordered (1) to refrain from importing, manufacturing, storing, marketing, selling or offering the medicinal products at stake containing the relevant active ingredient for the protected therapeutic indication; (2) to refrain from promoting or offering the medicinal products at stake for the treatment of the protected therapeutic indication; (3) to make it clear, in writing, to all prospective purchasers, in the context of private procedures for acquisition of generic medicines containing the active substance at stake, to inform and that its medicinal products are not indicated for the treatment of the protected therapeutic indication; and (4) when medicinal products containing the active substance at stake are purchased through a public procurement procedure for use in the treatment of the protected therapeutic indication, to ensure that any proposal made in the context of said procedure expressly states that the medicinal products are not for the treatment of the protected therapeutic indication and can only be used in the treatment of other therapeutic indications other until the expiry of the invoked patent.

No appeal was filed against the arbitration award.

ii Ruling of the Lisbon Court of Appeal of 19 February 2019 Case 236/16.2YHLSB-7

The Court had issued a decision on the matter of the industrial property rights’ holders liability for ungrounded preliminary injunctions. The Court had held that the liability arising from former Article 338-G(3) (currently Article 343(3)) of the IPC should be considered a strict liability and had ordered the preliminary injunction applicant to pay damages to the generic company that had been ordered to stay out of the market while the industrial property rights asserted were in force.

The Lisbon Court of Appeal overturned this decision and clarified that the liability provided for in said provision of the IPC demands the allegation and demonstration of the fault or negligence of the industrial property rights’ holder that applied for the preliminary injunction.

According to this ruling from the Lisbon Court of Appeal, the relevant provision of the IPC shall be read in light of the general Portuguese provisions of tort law and, notably, Article 483(2) of the Civil Code, that clearly establishes that ‘strict liability only exists whenever the law so specifies’. The Appeal Court’s interpretation of former Article 338-G(3) (currently Article 343(3)) of the IPC is that it does not suggest in any way whatsoever (expressly or even implicitly) a strict liability and that it would have been rather easy for the legislator to include such a reference.
In this case, where the industrial property rights’ holder filed for a preliminary injunction on the basis of the public record that attested a certain expiry date of its right, which was published in the Industrial Property Office Bulletin, the Lisbon Court of Appeal concluded that the IP holder acted in good faith and with the required prudence, in view of the official elements available at the time.

An appeal against this ruling is still pending before the Supreme Court of Justice.

IX OUTLOOK

There were significant changes in the Portuguese legal framework this year, including major changes to Law 62/2011 and the approval of a new IPC.

The legal system governing mandatory arbitration in respect of disputes over industrial property rights, including injunction proceedings, involving reference medicinal products (patent rights) and generic medicinal products, brought great developments in patent litigation in Portugal. However, this mandatory arbitration system was replaced by an alternative system and there are now many new and old issues to be overcome. In this new scenario, arbitration will not be an expectable way to generally enforce pharmaceutical patent rights against generic companies because is not likely that generic companies will accept to enter into arbitration agreements (as the short life of this new system is already confirming).

It is likely that in the coming years, these changes will impact on the current patent litigation landscape and on the Intellectual Property Court’s respective role.

Furthermore, the future of the Unified Patent Court (UPC) system is still uncertain. However, since the UPC is expected to have exclusive competence in respect of European patents and European patents with unitary effect, as it is designed, future developments in this field may have also significant impact on patent litigation in Portugal.

It should be also noted that in addition to the growing problem of counterfeiting, which is common to many economies, internet infringements are still increasing. Copyright, technology transfer, emerging technologies and software protection, namely in the field of computer-implemented inventions, are likely to undergo a great deal of development, which will be accompanied by corresponding litigation.
I OVERVIEW

Russia has only operated as an independent state, distinct from the former Soviet Union, since the early 1990s. Although a new patent law was enacted shortly after, it was not until 2008 that Russian patent law was fully modernised with the enactment of Part IV of the Civil Code.

During this period of transition, the patent office and the court system were also being established. On 3 July 2013, the Plenum of the Supreme Arbitration Court of the Russian Federation approved the commencement of the new Intellectual Property Court (IP Court) located in Moscow. With the amendment of Russian Federal Constitutional Law No. 4-FKZ of 6 December 2011, a new, specialised court, the IP Court, was introduced into the Russian judicial system.

Over the last five years since the IP court was created, there have been noticeable improvements in the quality of decisions in the field of trademarks and domain names, where the court seems to be most comfortable. Regarding patents, a large proportion of the infringement cases and appeals from the Chamber of Patent Disputes (Patent Chamber) have been in the area of pharmaceuticals. In this regard, the IP Court has shown substantial deference to Patent Chamber decisions regarding validity. Most appeals from the Patent Chamber have been denied. Accordingly, the court has clearly gotten involved in the sphere of trademarks. However, it is also clear that the court does not yet have the same depth of experience it needs to refine the intricacies in the law of patents from what it currently is to what it should be.

In 2014, Part IV of the Civil Code was amended further to introduce several new substantive improvements to the laws relating to patentability, infringement, and compensation, as well as the scope of protection to be accorded to utility models.

In April 2019, the Plenum of the Supreme Court of the Russian Federation issued a detailed resolution concerning the use of Part IV of the Civil Code. Although there is no doctrine of *stare decisis*, there are resolutions proclaimed from time to time by the Supreme Court that are intended to clarify procedural and substantive uncertainties relating to the application of its laws, in this case intellectual property. This resolution is comprehensive and touches upon most fields of intellectual property, including patents.

Alternative dispute resolution is seldom resorted to, and settlement is an infrequent outcome in patent cases in Russia because an action will quickly proceed to trial. Litigation costs are low because there is no discovery, no deposition process, and few pre-trial motions.
There is little testimony at trial, and awards of court costs, if any, are nominal. Moreover, the culture of alternative dispute resolution is not ingrained in the judicial or attorney psyche in Russia as it is in many other countries.

II TYPES OF PATENT

In Russia, patents cover three types of IP objects; namely, inventions, utility models, and industrial designs. All three are subject to the relevant patentability requirements. The patent term for inventions is 20 years with a possibility of up to five years’ extension for pharmaceuticals, pesticides and agrochemicals; for utility models, as of 2015, it is 10 years; and for industrial designs it is now a first term of five years, renewable four times for a total of up to 25 years. For inventions, national patents may be granted by the Russian Federal Service for Intellectual Property (ROSPATENT) or regional patents by the Eurasian Patent Office that are effective in Russia and seven other contracting states. For utility models or industrial designs, a patent may be granted by ROSPATENT only.

Invention patents

Patentability

An ‘invention’ is a technical solution, in any area, related to a product (including a device, substance, microorganism strain, and cell culture of plants or animals) or method (process of affecting a material object using material means). An invention may be granted if it is new, involves an inventive step, and is industrially applicable.

Patentable subject matter

The following is not patentable under Part IV of the Code:

- methods of cloning a human being;
- methods of modifying the genetic integrity of cells of the embryonic line of a human being;
- use of human embryos for industrial and commercial purposes; and
- other proposals that are contrary to public interest, principles of humanity, and morality.

The following are not deemed to be inventions in and of themselves:

- discoveries;
- scientific theories and mathematical methods;
- proposals concerning solely the outward appearance of manufactured articles and intended to satisfy aesthetic requirements;
- rules and methods of games and for intellectual or business activity;
- computer software; and
- ideas on presentation of information.

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2 Civil Code, Article 1350.
3 Civil Code, Article 1349.
4 Civil Code, Article 1350.
This subject matter is not patentable if the patent application refers to the above subject matter with nothing more.

**Utility/industrially applicable**

An invention is deemed to be ‘industrially applicable’ if it can be used in industry, agriculture, public health, and other branches of the economy or social sphere.

**Novelty**

An invention is deemed to be new, if it is not anticipated by prior art. Prior art includes any information that becomes generally accessible anywhere in the world before the priority date of the invention. In assessing novelty, the state of the art also includes, under condition of earlier priority, all earlier filed applications in Russia by other applicants for inventions and utility models that ultimately have been or will be officially published, and inventions and utility models that have been patented in Russia.

Disclosure of information relating to an invention by the inventor, applicant or other person having received this information directly or indirectly from them, that made information on the essence of the invention public, is not a circumstance precluding the recognition of the patentability of the invention if a patent application for the invention is filed in Russia or under the Patent Cooperation Treaty (PCT) within six months from the date of disclosure of the information. Note in this situation that the applicant cannot rely on the six months before the priority date but only the month before the actual filing date. In the Eurasian Patent Office, the applicant can rely on a grace period that is six months before the priority date. The burden of proof, that the circumstances that took place by virtue of which there was disclosure of information that does not prevent the recognition of the patentability of the invention, is on the applicant.

**Nonobviousness**

An invention must involve an inventive step. For an invention to meet this test, it must not be obvious to a person skilled in the art. The state of the art includes any information published anywhere in the world and made available to the public before the priority date of the invention.

**Supporting disclosure**

Article 1350 of the Civil Code previously required three conditions for patentability of inventions: novelty, inventive step, and industrial applicability. New amendments introduced in 2014 included a fourth requirement: sufficiency of disclosure. The new requirement is assessed by examiners in the course of substantive examination of applications.5

Insufficiency of disclosure is now a valid ground for both refusing an application and revoking an issued patent.6 ‘Sufficiency’ means, as of the filing date, ‘to disclose the essence of the claimed invention in the application documents in a manner sufficient for implementation of the invention by a person skilled in the art.’

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5 Civil Code, Article 1386.
6 Civil Code, Article 1398.
Prior to this amendment, sufficiency of disclosure was a practical but not a statutory requirement except to the extent that it had to be sufficient for ‘realisation’ of the invention. Sufficiency was assessed as a matter of practice, procedure, and regulation under the legal requirement for ‘industrial applicability’. However, the legal right to raise an objection of industrial applicability premised upon insufficiency of disclosure was often in doubt. To address this doubt, it was decided to formalise sufficiency as a separate requirement for patentability.

Regarding critical dates, it should be noted that although novelty and inventive step are determined as of the priority date, the assessment of sufficiency of disclosure is to be made on the basis of information contained in the specification as of the filing date (international filing date for PCT applications and the date of actual filing for applications filed directly with the Russian Patent Office).

Utility models

A utility model is a technical solution relating to a device. A utility model may be granted if it is novel and industrially applicable. There is no inventive step requirement.

Protection for utility models was introduced in Russia under the Patent Law of 1992. The public interest objective in introducing utility models was to grant patents expeditiously without substantive examination to encourage development of small businesses and innovation in an emerging economy.

Unfortunately, although the regime did deliver some benefits to the public interest, the system was manipulated for undesirable purposes. Utility model applications were often inappropriately used as a means for quickly obtaining a patent to use against others. Because there was no substantive examination, vexatious applicants would apply for patents for subject matter that was very likely already in the public domain. They would then try to assert those patents against *bona fide* business entities legitimately using the technology, for example, manufacturers of products or Russian distributors.

New revisions to the law were enacted in 2014. The new amendments seek, by various means, to curb these abuses:

\( a \) Prior art: until 2014, prior art for evaluation of the utility model’s novelty was limited to published information about any means having the same intended use as the claimed model. However, the amended Article 1351 expanded the meaning of prior art so that it includes any information that became publicly available before the priority date of the utility model, regardless of the technical field to which it applies. Moreover, under the previous definition of prior art, only information available in Russia regarding use of the means having the same intended purpose was considered. This restriction has now been removed, such that prior art includes information that was publicly available anywhere in the world. Moreover, prior art now includes earlier filed invention patents and also design patents.

\( b \) Substantive examination: in addition to broadening the definition of prior art, there is now substantive examination of applications. Previously, the only form of examination was clerical in respect of filing formalities. Substantive examination is carried out to verify compliance with both the requirements of subject matter and patentability.

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7 Civil Code, Article 1375(2).
8 Civil Code, Article 1351.
9 Civil Code, Article 1390.
Literal infringement only: the scope of protection granted to a utility model is now more limited. Under the previous legislation, a utility model patent was deemed to be infringed if the article possessed features equivalent to the features included in the utility model claims. Under the amended Article 1358, infringement based on the ‘doctrine of equivalents’ with regard to utility models is abolished.

These amendments are directed at positioning utility models where they were intended to be in terms of the public interest.

New

A utility model is deemed to be new if the sum of its essential features is not anticipated by the prior art. The state of the art includes any kind of information published anywhere in the world and made available to the public, before the priority date of the claimed utility model, concerning devices of similar function and in use in the Russian Federation or elsewhere. The state of the art also includes, on condition of their earlier priority, all applications filed in Russia by other applicants for inventions and utility models that have been in due course officially published, inventions, and utility models that have been patented in the Russian Federation.

Six-month grace period

Disclosure of information relating to a utility model by the author of the utility model, applicant, or other person having received this information directly or indirectly from them, who made information on the essence of the utility model public, is not a circumstance precluding the recognition of the patentability of the utility model if an application for the grant of a patent for the utility model was filed with ROSTPATENT within six months from the date of disclosure of the information. The burden of proof that the disclosure was permitted under the grace period falls to the applicant.

Industrially applicable

A utility model is deemed to be industrially applicable if it can be used in industry, agriculture, public health, other branches of the economy, or the social sphere. It is not a difficult test to satisfy.

Not utility models

Legal protection as utility models cannot be granted for proposals concerning solely the outward appearance of manufactured articles and intending to satisfy aesthetic requirements, or layout designs (topographies) of integrated circuits.

Industrial designs

A design qualifies as subject matter for a design patent if it is an artistically designed solution of an article, manufactured industrially or by artisans, that defines its outward appearance. An industrial design may be granted legal protection if its essential features are new and original.

10 Civil Code, Article 1351, §5.
11 Civil Code, Article 1352.
**Essential features**

The essential features of an industrial design include any features determining the aesthetic or ergonomic characteristics of the outward appearance of the article, or both, including shape configuration, ornament, and combination of colors. In 2014, the requirement to express in writing the claims to the essential features was eliminated from the law; however, for the moment, for classification purposes, the patent office continues to require the inclusion of a written description of the design.

**New**

An industrial design is deemed to be new if the aggregate of its significant features reflected on images of the article’s appearance is not known from information generally available in the world before the priority date of the industrial design application.

When determining the novelty of an industrial design, all pending priority applications for industrial designs filed in Russia by other persons that are ultimately granted will also be treated as prior art. If prior art is pending in Russia, it will not be cited against the other application, and the owner of the prior art will be required to file a subsequent revocation action in the Patent Chamber.

**Original**

An industrial design is deemed to be original if its essential features are the result of the ‘creative nature of the special aspects of the article.’

**Six-month grace period**

Disclosure of information relating to an industrial design by its author, the applicant, or other person having received this information directly or indirectly from those who made information on the essence of the industrial design public is not deemed to be a circumstance preventing the recognition of the patentability of the industrial design if an application for the grant of a patent for the industrial design is filed within six months from the date of disclosure of the information. The burden of proof that the proper circumstances have taken place falls to the applicant.

**Not industrial designs**

Legal protection as an industrial design is not available for solutions that are determined exclusively by the technical function of an article, solutions that relate to works of architecture (with the exception of minor architectural forms), industrial, hydro, technical, and other stationary structures; or solutions that relate to objects of unstable shape, such as liquids, gases, dry substances, and the like.

Russia joined the Hague Agreement Concerning the International Registration of Industrial Designs of 2 July 1999, which came into force in Russia on 28 February 2018.

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12 Civil Code, Article 1352, §2.
13 Civil Code, Article 1352, §3.
14 Civil Code, Article 1352, §5.
III  PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i  Overview of the Bifurcated System

In patent-related matters, there are two independent forums that merge at the appellate level in Russia.

Patent infringement actions are first commenced in the commercial courts, and at the second level of appeal, make their way to the IP Court. From there, cases move on further appeal to the Supreme Court as explained in more detail in Section III.ii.

Proceedings to revoke issued patents are first filed in the Patent Chamber within the (ROSPATENT). The first appeal from a decision of the Chamber is heard by the IP Court. A further cassation appeal may be heard by the Presidium of the IP Court, and from there on further appeal to the Supreme Court.

Each proceeding, for infringement and for validity, is independent from the other. The overall process is commonly referred to as a bifurcated patent system.

Until 2014, the highest court of appeal, in IP and commercial matters, was the Supreme Arbitration Court. In 2014, the Supreme Arbitration Court was liquidated and all of its powers were vested into the newly reconstituted Supreme Court,15 which is located in Moscow. Decisions of the IP Court, which is part of the Arbitration Court, are now supervised by a 30-judge Economic Collegium that is part of the redefined Supreme Court.

ii  Practice and Procedure in Patent Litigation

Procedural Law

Overview

There are about 81 commercial courts that hear patent litigation infringement actions in the first instance. The commercial courts of first instance are courts of general jurisdiction for all commercial matters. They are not IP-specialised courts. A single judge hears a patent infringement case in the first instance. There is no jury system. Statistically, the majority (as much as 80 per cent) of patent-related disputes are tried in the Moscow City Commercial Court because qualified IP professionals and the parties themselves are most often located in the region.

There are 20 commercial courts of appeal. Appeals in infringement cases from the first instance commercial court decision of the single judge are heard by three judges of the commercial courts of appeal. The panel of judges is empowered to review the record and render what it deems to be the correct decision in fact and in law. Then there is the second appeal to the IP Court.16 The appeal to the IP Court is a cassation appeal. On a cassation appeal, the presiding cassation court does not review the case de novo, as the lower courts did. Its jurisdiction is confined to reviewing the lower court decision for legal correctness.

An additional appeal against the ruling of the IP Court, acting as a cassation court, may be heard by the Supreme Court, provided that leave to appeal is granted by three judges of the Supreme Court. The Supreme Court hears a case only if the case severely violates an applicant’s rights due to the wrongful application or violation of a material or procedural law by a lower court. In practice, the Supreme Commercial Court (SCC) hears a case only if a lower court ruling is inconsistent with or negatively affects the established court practice.

16 See http://ipc.arbitr.ru/.

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There can be both civil and criminal liability for patent infringement. The latter arises pursuant to the Article 147 of the Criminal Code in instances in which the infringement has resulted in significant harm to the patentee or has been committed by a group in conspiracy or by an organised group. There are no customs or border measures available for patent infringement as there are in relation to counterfeiting of trademarks or copyright infringement. Criminal charges are brought by the Investigative Committee of the Russian Federation. Possible criminal sanctions for patent infringement include up to five years of imprisonment. Although there have been no recent criminal cases involving patents, there are many each year in the copyright field, usually involving piracy, and some have resulted in imprisonment. Therefore, it is statistically unlikely but not inconceivable that imprisonment might occur in a patent case.

Patent revocation proceedings are first initiated and tried in the Chamber for Patent Disputes, a quasi-administrative body associated with ROSPATENT, and is headquartered in Moscow. Appeals from decisions of the Patent Chamber are heard in the IP Court.

On an appeal of a patent revocation decision from the Patent Chamber, the IP Court is entitled to appoint an expert to review the case and provide an opinion regarding validity based on his or her own expertise, without regard to the Patent Chamber decision. The IP Court may then review the lower Patent Chamber decision in the context of the expert opinion it commissioned and decide on the proper outcome. That decision may be further reviewed for legal correctness by the Presidium of the IP Court, acting as a cassation court.

In addition to the above circumstances, the IP Court may also act as a court of first instance with competence over the following subject matter:

a. cases contesting legislative acts of federal executive authorities that affect a claimant’s rights and legitimate interests in relation to the protection of patents;
b. cases to determine issues regarding the proper inventor and owner of a patent; and
c. cases contesting nonnormative legal acts, reviewing decisions, and reviewing refusals to take action by ROSPATENT.

A defendant may not allege invalidity of a patent as a defence to an allegation of infringement in a court action and may not counterclaim in a court action or file a parallel court action to declare a patent invalid or not infringed. A challenge of invalidity by way of revocation proceeding must always be first raised in the Patent Chamber.

Representation

A lawyer or patent attorney duly empowered to represent a party under a properly executed power of attorney may represent a party in patent infringement proceedings and revocation proceedings.

The evidentiary process

Pre-complaint discovery/fact-gathering\(^\text{17}\)

The plaintiff in an infringement action bears the burden of proving the allegations put forward in the statement of claim by way of admissible evidence. Such evidence is almost entirely documentary in nature and should accompany the filing of a statement of claim or defence, as the case may be. In practice, the concept of discovery of documents and witnesses

\(^{17}\) Commercial Court Procedural Code (CCPC), Article 65.
is essentially not provided for and is not required or permitted. In view of this, the plaintiff’s burden of proof is a very onerous one because the plaintiff must make out its case almost entirely from documents that it has assembled from various sources and in respect of which the defendant cannot be directly asked any questions. As indicated below, it is possible to use evidence from other court proceedings in which a final decision has been rendered but it is within the discretion of the judge to accept.

In June 2016, it became necessary for a prospective plaintiff to issue a demand letter at least 30 days before any action for infringement could be instituted. That obligation was slightly modified in 2017 such that a demand letter is only required when monetary compensation is being sought and not when, for example, only a preliminary or permanent injunction is sought. It is thought that, at a minimum, the notice should provide: the name of the patentee and identification of the patent in question; the name of the accused infringer or infringers; a brief summary explaining the acts in question and how they constitute infringement; the relief to which the patentee believes it is entitled; a time limit for response by the recipient; and advice recommending settlement failing which a court action will be instituted.

**Post-complaint discovery/fact-gathering**

No discovery by deposition exists in Russia. There is no rule forcing parties to disclose all relevant documents or information other than what a party chooses to file to support or refute an allegation. The law does provide a right to file a motion with the court requesting the other party to provide evidence and documents in instances in which it can be shown that the evidence is not available to the moving party; however, such requests are seldom granted. In practice, there is no effective procedure to obtain documents, for example to prove that a process is being carried out in a plant or to prove the extent of revenues a defendant has generated in connection with an infringing act. This affects the extent to which a patentee can reasonably predict the damages it might recover. As a result, damages awards are usually quite nominal and typically less than US$10,000.

Another noteworthy observation is that witnesses are not commonly called or required to testify in patent-related disputes, save for court-appointed experts who file reports and can be questioned thereon.

It is possible to obtain and use evidence from earlier court proceedings, in Russia or elsewhere, in which a final ruling was already issued, but it is within the Russian judge’s discretion whether to accept it and, if accepted, what weight to give that evidence.

**Evidence at trial**

In infringement cases, trials at the first instance are by judge alone, without a jury. The record before a judge will typically include:

- a copy of the patent;
- a certificate of good standing relating to the patentee;
- samples of the product alleged to infringe, along with any publicly available support materials, such as user manuals, published specifications, and so forth;
- documentary proof regarding the availability of the product in Russia;
- any third-party documents that are officially obtainable and that tend to prove infringement; and

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18 CCPC, Article 66.
an expert report of the plaintiff showing what the salient features of the impugned product are (and possibly a patent attorney’s expert opinion showing that the product falls within the claims).

The use of experts

Experts play an important role in patent-related disputes in Russia because the courts in most cases place substantial weight upon the expert’s report. Often, the parties attach preliminary expert opinions to the statement of claim, or defence. Such expert opinions are considered as evidence submitted by a party. In many cases, the court itself also appoints an expert. The parties may suggest the expert candidates to the court, as well as the technical questions to be resolved.

Parties to the trial have a right to suggest experts or expert organisations to act as witnesses. Resort to an expert, sometimes referred to as a specialist, may also be made at the court’s initiative. In either case, the experts should have competence in the technical field in question. Typically experts are patent examiners or university professors with backgrounds in science and engineering. They would not be lawyers. The expert may not opine on the issue of law. The expert may be summoned and questioned at trial by both parties at the request of a party or on the court’s own initiative.

Preliminary injunction

A court may grant a preliminary injunction before the statement of claim is filed. The proceeding is *ex parte*. The law does not provide for any specific type of evidence to support a request for a preliminary injunction. If a preliminary injunction is granted, the statement of claim must be filed within 15 days of the injunction order. If no statement of claim is filed, the injunction is withdrawn. Courts will grant such injunctions if it can be shown that it would be difficult or impossible to enforce a court ruling without the injunction or to prevent irreparable harm faced by the defendant. Therefore, the submissions and evidence should meet this burden.

A court may also grant an injunction after the infringement complaint is filed. Preliminary injunctions in patent infringement cases are seldom granted.

IV SUBSTANTIVE LAW

i Infringement

Literal infringement

A patentee has the exclusive right to use an invention, utility model, or industrial design by any means not prohibited by the law. The exclusive right to the use of an invention, utility model, or industrial design includes, in particular, the following:

- importation into Russia, manufacture, exploitation, offer for sale, sale, other introduction into civil circulation or the storage for such purposes in Russia, of a product that incorporates the invention or utility model, or articles incorporating the industrial design;

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19 CCPC, Article 99.
20 CCPC, Article 90.
performance in Russia of the acts provided for above in respect to a product obtained directly by a patented process. If the product obtained by the patented process is new, an identical product is considered as being derived from the patented process in the absence of proof of the contrary;

c performance of the acts provided for by the item above with respect to a device, the functioning use of which in accordance with its purpose automatically involves a patented process;

d performance of the acts provided for above by item a with respect to a product intended for use in accordance with the purposes specified in the claims, when the invention is directed to a use of a product for a specified purpose; and

e performance of a process in which the invention is used, in particular by the application of this process. 21

Some acts do not constitute patent infringement, 22 such as the use of foreign vehicles temporarily in Russia, experiments, emergency uses etc. National exhaustion of rights applies as regards importation into Russia, use, offer for sale, selling, other introduction into civil circulation, or storage for these purposes of a product, incorporating the invention or utility model or of a device, incorporating the industrial design. Therefore parallel importation is, strictly speaking, a form of infringement, although the remedies can be quite soft.

**Infringement under the doctrine of equivalents**

Russian law recognises infringement based on the doctrine of equivalents. An invention or utility model is deemed to be used in association with a product or process if the product contains or the process involves each feature of the invention or utility model stated in an independent claim in the claims for the invention or utility model, or contains a feature equivalent thereto that has become known.

In 2014, the statutory definition of equivalents was modified. The amended provision in Article 1358 subsection 3, which applies only to invention patents and not to utility models, now reads as follows:

> 3. Inventions shall be deemed to be used in the product or method, if the product comprises and the method uses each feature of the invention stated in the independent claim of the patent claims, or a feature equivalent to it and that has become known as such in this art before the priority date of the invention.

Under the previous provision, a person could be found to be infringing by reason of the use of an equivalent feature to one set out in a claim if the equivalent feature was known at the time the infringing act began.

Under the new provision, the feature may only be deemed to be an equivalent one if the feature was known at the priority date of the patent in issue.

As mentioned above, the doctrine of equivalents does not apply in the case of utility models.

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21 Civil Code, Article 1358, §2.
22 Civil Code, Article 1359.
Joint infringement
There is separate liability for each infringer along the supply chain, from the manufacturer, distributor, and retailer to the end user. However, note that if the patent claims enumerate a number of elements in a product or a number of steps in a process, there is only infringement by the person or entity who deals with the end product or the results of the entire process.

There was, until 2014, no concept of joint tortfeasor infringement in situations in which one person carried out only one step in a process or produced only one of the claimed elements in a patented product, even if that person carried out that step or produced that element knowing that it would form part of a patented product or process. There was also no liability for indirect infringement.

Article 1252, the provision that sets out the various types of infringement, was supplemented in 2014 with the provision of joint and several liabilities of multiple parties, if one (common) infringement of right has been committed through their common actions.

It is not clear yet how broadly this new provision will be interpreted.

Defences
Non-infringement and invalidity
Non-infringement is a defence to infringement, but invalidity is not. Invalidity may be raised in a separate and independent proceeding. In Russia, the institution of a parallel revocation proceeding is the most common response to being served with a patent infringement suit. According to Article 1389 of the Civil Code, ‘[I]ssued patents may be opposed by any party by filing an action with PTO [the Patent and Trademark Office] in case they [patents] are not in compliance with patentability requirements set by this article.’ A patent revocation proceeding must be first initiated in the Patent Chamber and will proceed independently from any patent infringement action that may have been commenced in the commercial court. The burden of establishing invalidity of a patent or any claim in a patent falls on the party asserting invalidity.

Other statutory defences
In the infringement action, the defendant can claim non-infringement by reason of the fact that the product or process does not fall within the scope of any of the asserted claims, or that there is a licence. A defendant can also claim that its activities fall within the prior and continuing right to use exception. A defendant can also claim that the plaintiff does not have title to the patent or that national exhaustion of rights, abandonment, compulsory licence, or limitation period apply.

There are no legal defences of laches, equitable estoppel, or inequitable conduct. However, the defendant may try to raise an abuse of rights argument if, for example, obtaining a patent was not a bona fide act.23 This approach seldom succeeds.

23 Civil Code, Article 10.
V FINAL REMEDIES FOR INFRINGEMENT

i Forms of relief

A rights holder enjoys the exclusive right to a patent. Under Article 1229, a rights holder has the right to prohibit others from using that right. Any unauthorised use of the right is deemed to be unlawful. Protection of the exclusive right entitles the owner to request one or more of the following forms of relief in the courts:

a Recognition of rights: in effect a declaration, this remedy entitles the rights holder to recognition that the rights in question have been infringed by the defending party.

b Termination of the activities: the rights holder is entitled to claim injunctive relief, both interim and permanent, to enjoin the infringing activities or the threat of infringing activities; in cases of interim relief, the rights holder may be required to post security with the court.

c Compensation: the infringer may be obliged to pay compensation to the rights holder, either in the form of compensation for damages or alternative relief in the form of compensation for infringement, for example, an accounting of profits or a reasonable royalty. In that case, the rights holder does not need to prove actual damage and can turn to the court for compensation from the infringer for each case of unlawful use.\(^\text{24}\)

d Reasonable compensation: As of 1 January 2015, a patentee in an infringement action relating to patents for inventions, utility models, or designs has been entitled to claim, in the alternative to damages or profits, payment of reasonable compensation: (1) in the amount from 10,000 to 5 million rubles; or (2) twice the value of the right of use (market value of the lawful right to use a patented invention, utility model or industrial design). This provision gives the court the right to award damages in its discretion without the requirement to prove the extent of damages suffered or profits obtained.

e Seizure: equipment and physical carriers associated with an infringement may be ordered to be removed from circulation and destroyed.

f Publication of decision: the rights holder may request publication of the decision declaring him or her to be the owner and the defendant the infringer.

g Bad faith: in cases in which the court recognises the infringement as having been in bad faith, protection may be available under anti-monopoly legislation as well as under Part IV of the Civil Code.

Under Article 1253, if a legal person – in other words, a corporation established under Russian law – repeatedly violates IP rights, including patent rights, the court may direct that the legal entity be dissolved. In the case of an individual, the court may direct that his or her activity as an individual entrepreneur be terminated. There is also a right to seek and recover attorney fees (albeit very nominal) and some expenses.\(^\text{25}\)

In addition, a general statute of limitations is three years ‘from the date a party has become aware or should have become aware of the infringement of its rights’.\(^\text{26}\) Therefore, no recovery of damages is available for any infringement committed more than three years prior to the filing of the statement of claim in an infringement action.\(^\text{27}\)

\(^{24}\) CCPC, Article 1252, §§1(3) and 3.

\(^{25}\) CCPC, Article 110.

\(^{26}\) Civil Code, Articles 196 and 200.

\(^{27}\) Civil Code, Article 199.
Generally speaking, the purpose of damages is to put the patent owner in the economic position it would have been in, in the absence of infringement. Damages under Russian law are compensatory and not punitive in nature. In Russia, courts do not have authority to grant punitive damages except in the limited context of bad faith, as described above.

Compensation in the form of damages includes the expenses that the person whose right was violated has incurred, or must incur to reinstate the right that was violated, or the loss or harm to property (actual damage). Compensation also includes income not received that this person would have received under the usual conditions of civil commerce if his or her right had not been violated (lost profits). If the infringing party has gained any profits resulting from unauthorised use of a patent, the patentee may claim lost profits in the amount not less than such infringer’s profits.  

Pre judgment interest is not available in Russia. Post-judgment interest is not specifically provided for as a remedy available to a plaintiff under the Civil Code. To claim such relief, a plaintiff would have to reapply to the court for additional compensation based on a claim of further damage incurred by reason of nonpayment of the original award. It is rarely obtained in practice.

**Attorneys’ fees**

To be eligible for an award of reasonable attorneys’ fees, a party must provide the documents showing actual payment of the fees. The award of attorneys’ fees is a discretionary determination by the court. More and more frequently, the court is exercising its discretion more liberally. Although the average award might fall within the range of US$5,000–10,000 for the successful party, there have been recent awards as high as US$35,000.

**Permanent injunction**

The most valuable outcome for a plaintiff in a patent infringement action is the permanent injunction to which the patent holder is entitled under Article 1229 should infringement be found. Enforcement against the defendant is highly effective because a defendant would face possible criminal sanctions if the injunction were simply ignored. In cases involving private individuals, they could elude the authorities by moving away or leaving the country, as is the case in any country.

**Criminal sanctions**

Article 147 of the Criminal Code provides criminal sanctions for patent infringement that resulted in significant harm to the patentee or that has been committed by a group in conspiracy or by an organised group. The sanctions include a fine up to US$10,000, compulsory labour for up to five years, or imprisonment.

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28 Civil Code, Article 15.
29 CCPC, Article 183.
VI OTHER TYPES OF PATENT PROCEEDING

Compulsory licences are available to applicants if they can demonstrate either that the patentee is not practicing the invention in Russia or that the owner of a second patent cannot practice the second invention without infringing an earlier patent. This is often referred to as a compulsory licence for a second dependent invention.

VII OUTLOOK

In 2019 the Supreme Court released a very comprehensive Resolution Concerning the use of Part IV of the Civil Code. This is a comprehensive document that touches upon many forms of intellectual property, including patents. For patents, it deals with employee remuneration and the right of inspection. However, the Resolution does not affect fundamental principles.
Chapter 20

SLOVENIA

Aleksandra Jemc Merc and Eva Gostiša

I OVERVIEW

The main act regulating patents in Slovenia is the Industrial Property Act (ZIL-1). The act contains substantive rules relating to industrial property rights, including patents, as well as some procedural rules specific to litigation concerning said rights.

Issues concerning patent infringement and invalidity, and owing to very limited possibilities of prosecution of patents in Slovenia, are resolved by the competent courts (i.e., the Ljubljana District Court in first instance, the Ljubljana High Court in the second instance, and the Supreme Court of the Republic of Slovenia, which deals with extraordinary legal remedies in patent matters).

In Slovenia, the volume of patent litigation cases is quite low, with only a couple of cases pending each year. The court practice concerning patent invalidity and enforcement issues has been evolving, mainly in the past decade, but it is still rather limited. On the other hand, as ZIL-1 also regulates other industrial property rights, certain court practice, for example, in trademark cases (the volume of which is a bit larger), may also be useful to patent cases.

II TYPES OF PATENT

Two main types of patent exist in Slovenia: a national patent and a European patent for which protection is sought also for Slovenia.

A national patent is applied for and granted by the Slovenian Intellectual Property Office (SIPO). Prior to the publication of a patent application, the SIPO examines if the invention (1) is *prima facie* new, involves an inventive steps and is industrially applicable and (2) is not excluded from patentability (exclusions based on public order and morality as well as of certain medical treatment). If SIPO is satisfied with the outcome of such examination, then it resolves that the application shall be published. A national patent application is generally published 18 months after the application date or after the date of priority (if sought). Grant of the patent is published at the same time.

The term of the patent is 20 years from the application date. During the term of the patent and at the latest until the end of the ninth year of patent validity, the patentee is required to present a document evidencing that the invention is fully compliant with the requirements for patent protection. Such document of evidence can be a European patent
granted for the same invention. If a European patent was not applied for, then the document of evidence may be a Slovenian translation of a patent for the same invention that was granted by any other institution holding a status of an international preliminary examining authority under the Patent Cooperation Treaty (PCT) or another patent office with which an applicable contract was entered into. Alternatively, the patentee can request SIPO to obtain such evidence from the mentioned authorities against a payment of applicable fees. If this document of evidence is not submitted the national patent expires at the end of the 10th year of its validity. If the document of evidence is submitted, then SIPO issues a decision declaring that the invention is fully compliant with the requirements for patent protection (such decision is also called a declaratory decision).

Before the declaratory decision is issued, although the patent is valid, its enforceability is limited. Based on such patent an infringement action may be started, but the court will stay the proceeding pending the issuance of the declaratory decision. After the declaratory decision is issued the proceeding may continue, but for the term between the patent grant and the issuance of the declaratory decision the only available relief is damages (which may even be reduced considering the circumstances).

On the other hand, Slovenia is a party to the European Patent Convention (the EPC) and as such European patents may also be valid in Slovenia. Under ZIL-1, a European patent confers upon its proprietor the same rights as a national patent, provided that the proprietor lodges a translation of claims of the European patent to SIPO in three months after the date of publication of grant of the European patent. Failure to submit the translation of claims within the time limit renders the European patent null and void in respect of Slovenia.

The 20-year term of validity of a patent can be extended for up to five years with a supplementary protection certificate (SPC). In that regard the EU regulations concerning SPCs for medicinal products and for plant protection products apply directly in Slovenia. SPC applications are lodged with and SPCs are granted by SIPO. Slovenian law provides that a SPC is valid up to five years. However, given the direct applicability of the EU regulations, a further six-month extension under the EU regulation on medicinal products for paediatric use is also available.

An extension to the patent term may also be available in case of war or similar extreme circumstances, for the duration of the circumstances, but no longer than five years.

For an invention that is novel, industrially applicable and achieved with a creative work, a short-term patent can be granted (excluded from such type of patentability are inventions of a process, plant type and animal variety). A short-term patent is valid for 10 years following the application date. Short-term patents are also granted based on a prima facie review of patentability. Generally, rules applicable to patents apply mutatis mutandis also to short-term patents, unless provided otherwise by the law. No declaratory decision is issued in respect of a short-term patent. There is no established court practice on what the mutatis mutandis application of rules regulating patents means, for example, in relation to enforcement of a short-term patent.

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III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

In Slovenia, the Ljubljana District Court has exclusive jurisdiction to decide on patent enforcement and invalidity actions as well as on interim injunction applications. Judges who are designated to hear patent cases are judges of the commercial division of the Ljubljana District Court; they are not designated solely to patent matters.

Prosecution of patents in Slovenia is very limited as SIPO does not undertake a full examination of national patents. Therefore, invalidity issues are raised and resolved mostly in litigation before the court.

ZIL-1 provides that any interested party may start an action for determination of nullity of a patent. The term ‘interested party’ is not defined in the law. While according to court practice a patent nullity action is not actio popularis (where anyone could file such claim) the bar for legal standing is not set high. For example, a competitor claiming it would be interested in using the invention will normally have legal standing. An entity sued for infringement will have legal standing for a nullity counteraction.

If there are several holders of the patent, a nullity action shall be brought against all of them; otherwise the lawsuit shall be rejected on that basis alone.\(^4\)

A nullity action may be started at any time during the patent term and also after the patent expired. If a nullity action relates to a European patent in respect of which an opposition was filed before the EPO, the court shall stay the proceeding pending a final decision by the EPO on the opposition. A patent cannot be amended in nullity proceedings.

A patent infringement action can be brought by the patentee or the holder of an exclusive licence (in the scope of its exclusive rights). A patent infringement action can be filed during the term of validity of the patent. A claim for damage can be filed up to three years after the patentee had learned about the damage and the perpetrator, but no more than five years after the damage had emerged.

As regards disclosure of evidence not held by the party who would benefit from it, such party may request the court to order its adversary in possession of a relevant item of evidence to submit it. The court then decides whether to not to issue such order. If the party does not follow the court order, it cannot be forced to submit the evidence; however, the court may consider that the content of the respective evidence is such as argued by the party requesting submission. For any evidence so requested and presented the court should, however, ensure confidentiality of confidential information, and that the court proceeding is not used in bad faith with the sole purpose of obtaining confidential information of the adversary.

ZIL-1 also provides for a possibility for a party to request a securing of evidence. This request may be lodged even before a main action is started. The applicant may request any type of evidence to be obtained (e.g., seizing of samples, review of documents, hearing of witnesses, etc.). The party requesting such measure shall show reasonably available evidence that it is a holder of a patent, that there is an infringement or an actual threat of infringement, and that the respective evidence will be destroyed or will not be available later. Perhaps mostly owing to the latter condition, the proceeding is in practice hardly ever used in patent

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\(^4\) Judgment of the Supreme Court of the Republic of Slovenia, No. III Ips 14/2001 dated 18 May 2001. The case related to trademarks, but given that the same provision of ZIL-1 regulates legal standing for patent and trademark nullity matters, the decision of the Supreme Court can also be applied to patent matters.

\(^5\) Judgment and resolution of the Ljubljana High Court, No. V Cpg 1150/2015 dated 16 September 2015.
litigation. Securing of evidence cannot be granted on the basis of a national patent, for which a declaratory decision was not issued yet. Further, the measure cannot be granted if more than three months have elapsed since the rightholder right learned about the alleged infringement.

In terms of the technical aspects of the case, no technical judges are involved in hearing patent cases. To assist with technical questions, the court can appoint an expert who provides responses to any questions raised by the court, and with the approval of the court, also the parties. Opinions of any experts engaged by the parties themselves are not regarded as expert opinions but are in terms of evidentiary value closer to statements of parties themselves. Nevertheless, presenting opinions via experts engaged by the parties may be useful in view of presenting such party’s technical arguments that are later assessed by the court-appointed expert. The parties are able to challenge the findings of the court-appointed expert, mainly by follow-up questions and hearing of the expert. The findings of the court-appointed expert will typically play an important role in the court’s decision.

A defendant in an infringement action may challenge the validity of a patent as a defence in the infringement proceedings. However, it shall do so by formally filing a counter action; raising the argument in infringement proceeding alone (irrespective of how well it is founded and supported by evidence) is insufficient.6 If a nullity and an infringement action are pending at the same time, they will initially be regarded as separate proceedings. It is at the court’s discretion whether to join the two proceedings into one or not. It is also at the court’s discretion whether to stay the infringement action pending the outcome of the nullity action.

The time it takes from filing a lawsuit to obtaining a first instance court judgment varies, but is usually about two to three years.

As regards preliminary relief, interim injunctions are available in relation to patent infringement. For an interim injunction to be issued the claimant needs to prove the degree of likelihood that (1) it is a holder of a European patent or a national patent, holding a declaratory decision of SIPO (see Section II), (2) there is infringement or actual threat of infringement, and (3) at least one of the following further conditions is fulfilled:

a danger exists that enforcing the claims of the patentee shall become impossible or considerably more difficult;7

b the interim injunction is necessary for the prevention of hardly repairable damages;

c the person allegedly infringing the patent would not suffer greater unfavourable consequences if it were established later that a granted interim injunction was unjustified, than the consequences suffered by the patent holder, if an interim injunction was not granted; or

d the person allegedly infringing the patent shall suffer only insignificant damages, if the interim injunction is granted.

6 The Ljubljana High Court with its judgment dated 31 August 2017 in matter No. V CPG 479/2017 concerning a trademark infringement decided that a nullity objection suffices and there is no need to file a counterclaim. It is yet to be seen whether the court practice will develop in this direction.

7 Owing to the nature of claims in interim injunction proceedings relating to patent infringement this particular condition, even though specifically mentioned as a possibility in ZIL-1, will typically not be of use (confirmed also by a High Court decision).
In addition to the above-mentioned conditions provided by ZIL-1, the courts also sometimes refer to a Constitutional Court decision, which (in a non-patent related matter) provided the basis for granting interim injunctions that in terms of claims match the claims of a final injunction (called in Slovenian legal theory and practice ‘regulatory interim injunctions’). The Constitutional Court, while at the time broadening the concept of interim injunctions, set a rather high standard for regulatory interim injunctions as they present a significant interference with the defendant’s rights before a main action was carried out. It seems that considering that in patent infringement matters a ‘regulatory interim injunction’ (claiming prohibition of patent infringement for the term of the interim injunction) is the most effective way to assert the rights conferred by a patent, the limited term of validity of a patent as well as specific provisions in ZIL-1 allowing for such interim injunctions, the standards from said Constitutional Court decision may be applicable by courts to patent matters, but in a less restrictive form.

General rules that regulate interim injunctions and that also apply mutatis mutandis to interim injunctions in patent matters unless provided otherwise by ZIL-1, offer a possibility to the claimant to provide security instead of proving the existence of conditions for an interim injunction. However, according to a High Court decision, such possibility is not available for patentees seeking preliminary relief that is equivalent to a final relief (such as prohibition of infringement).

Interim injunctions can be requested ex parte, but for the court to grant such request the applicant needs to show as likely that any delay in issuing the interim injunction would cause the applicant hardly reparable harm. Ex parte injunctions are rare in practice. On the other hand, there are also no protective letters or similar measures available to lower the risk of an ex parte interim injunction.

According to court practice, an interim injunction will not be available on the basis of a European patent that is formally valid but in respect of which there is serious doubt as regards its validity, most notably if the asserted European patent was revoked by the EPO Opposition Division, but such decision is not final yet. Judgments of the courts establishing the nullity of the same patent in Europe may also cast such doubt on the validity of the patent that the interim injunction may not be granted for this reason alone.

Appointing court-appointed experts in interim injunction proceedings is possible, but rare in practice. Therefore materials, such as opinions by experts engaged by the parties or judgments on the same issues by courts in Europe, may play a more significant role in interim injunction proceedings (where the court decides quickly and on the balance of probability) compared to main action proceedings (where the court needs to resolve all disputed issues by itself to a degree of persuasion).

In terms of timing, interim injunctions owing to patent infringement shall be applied for up to three months after the patentee had learned about the alleged infringement. It typically takes from a few weeks to a few months to obtain a decision on an interim injunction application.

There are no specific statutory provisions or any court practice with respect to the question if patentees can face liability for threatening infringement proceedings.

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9 Resolution of the Ljubljana High Court No. I Cpg 1014/2010 dated 16 September 2010.
10 For example, resolution of the Ljubljana High Court No. V Cpg 196/2018 dated 12 April 2018.
As regards costs of proceedings, the total cost of first instance proceedings on infringement or on validity (including stamp duty, attorney fees, court-appointed expert fees, and translation fees), varies, but it could typically be expected to be about €100,000 to €150,000. The recoverable cost varies depending mainly on the value of the dispute. If no monetary claims are asserted, the value of the dispute is determined by the plaintiff. For example, at a value of dispute of €500,000, the winning party could typically recover about €20,000 to €40,000 in costs.

Slovenia has not yet implemented the decision of the Court of Justice of the European Union No. C-57/15, according to which the amounts of attorney fees to be reimbursed in intellectual property matters need to be reasonable; the current levels of recoverable attorney fees seem too low to be deemed reasonable. There is also no published court practice on the matter so far.

IV SUBSTANTIVE LAW

i Infringement

In regulating the rights conferred by a patent, ZIL-1 follows the wording of Article 28 of the Agreement on Trade-Related Aspects of Intellectual Property Rights. According to ZIL-1, a patent confers on the patentee the following exclusive rights:

a where a patent protects a product: to prevent third parties, who do not have the consent of the patentee, from manufacturing, using, offering for sale, selling or for these purposes importing the relevant product; and

b where a patent protects a process: to prevent third parties, who do not have the consent of the patent holder, from using the process and offering for sale, selling or for these purposes importing the product that is obtained directly by this process.

ZIL-1 contains very limited provisions that indicate a person who contributed to the infringement may also be liable for infringement. Although there are no specific statutory provisions in relation to indirect patent infringement, there is some guidance from the court on the matter. In a first instance court decision of 2015 (in a main infringement action which related to a patent with a Swiss type claim), which was confirmed by a High Court decision, the courts took a position that a patentee may also seek prohibition of indirect infringement of its patent. The courts came to such conclusion by looking at the respective regulations in some other countries and by seeking analogies with other areas (civil and criminal) of Slovenian law. Further, according to the general principles of liability for damages, the parties who do not directly infringe rights but nevertheless make contributions to the infringing acts of others are jointly and severally with the infringers liable for damages. There are no specific provisions, but it seems that the patentee can also seek injunctions against several persons who act together to infringe a patent.

As Slovenia is party to the EPC, the Protocol on the Interpretation of Article 69 EPC is applicable also in Slovenia. The courts do take the interpretation guidance from said Protocol into account, including the doctrine of equivalents. According to a recent guidance from the Ljubljana High Court (in a case that related to construction of a snowboard), an element

should be considered equivalent to the element of the invention if it has the same technical
effect or resolves the same technical problem in the same way as the respective element of the
invention, meaning that it has essentially the same function and that an expert with his or her
common general knowledge would be able to identify the allegedly equivalent element as an
alternative working in the same way.

There are no specific provisions in ZIL-1 on the potential personal liability of directors
or officers of infringing companies. Although personal liability could in certain circumstances
be construed from general rules on liability for damages, there seem to have been no cases
finding for such personal liability yet.

ii Invalidity and other defences
A patent is declared null if:

- the invention lacks novelty (content of the prior filed but not yet published patent
  applications for Slovenian national patents, applications for European patents that
designate Slovenia, and international applications that were initially filed under the
Patent Cooperation Treaty (PCT) but that SIPO received as an elected Office under
Article 39 of the PCT, is novelty destroying);
- the invention lacks inventive step (i.e., it is obvious to a person skilled in the art –
content of the applications from previous paragraph is not taken into account when
assessing inventive step);
- the invention lacks industrial applicability (i.e., the subject matter of the invention
cannot be produced or used in any commercial activity);
- the subject matter of the invention was not patentable; a patent cannot be granted for
an invention, the use of which is contrary to public policy or morality, or of surgical
or diagnostic methods or methods of treatment practised directly on a living human
or animal body, with the exception of inventions relating to products, in particular
substances or compositions for use in any of these methods. A short-term patent cannot
be granted for an invention of a process or plant or animal varieties;
- the patent description does not disclose the invention in a manner sufficiently clear and
complete for it to be carried out by a person skilled in the art to which the invention
relates; or
- the content of the protection extends beyond the content of the first received application
or, if the patent was granted on a divisional application, beyond the content of the
initial application.

According to the Ljubljana High Court resolution¹³, the test of novelty is carried out by
individual comparison whereby the subject matter of the patent is compared with the whole
contents of each individual information. The decisive point is what an expert can directly
find out from a publication. In assessing the content of information in the prior art, the
(fictitious) knowledge of the expert plays a decisive role.

In addition to challenges to validity, other defences to infringement claims exist, such
as private and non-commercial use; research and any type of testing regardless of their goal;
individual preparation of medicinal product in pharmacies in accordance with doctor’s orders
or prescription; certain uses of inventions in ships and aircraft temporarily located in Slovenia.

A Bolar-type defence is provided by the Medicinal Products Act, according to which the carrying out of studies necessary to fulfil the requirements of said act and fulfilment of other requirements that relate to obtaining a marketing authorisation for medicinal products shall not be considered as infringement of patent or SPC for the medicinal product.

To defend against infringement, the defendant may also argue prior use. A person is entitled to continue to use the patented invention, if it used it, or prepared for its use, in good faith in Slovenia prior to the patent application date or priority date.

In addition, exhaustion of rights can also be claimed as a defence. According to ZIL-1 exhaustion relates to actions in Slovenia in relation to a product that was put on the market in Slovenia by or with the consent of the patentee (at this point ZIL-1 allows for exceptions but keeps the rule on a very general level). While ZIL-1 does not specifically regulate EU-/EEA-wide exhaustion, it does provide that exhaustion of rights conferred by a patent may extend beyond Slovenia if that is in accordance with an international treaty that is binding on Slovenia.

On the other hand, lack of knowledge is not a defence against patent infringement.

V FINAL REMEDIES FOR INFRINGEMENT

The patentee or exclusive licence holder can file a lawsuit against the infringer and request one or several of the below non-monetary remedies:

- a prohibition of present and future infringing actions;
- b recall of objects of infringement from the economic flows (taking into consideration bona fide rights of third parties);
- c elimination of the situation occurred with the infringement;
- d irrevocable removal of objects of infringement from economic fluctuation;
- e destroying of objects of infringement;
- f destroying of the objects used for infringement acts, if such objects are exclusively or predominantly intended or used for the infringement and are owned by the person infringing the rights;
- g delivery of the objects of infringement to the plaintiff, who pays the manufacturing costs; and
- h publication of the judgment.

When deciding on the claims (b) through (g) above the court takes into consideration all circumstances of the case, in particular the proportionality between the infringement act and the claim and the interests of effective protection of patentee’s rights.

Damages can be sought. The general rules for liability for damages also apply to damages in patent infringement cases. With respect to the amount of damages sought, the patentee can claim actual loss suffered as well as lost profit. Alternatively, the patentee can claim damages in the amount of agreed or usual royalties. There is no statutory guidance in relation to the licence analogy and there is very limited court practice on damages for patent infringement. The Ljubljana High Court with its judgment and resolution in a patent infringement matter set the damages by using the licence analogy to be 4 per cent of sales, as requested by the plaintiff.

14 Medicinal Products Act (Official Gazette of the Republic of Slovenia No. 17/2014; in Slovenian: Zakon o zdravilih, abbreviated as ZZdr-2).
During the proceedings, the defendant did not challenge this percentage. The provisions of ZIL-1 on final remedies for infringement apply also to other industrial property rights, and there is more court practice on damages for trademark infringement, mainly calculated by way of licence analogy. Those might also be of some limited use in patent infringement matters.

An appeal automatically stays the enforceability of the final injunctions awarded by the judgment.

VI OTHER TYPES OF PATENT PROCEEDING

There are certain other types of proceedings relating to patents available in Slovenia.

In terms of challenge of ownership, an inventor or his or her successor in title can start an action before the court requesting to be declared as the patent holder, if the patent was granted to someone who was not the inventor or its legal successor. Such action can be started at any time during the term of the patent.

Further, a compulsory licence may be requested before the court. According to ZIL-1, a compulsory licence shall be granted if that is in the public interest or if the patentee or licensee abuses the patent in a manner that it restricts competition contrary to the provisions of the law. A compulsory licence may be granted provided that the claimant had tried to enter into a licence agreement with the patentee under reasonable business conditions and that such efforts, given reasonable time, were unsuccessful. Any granted compulsory licence shall be limited in scope and duration with respect to its purpose, shall generally be non-transferable and non-exclusive and its purpose will be mainly to supply the Slovenian market. A royalty to the patentee will also be set. There is, however, no publicly available court practice on compulsory licenses.

Customs proceedings based on the EU Regulation 608/2013 concerning customs enforcement of intellectual property rights can be used in relation to patent infringement. However although patentees sometimes do submit applications for actions by the competent customs authority (the Slovenian Financial Administration) in relation to their patents, seizures for patent infringement are very rare in practice. Said procedures are more common for trademark infringement.

In Slovenia there are no proceedings similar to declarations of non-infringement.

Patent infringement can also constitute a criminal offence and legal entities can be found liable for such offence. A legal entity can be fined for the criminal offence of patent infringement with a fine of up to €500,000 or hundredfold the amount of damage caused or benefit obtained.

VII APPEAL

The right to appeal a first instance court judgment is a constitutional right. Therefore, any first instance court judgment also in patent infringement or invalidity matters is open to appeal. Grounds for appeal are rather broad as appeal can be brought for incorrect finding of facts and incorrect use of substantive law as well as for procedural breaches. An appeal can be lodged within 30 days of service of the judgment on the respective party. In turn, the adversary can lodge a response to the appeal, in 30 days upon service of the appeal.

The appeal is decided by the Ljubljana High Court. Though possible, the High Court typically does not schedule oral hearings; rather it decides on the matter on the basis of the written appeal and the response to the appeal.

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Adducing new evidence is generally not possible in appeal proceedings. In the appeal a party may only propose new evidence if it can show that it was unable to propose it to the court before through no fault of its own.

The time to resolve the appeal varies, but it typically takes up to a year. The High Court may (1) decide on the matter with a final judgment, either denying the appeal or granting the appeal and changing the first instance court judgment, or (2) revoke the first instance court judgment and return the matter for a retrial to the first instance court. A judgment following retrial is again open to appeal.

As regards costs of proceedings, the total cost of appeal on infringement or on validity (which typically includes stamp duty and attorney fees) varies, but would typically be about €20,000. The recoverable cost varies, depending mainly on the value of the dispute. For example, at a value of dispute of €500,000, the winning party could typically recover about €8,000 in costs.

A change in the law in 2017 abolished the automatic (previously available for any commercial disputes over €200,000) right to lodge further (i.e., an extraordinary) legal remedy called ‘revision’. Under new regulation in respect of a final judgment of the High Court the unsuccessful party may only request the Supreme Court of the Republic of Slovenia for permission to lodge a revision. The Supreme Court will permit the revision if it is well founded and mainly to establish or unify the court practice on legal questions. There is a two-step process in that regard. In the first step, the unsuccessful party may ask for permission to lodge the revision and if permission is granted, then the party may lodge the revision in the scope in which it was permitted. The Supreme Court decides on a revision about a year after the revision was lodged.

**VIII THE YEAR IN REVIEW**

Over the past 18 months, two High Court decisions (both in interim injunction proceedings) were issued and published.

One of the High Court decisions\(^\text{16}\) is noteworthy for the fact that for the first time it provided some guidance on what is to be considered an equivalent. It is also noteworthy for its decision that in retrial, the first instance court shall appoint an expert to determine whether it is likely that the patent was infringed with an equivalent. In recent years, experts have typically not been appointed in interim injunction proceedings relating to patents.

Another High Court decision\(^\text{17}\) confirmed the more recent court practice that invalidity defence can be raised in interim injunction proceedings relating to a granted European patent, for example, if the patent has been revoked with a decision of the EPO Opposition Division, in relation to which an appeal is still pending.

**IX OUTLOOK**

There are currently no particular hot topics developing in Slovenia and there is also no published forthcoming legislation significantly affecting patent litigation.

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\(^{16}\) Resolution of Ljubljana High Court No. V Cpg 894/2017 dated 23 November 2017.

\(^{17}\) Resolution of Ljubljana High Court No. V Cpg 196/2018 dated 12 April 2018.
I OVERVIEW

With the coming into force of Law 24/2015 on Patents (the new Patents Act) on 1 April 2017, a new era began in the field of patents in Spain.

As regards litigation, with approximately 50 patent cases per year, Spain still lags far behind other European jurisdictions such as Germany, where courts deal with hundreds of patent cases every year. Notwithstanding this, over the past decade the quality of judgments has increased dramatically, due to the specialisation of a small number of commercial courts that deal with patent matters.

II TYPES OF PATENTS

In Spain, three types of patents are available: European patents, Spanish patents and utility models.

European patents are granted by the European Patent Office (EPO) in Munich. The main advantage of this route is that one single application filed before the EPO results in a patent with effects in all countries that are party to the European Patent Convention (EPC) designated by the applicant. Once granted, this patent is decomposed into as many national patents as the applicant may have chosen. According to Articles 2.2 and 64 of the EPC, European patents, once granted, provide the same rights and obligations as a Spanish national patent.

Spanish patents are granted by the Spanish Patent and Trademark Office (SPTO). Since 1 April 2017, under the new Patents Act, all Spanish patents are examined. This has been a dramatic change, as under the old law substantive examination was optional. In practice, less than 10 per cent of Spanish patents were examined. As a result, the quality of the vast majority of Spanish patents was questionable. One of the main purposes of the new Patents Act is to increase the quality of Spanish patents, which may become an attractive and cost-effective alternative to the planned European patent with unitary effect.

Utility models are also granted by the SPTO. The new Patents Act modernised utility models to make them the natural alternative to the former non-examined Spanish patents. Unlike Spanish patents, utility models will not be examined. Under the new Patents Act, the main difference with respect to Spanish patents is that the threshold of inventive activity is lower (‘very obvious’ instead of ‘obvious’). Another salient feature of the new Patents Act is that, since 1 April 2017, utility models have been available for inventions in all fields of
technology. The only exceptions are process inventions and those that deal with biological matter and pharmaceutical substances and compositions. The wording of these exceptions, which is very unclear, is an invitation to litigate. It is hoped that, like in Germany, courts will make a restrictive interpretation of these exceptions. Also, it is doubtful whether the discrimination of inventions in some fields of technology (in particular, pharmaceutical inventions) is compatible with the obligations of protection derived from the international treaties to which Spain is a party.

Finally, for the time being, Spain is not taking part in the initiative to create a ‘European patent with unitary effect’ and a Unified Patent Court. However, Spanish companies will of course be able to obtain this type of patent, in the same way that nationals of countries that are not parties to the EPC are able to obtain European patents.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Procedural aspects

Which courts deal with patent cases?

One of the main developments of the past few years has been the dramatic reduction of the number of courts with jurisdiction to deal with patent cases. This trend began in 1993, when the Barcelona Court of Appeal decided that all intellectual property matters would be decided by its Section 15. This resulted in the specialisation of the judges who handled cases assigned to this Section and, as a result, the quality of the judgments increased. The success of Section 15 inspired the creation of commercial courts in 2004. These are first-instance courts with jurisdiction on commercial matters (intellectual property, insurance law, transport law, company law, bankruptcy law, etc). Some years later, the commercial courts in Barcelona decided to dedicate three courts to specialise in patent matters. As a result, only commercial courts numbers 1, 4 and 5 have jurisdiction to deal with patent cases.

Following the example of the Barcelona commercial courts, a small number of commercial courts with jurisdiction to deal with patent cases have been established in other Spanish cities, such as Madrid. Also, the Madrid Court of Appeal established a specific section (Section 28) to decide intellectual property cases, which has also gained great prestige in recent years. The vast majority of cases are filed in Barcelona, where the courts are quicker and more experienced. ‘Forum shopping’ (choosing the venue) is possible, as the law allows the patent owner to file the action before the courts of any region where the acts of infringement may have caused effects.

Under Spanish law, patent infringement is a criminal offence. However, criminal cases are very rare. This is because Criminal Courts do not have any experience in patent matters; they are extremely slow and the threshold of evidence required is higher than before commercial courts. As a result, the criminal route is only used in exceptionally clear-cut cases or when the facts as set out entail additional criminal offences such as crimes against public health or against consumers. The typical case would be an action filed against a defendant that has marketed a substance to prevent diseases in plants that is patented by a third party, without obtaining the necessary authorisation from the health authorities.

Threat of patent infringement

According to Spanish Courts, a ‘threat’ of patent infringement may be proved with a variety of indicia. For example, in the case of pharmaceutical products, obtaining a marketing authorisation and price from the regulatory agencies several months ahead of the expiry
date of the relevant patent may be considered a ‘threat’ of patent infringement. The evidence would be further reinforced if the patentee sends a ‘warning letter’ and the addressee does not undertake to refrain from launching its product into the market all the while the patent remains in force.

Under Spanish law, a ‘warning letter’ does not normally expose the patent owner to any liability, provided that the content of the warning letter is accurate. In fact, sending a warning letter is mandatory for the purpose of retaining the ability to claim damages against third parties acting in good faith who are neither manufacturers nor importers.

By contrast, in situations where a patent owner has included false statements in the warning letter, the third party affected could have a course of action under the 1991 Act on Unfair Competition.

**Infringement proceedings**

Spain follows a front-loaded system, which means that the initial complaint must contain all the facts and points of law that the patent owner plans to rely on. Unlike in other jurisdictions, these arguments cannot be supplemented at a later stage. Therefore, a patent owner should not file an infringement action until all preparatory work has been done.

General discovery (i.e., United States-type ‘fishing expeditions’) is not available in Spain. However, limited disclosure (i.e., the disclosure of specific documents in possession of the other party or a third party) may be ordered by a court, if the applicant identifies the documents to be disclosed and the court considers that the applicant needs the disclosure of such documents for the purpose of proving a relevant fact.

Also, prior to filing a patent infringement action, the patent owner may file an application for Proceedings for the Verification of Facts, an inspection procedure that is very similar to the French *saisie-contrafaçon*. The main difference is that Spanish courts require a higher threshold of *prima facie* evidence of infringement before ordering this type of *ex parte* inspection.

One salient feature of Spanish patent litigation is that experts are key. They are examined and cross-examined at the main hearing. However, in contrast to England, for example, where the interrogatory of an expert may last several days, in Spain it is very unusual for an expert to be questioned for more than two hours (one hour per party). A case normally requires the involvement of one or two experts per party.

Moving on to the procedure of patent infringement proceedings, these consist of two distinct stages. In the first, the ‘declaratory’ stage, which ends with the judgment, and any infringement and validity issues will be determined. As regards damages, according to the new Patents Act, damages will be calculated during the second ‘execution’ stage. The main milestones of the declaratory stage are set out below, in order of occurrence:

- complaint;
- defence and counterclaim;
- reply to the counterclaim;
- preliminary hearing; and
- trial.

**The commencement of an action: complaint**

Court proceedings for patent infringement and for patent revocation are begun by the filing of a complaint. As mentioned, all the facts and points of law must be set out in the initial complaint. This must also include all documents and expert opinions that the plaintiff plans
to use to support its claims. If the plaintiff considers that, for the purpose of deciding the case, it would be advisable for the court to appoint an independent expert, this must also be requested in the initial complaint.

It can thus be seen that the preparation of a complaint is an extensive exercise. Discussions with in-house business staff, together with technical experts and, often, independent experts are usually required.

The statement of defence and counterclaim

Within two months of the service upon the defendant of the complaint, the defendant must submit its statement of defence and, if appropriate, its counterclaim. The statement of defence should respond to the detailed allegations made in the complaint. In patent infringement actions, the statement of defence will often include either:

a an allegation of the invalidity of the patent in suit, but without the judge having to declare the revocation of the patent (in which case the patent holder will have eight days, counting from the date on which the statement of defence is served, to request the judge to address these allegations as a counterclaim); or

b a counterclaim seeking the revocation of the patent in suit. The format of the counterclaim will be similar to that of the complaint.

Expert opinions must, in principle, be filed along with the statement of defence (and, where applicable, the counterclaim).

The reply to the counterclaim

If the statement of defence includes a counterclaim, then, within two months of its service upon the plaintiff, the plaintiff must issue a reply to the counterclaim, setting out all the arguments upon which it intends to rely in respect of the validity of the patent in suit.

Expert opinions must, in principle, be filed along with the reply to the counterclaim.

Preliminary hearing

After the defendant has submitted its statement of defence to the complaint, or the plaintiff its reply to the defendant’s counterclaim, as the case may be, the judge will call the parties to attend what is termed the ‘preliminary hearing’ (i.e., directions hearing).

At the preliminary hearing, the judge first encourages the parties to reach an amicable settlement, which is very rarely reached in practice.

If no settlement is reached, the judge then examines any formal defects that might prevent him or her from handing down a judgment on the merits of the case at a later stage, such as the lack of capacity or representation of the parties, res judicata or lis pendens or other defects regarding the procedure used or the way in which the complaint has been drafted.

After this, the parties are entitled to complement the allegations made in their initial writs and make new allegations in relation to any relevant facts that occurred after the complaint or the statement of defence was filed. If the parties disagree on the facts of the case, which is normally the case, they will be invited to submit evidence.

If that is the case, the parties will then be invited to propose all evidence they wish to use to support their claims and the judge will decide, for each piece of evidence, whether to admit it or not. The admissibility of the evidence proposed by each party is one of the key aspects to be decided at the preliminary hearing.

At the end of the preliminary hearing, the judge sets a date for the trial.
**Trial**
The purpose of the trial will be to examine the evidence submitted by the parties, including the cross-examination of the parties, witnesses and experts.

Once the evidence has been examined, the parties give their concluding remarks verbally on the disputed facts, as well as their closing arguments on the points of law on which their claims, which cannot be altered at this point, are based.

**Judgment**
Judgment is normally handed down within two to six months after the trial, depending on the workload of the court.

**Provisional enforcement of the judgment**
Under Spanish law, it is possible to apply for the provisional enforcement of the judgment, which should be granted automatically by the court unless one of the limited exceptions set out in the Spanish Civil Procedure Act applies. One of these exceptions is a judgment declaring the invalidity of a patent, which cannot be provisionally enforced.

**Costs**
The basic rule is that the ‘loser pays’ the legal costs of the winner, unless the judge considers that exceptional circumstances exist and decides otherwise. In its judgment of 28 February 2018, the Barcelona Court of Appeal (Section 15) highlighted that if the judge deviates from the general rule, he or she must explain and justify the reasons.

**Duration of main proceedings**
First-instance proceedings before the commercial courts usually last between approximately one and one-and-a-half years.

Court of appeal proceedings may last one to two years.

Supreme Court proceedings may last three to six years. However, many cases come to an end at the second-instance level, because the Supreme Court is reluctant to hear appeals in patent cases.

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<tr>
<th>Court of first instance</th>
<th>1–1.5 years</th>
<th>Aggregate</th>
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<tr>
<td>Court of appeal</td>
<td>1–2 years</td>
<td>2–3.5 years</td>
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<tr>
<td>Supreme Court</td>
<td>3–6 years</td>
<td>5–9.5 years</td>
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**Preliminary relief**

**Introduction**
According to Spanish law, the patent holder whose rights are being infringed, or might be infringed imminently, can apply for the interim injunctions necessary to secure the future enforcement of the favourable judgment to be obtained in the main proceedings.

According to the Spanish Civil Procedure Act, interim injunctions must be applied for, in normal circumstances, when the main claim is filed. Applications filed before the main action will only be accepted if the applicant proves reasons of urgency or necessity. On the other hand, applications filed after the main claim will only be accepted when such application is based on facts or circumstances that justify the request at such time.
The interim injunctions proceedings progress independently of the main proceedings, with their own self-contained procedure. The application for an interim injunction is normally made inter partes, namely, with notice to the other party. However, when the applicant proves special reasons of urgency or that hearing the other party might frustrate the purpose of the interim injunction, the court is entitled to order such interim injunctions within the following five days, without hearing the defendant, who is then entitled to file an opposition against the interim injunctions ordered. For example, on 17 July 2019, the Barcelona Patent Court ordered a preliminary injunction ex parte because the defendant had already announced the launch of its product into the market.

The court order containing the interim injunction, if granted, may order the defendant to do the following, inter alia:

- to cease any act that infringes the applicant’s patent rights, or prohibit it, where there are reasonable signs that it is about to begin immediately;
- to seize infringing items;
- to deposit a bond, guaranteeing payment of the damage already caused to the patent holder; and
- to record appropriate notices at the Patent Office to alert third parties of the existence of legal proceedings.

Requirements for obtaining interim injunctions

The requirements for obtaining an interim injunction, the fulfilment of which must be demonstrated by the applicant, are as follows.

- **Fumus boni iuris** (prima facie evidence of infringement): the applicant must have strong prima facie evidence supporting its application. Normally, this is proved by obtaining expert opinions that set out the reasons that lead an expert in the field to conclude that the defendant’s product falls within the scope of the allegedly infringed patent.

- **Periculum in mora** (danger in the delay): the applicant must show that circumstances could occur during the main action that, unless an interim injunction is ordered, could prevent a favourable judgment or at least jeopardise the enforcement thereof. Abundant case law and legal doctrine have declared that in specific cases of patent infringement, a danger in the delay derives from the mere continuity of the infringing acts that are hoped to be avoided. In other words, this requirement is normally met where there is a well-founded risk that the conduct will be repeated and will persist while the main proceedings are being heard.

- The posting of a bond in order to compensate the defendant for any damages that the interim injunction might cause, and specifying the amount of such bond. This amount will vary depending on the circumstances of the case. To date, in patent cases, an amount of approximately €1 million per defendant is normally considered sufficient by the Spanish courts, although higher amounts are requested in some cases.

Amendment of the patent

The patent owner is entitled to amend or limit its patent during court proceedings (as a main or auxiliary request), filing the set or sets of claims and their justification along with its statement of defence, reply to the revocation counterclaim or reply to the revocation plea. In cases where the patent holder has brought an infringement action, it must justify (and, where applicable, prove) how the amendments affect such action.
The court will give the other party leave to make allegations about the requested amendment or limitation, so that it can maintain or modify its requests in light of the same. The two-month period allowed for this will begin as from the date of receipt of the request. Notwithstanding the above, when the patent is amended outside of the court proceedings while such proceedings are under way, the holder can request that the patent thus amended be considered as the basis for the proceedings. In such cases, the court will grant the other parties the possibility to make allegations. Once the request for an amendment or limitation has been filed, the court will inform the Spanish Patent and Trademark Office so that the request is recorded in the form of a caveat or preventive registration. Once there is a final decision about the patent amendment, the Office will be notified ex officio so that it is reflected in the registry and, where applicable, the patent is modified.

An alternative route for amending a patent after it has been granted is filing an application before the SPTO. One of the highlights of the past year is that the SPTO has accepted this type of administrative amendments not only in the case of Spanish patents but also in the case of European patents.

IV SUBSTANTIVE LAW

i Locus standi

The patent holder and the exclusive licensee whose licence has been registered with the SPTO have locus standi to initiate infringement actions. Where the patent is jointly owned by several persons, any of them will have locus standi, although the party filing the complaint is obliged to inform the other co-owners so that they may take part in the proceedings. Exclusive licensees also have locus standi when they litigate together with the patent holder.

ii Acts of infringement

According to Article 59 of the new Patents Act:

1. The patent grants its holder the right to prevent any third party, acting without its consent, from:
   (a) manufacturing, offering for sale, introducing into trade or using a product protected by the patent or the importation or possession of the same for the above purposes.
   (b) using a process protected by the patent or offering such use, when the third party is aware, or circumstances make it obvious, that the use of the process is prohibited without the consent of the patent holder.
   (c) offering for sale, introducing into trade or using the product directly obtained by the process protected by the patent or the importation or possession of such product for any of the above purposes.

2. When the subject of the patent is biological matter that, due to the invention, has certain properties, the rights granted by the patent will extend to any biological matter obtained from the patented biological matter by reproduction or multiplication, in an identical or differentiated manner, that has the same properties.

3. When the subject of the patent is a process that facilitates the production of biological matter that, due to the invention, possesses certain properties, the rights granted by the patent will cover the biological matter directly obtained from the patented process and any other biological matter obtained from the same via reproduction or multiplication, in an identical or differentiated manner, and that possesses the same properties.
4. When the subject of the patent is a product containing genetic information or consisting of genetic information, the rights granted by the patent will, notwithstanding Section 4 of article 5, cover all subject matter in which the product is included and in which it is contained and the genetic information exercises its function.

These are the typical acts that constitute ‘direct’ patent infringement.

In addition, Article 69 addresses the acts that constitute ‘indirect’ patent infringement:

1. When a product is introduced into Spain in relation to which there is a process patent for the manufacture of the same, the holder of the patent will have the same rights in relation to the introduced product that the law grants in relation to products manufactured in Spain.

2. If the subject of a patent is a process for the manufacture of new products or substances, it is assumed, in the absence of evidence to the contrary, that any product or substance with the same characteristics has been obtained using the patented process.

3. When performing the evidentiary measures envisaged in the foregoing section, account will be taken of the legitimate interests of the defendant with regard to the protection of its manufacturing and business secrets.

iii Preparatory acts

Preparatory acts may be prohibited if it is shown that, otherwise, an act of infringement may take place imminently. This imminence requirement was introduced by the law that implemented the Enforcement Directive (i.e., EU Directive 2004/48) into Spanish law. Spanish courts have interpreted the meaning of ‘imminence’ on a case-by-case basis. According to the Ruling of 10 June 2013 (No. 81/2013) from the Barcelona Court of Appeal (Section 15), there is imminence if the launch of an allegedly infringing product is likely to take place within a few months. For example, in the case of pharmaceutical products, if a third party has obtained marketing authorisation and price, these are normally sufficient indicia for the purpose of showing that there is an imminent threat of infringement.

iv Limitation period

Civil actions in respect of patent infringement may be brought up to five years from the date on which the action could have first been brought (i.e., the date on which the patent holder discovered the infringement). If the patentee waits longer than this five-year period, it will lose its cause of action against the infringer, who will be entitled to use the invention with impunity.

However, the prevailing view of the Spanish courts is that in the case of continuing acts of infringement (e.g., sales of the product over a continuous period of time), the five-year period must be calculated from the date when the last infringing act took place.

v Liability for patent infringement

The persons liable for patent infringement are normally the ones who carry out any of the direct or indirect acts of patent infringement set out in Articles 59 and 60 of Spain’s new Patents Act, as explained above. Unlike in other jurisdictions, Spanish courts have not yet had the opportunity to address the situation of a person located outside Spain who induces a third party to infringe the patent in Spain, or who supplies a product knowing that it will be used for the purpose of infringing a patent in Spain.
As regards directors, they are not normally liable for patent infringement by their companies. However, there may be cases where they could be held liable, particularly in the context of criminal proceedings.

vi Interpretation of claims
Spanish Courts follow very closely the case law from the board of appeal of the EPO. They consider that claims must be interpreted in the same way in the context of infringement as in the context of validity. As Spain is party to the EPC, Spanish courts follow the Protocol of Interpretation of Article 69 of the EPC.

As regards the ‘doctrine of equivalents’, some years ago the Barcelona Court of Appeal (Section 15) imported the three-question test that the English courts crafted in Catnic. This landmark case concluded with the judgment of 10 May 2011 (Olanzapine) of the Supreme Court (en banc), where this test was endorsed. However, the recent judgment of 12 July 2017 (Pemetrexed) of the UK Supreme Court, which has substantially updated the old three-question test (in particular, by changing the second question), has sparked the debate as to which test will be applied by Spanish courts in future cases: the ‘old’ English test or the ‘new’ English test.

Common sense would suggest that they should follow a path along the lines of the ‘new’ English test, as one of the objectives pursued by the UK Supreme Court when updating the rather outdated ‘old’ test has been to try to align the doctrine of equivalents throughout Europe. It would be odd for Spanish courts to continue to follow a test that the English courts have just been required to abandon. In this regard, it will be interesting to see if Spanish courts will continue to follow the file wrapper estoppel doctrine, of which the UK Supreme Court does not appear to be too fond, as illustrated by this judgment.

On a different note, in its judgment of 19 April 2018, the Barcelona Court of Appeal (Section 15) declared that unless the reasons for alleging infringement under the doctrine of equivalents have been spelled out in the initial complaint, they cannot be introduced at a later stage.

vii Defences that a defendant may raise

Substantive law aspects
Where a party seeks revocation of a patent on the grounds that it is not valid (i.e., a petitioner for revocation or a counterclaiming defendant in an infringement action), that party’s invalidity complaint or statement of defence, as appropriate, must again detail the factual and legal arguments used to support their claim. A patent may be considered invalid if:

a any of the patentability requirements are not met (i.e., lack of novelty, obviousness and lack of industrial applicability);
b the description is not clear and comprehensive enough for the patent to be executed by a person skilled in the art (i.e., lack of enablement);
c the patent discloses matter that was not disclosed in the application as it was initially filed (i.e., added matter);
d the protection conferred by the patent after its granting has been extended; or
e the patent holder is not entitled to the patent, in other words, it is not the inventor or its legal successor. However, only the party actually entitled to the patent can rely on this ground.

In practice, the invalidity ground most frequently adduced is lack of inventive activity.
The most frequent defence is challenging the validity of the patent. In 26 years in this profession, this author has been involved in only two cases where the validity of the patent was not challenged. The statistics would probably be different if losing an invalidity action entailed significant costs, as in Germany, for example.

In Spain, any person has locus standi to challenge the validity of a patent before Spanish courts. At the suggestion of the Spanish competition (i.e., antitrust) authorities, when the new Patents Act was debated, the classical ‘legitimate interest’ requirement was abandoned. As a result, any person may file a revocation action as a ‘stand-alone’ action. Also, a person sued for patent infringement may file a revocation counterclaim in the statement of defence. Alternatively, it may adduce the invalidity of the patent as a ‘defence’. The main difference is that in the latter case, if the defence succeeds, the infringement action is dismissed but the patent is not revoked (i.e., the invalidity finding has inter partes effects only). In contrast, if a revocation action succeeds, not only is the infringement action dismissed, but the patent is also cancelled in the registry (i.e., the invalidity finding has erga omnes effects).

Unlike in other countries such as Germany, where infringement and invalidity actions are ‘bifurcated’, in Spain they are all decided by the same court.

If an infringement action is based on a patent, the validity of which has been challenged before another court, either party in the infringement proceedings may request the joinder of the two cases so that they are decided by the same court in the same judgment. In cases where the requirements for joining two cases are not fulfilled (for example, because the two cases are in different instances), either party may request the stay (i.e., suspension) of the infringement proceedings until the validity proceedings have been resolved. The court will make a decision after hearing the other party. Whether or not the infringement proceedings are stayed depends on the particular circumstances of the case. In contrast, Spanish courts have traditionally taken the view that infringement proceedings cannot be stayed when the validity of the patent has been challenged before the EPO.

As regards the availability of other possible defences, this will of course depend on the specific facts of the case. For example, experimental use and Bolar-type defences are certainly available, although there have been very few cases where they have been alleged. Other defences may include the exhaustion of rights although, again, this type of defence is very rare.

There have been a few cases where defendants raised arguments based on competition law, particularly in the field of telecoms patents. However, these cases were settled.

V FINAL REMEDIES FOR INFRINGEMENT

Spain’s new Patents Act contains an ‘open’ list of remedies, where the following are mentioned by way of example:

\[
\begin{align*}
\text{a} & \quad \text{an order for the cessation of the infringing acts (i.e., an injunction);} \\
\text{b} & \quad \text{an award of damages;} \\
\text{c} & \quad \text{an order for the seizure of infringing items and the means exclusively used for their production or for carrying out the patented process;} \\
\text{d} & \quad \text{an order for the assignment of the ownership of infringing items seized to the patent holder whenever possible;} \\
\text{e} & \quad \text{the adoption of any other measures necessary to prevent the patent infringement from continuing and, in particular, the alteration or destruction of infringing items when this is essential to prevent infringement of the patent; and}
\end{align*}
\]
the publication of the judgment against the patent infringer, at the infringer’s expense, by means of advertisements and notification to other interested parties.

However, since, as mentioned, this is an ‘open’ list, other remedies may be appropriate, depending on the circumstances of the case. For example, on 13 December 2004, the Barcelona Court of Appeal (Section 15) ordered a ‘springboard’ preliminary injunction preventing the defendants from marketing their product during X months after the patent expired. The rationale was that they had used these X months as a ‘springboard’ before the patent had expired. This ruling was inspired by a similar springboard injunction ordered by the English Courts in the Dyson case (2001, EWCA Civ 1440: Dyson Appliances Limited and Hoover Limited). More recently, in a judgment of 28 February 2018, in a different case the same court ordered the defendant to alter a machine so that it would no longer make use of the invention.

If a final injunction is ordered, as already mentioned above, the patent owner is able to obtain the provisional enforcement of the judgment. This means that any appeal lodged will not have suspensive effect.

When infringement is found, the plaintiff is entitled to be awarded damages. Damages can only be claimed, however, for events occurring during the five years immediately preceding the date on which the appropriate action is brought. Under Spanish law, the general rule for awarding damages deriving from patent infringement is that damages will comprise not only the value of the loss that the patent holder has suffered (damnum emergens), but also the profits not obtained as a result of the infringement of its rights (lucrum cessans).

The lucrum cessans consists of the profit not obtained as a result of infringing the patent. For the assessment of the amount of profit not obtained, the claimant of damages is entitled to choose one of the following criteria:

a. a lump sum that includes, at least, the amount the infringing party would have had to pay to the patent holder for a licence, in order to legally use the patent (the ‘notional royalty criterion’). In establishing this amount, special consideration will be given to certain factors, for example: the economic importance of the patented invention, the remaining term of the patent at the time the infringement commenced and the number and type of licences granted at that time; or

b. the loss of profits suffered by the injured party (the patent holder’s ‘loss of profit criterion’); or

c. the profits obtained by the infringing party from exploiting the patent (the ‘infringer’s profit criterion’).

Punitive damages are not normally available in Spain. Choosing the loss of profit criterion will require the patent holder to prove the cause-effect nexus between the patent infringement and loss of sales, and will also require the margin of the patent in relation to the product embodying the patent to be disclosed. This is the criterion normally chosen when it is thought that the margin of the patent holder is substantially greater than that of the defendant (as is usually the case in pharmaceutical patent litigation against generics companies). Where the patent holder, for commercial reasons, does not wish to disclose its actual profit margin, a usual course of action is to restrict the margin to a fictional figure below the actual figure, thus sacrificing part of the damages to be awarded in exchange for confidentiality.
It should also be noted that if the patent holder has not used the patent within the territory of a World Trade Organization state, under *lucrum cessans* it will only be able to claim damages according to the notional royalty criterion. However, it will still be able to claim compensation for the value of the loss that it has suffered under *damnum emergens*.

The new Patent Act also sets out that when a judgment orders the defendant to cease its acts of patent infringement, the court will set coercive damages for every day until the infringement effectively ceases. The final amount of these damages, and the date as from when there will be an obligation to compensate, will be determined when the judgment is enforced, following the general rules set out in the Spanish Civil Procedure Act. Such damages will be added to the general compensation for damages described above.

Until the new Patents Act came into force on 1 April 2017, damages were calculated during the main ‘declaratory’ stage of proceedings. This has now changed, and the calculation of damages has been postponed to the second, ‘execution’ stage.

VI OTHER TYPES OF PATENT PROCEEDINGS

Other than infringement and invalidity proceedings, the most frequent proceedings, although not very usual, are declaratory non-infringement actions.

Any interested party may bring court proceedings requesting a declaration that a specific act does not constitute infringement of a particular patent. However, the action cannot be brought if the interested party has been sued for infringement of the relevant patent. The declaratory non-infringement action can be filed along with a patent revocation action.

Before filing the complaint, the potential claimant must notify the patent holder by verifiable means so that it can make allegations about the patent and about the industrial exploitation carried out in Spanish territory by the potential claimant (or the effective and serious preparations to carry out such exploitation). If the patent holder does not reply within one month as from the date of the request, or if the potential claimant does not agree with the reply, it will be entitled to bring the declaratory non-infringement action.

The action must be directed against the patent holder. Furthermore, all persons holding rights over the patent in question who have been duly registered at the SPTO must be notified of the complaint, so that they have the option to appear and intervene in the proceedings. Nevertheless, licensees will not be entitled to appear in the proceedings when their licence agreement prevents this.

The judgment of 19 April 2018 handed down by the Barcelona Court of Appeal (Section 15), which rejected a declaratory non-infringement action, illustrates the risks involved with this type of action.

There have also been a handful of cases where the ownership of a patent has been disputed, although these types of cases are not frequent in Spain.

VII APPEAL

i Appeal before the court of appeal (second instance)

The judgments of commercial courts may be appealed before the court of appeal. No permission to appeal is required. In other words, the losing party has an automatic right of appeal.

The court of appeal consists of three appeal judges. In normal circumstances, it would take 12 to 18 months for an appeal to be heard following a judgment from the commercial court.
The court of appeal can decide the case afresh, on the basis of the evidence submitted to the commercial court. Alternatively, if there has been a defect in the procedure adopted by the lower court, the court of appeal can refer the case to the lower court and instruct it to resume proceedings from the date when the defect occurred.

Although it is possible to submit and examine evidence in court of appeal proceedings in certain particular cases (for example, when new evidence emerges), the court of appeal adopts a restrictive position and, in practice, it is rare for it to admit evidence to be examined in this second instance.

Appeals are decided after considering the written submission filed by each party. The court of appeal only calls the parties to a hearing in the unlikely event that new evidence has been admitted or when both parties have requested a hearing and the court considers that a hearing would be appropriate, considering the circumstances of the case.

**Appeal before the Spanish Supreme Court**

Further appeals to the Spanish Supreme Court are permitted only in exceptional circumstances. Two different appeals are possible:

a. appeal in cassation: an appeal denouncing a breach of substantive law or case law. However, this appeal is only possible when:
   - constitutional rights (other than the right to due process) are at stake;
   - the plaintiff has justified in the complaint that the relief sought is an amount exceeding €600,000 (this is usually not the case in patent cases, as the damages awarded are only specified at a later stage in the proceedings); or
   - the judgment in the second instance has applied rules with no unified consolidated precedents from the Supreme Court; or

b. extraordinary appeal owing to breach of procedure, which is only possible in a series of situations involving a breach of certain procedural rules or an encroachment of the constitutional right to due process. This type of appeal requires the appellant to have previously exhausted all appeals and remedies at the lower instances in order to remedy the breach or encroachment suffered.

The Supreme Court will not review the findings of fact made by the lower courts. On the contrary, the role of the Supreme Court will typically be limited to verifying the application of the law by the lower courts.

**VIII THE YEAR IN REVIEW**

During the past year, patent litigation in the pharmaceutical sector has picked-up, which is expected to keep patent courts busy next year as well.

**IX OUTLOOK**

This year has been a year of transition for the new Patents Act after its coming into force on 1 April 2017. The experience to date is that the new Act has resulted in a more rational way of prosecuting and litigating patents.

Another noteworthy development is that, as mentioned, Spain has decided, for the time being, not to take part in the project aimed at creating a European patent with unitary effect and a Unified Patent Court.
Chapter 22

SWITZERLAND

Andri Hess

I OVERVIEW

i Patent litigation landscape in general

Until the end of 2011, each of the 26 Swiss cantons had one court that acted as the court of first instance for patent-related disputes. Most of these 26 courts had only limited experience in patent law because the majority of the patent cases were brought before the four commercial courts of the cantons of Zurich, Argovia, Saint-Gall and Berne. Even these four commercial courts were not as experienced as the stakeholders would have wished because the number of cases handled by each of the commercial courts was still relatively low. The shortcomings of the old system were evident, but efforts to establish a new federal court before which all patent disputes could be concentrated failed for a long time due to constitutional restraints. This changed in 2000 when the Swiss Constitution was amended and the power to legislate in the field of civil procedure law moved from the cantons to the federal level. In a common effort, stakeholders sought to convince the federal government of the need to improve the legal system for patent litigation by creating a specialised court to serve as the sole court of first instance in patent matters in Switzerland. These endeavours were successful: the federal legislator addressed the issue and passed the Federal Patent Court Act (PCA) in March 2009, establishing the Swiss Federal Patent Court in Saint-Gall, a city in the north-eastern part of Switzerland, one hour away from Zurich.

The Federal Patent Court is vested with Switzerland-wide exclusive jurisdiction over those actions that require the application of substantive patent law, and the PCA provides for concurrent jurisdiction of the Federal Patent Court and the cantonal courts for other patent-related disputes, such as disputes arising from patent licensing agreements. Accordingly, the Federal Patent Court has exclusive jurisdiction over:

a actions regarding the validity of patents, patent infringement actions and actions for compulsory licences;

b applications for preliminary measures; and

c enforcement proceedings regarding judgments issued under the Federal Patent Court’s exclusive jurisdiction.

The Swiss Federal Patent Court shares its name with the German Federal Patent Court. This coincidence should not disguise that the two courts play fundamentally different roles in the patent litigation systems of the two countries. While the German Federal Patent Court...

1 Andri Hess is partner at Homburger AG and a non-permanent judge at the Swiss Federal Patent Court.
2 Article 26 Patent Court Act.
Court is not competent to adjudicate claims regarding the infringement of patents, the Swiss Federal Patent Court’s jurisdiction extends to any and all questions that may arise in a patent litigation, including infringement and validity.

A notable feature of the Federal Patent Court is that it comprises both legally and technically trained judges. Roughly two-fifths of the technical judges graduated in chemistry, biochemistry or biology, a third in physics, and the rest in mechanical and electrical engineering. The vast majority of the technically trained judges are European patent attorneys. While the president is the only full-time judge of the Federal Patent Court, one technically trained judge has a part-time appointment and the further judges are called on a case-by-case basis.

In litigations before the Federal Patent Court, the parties are free to use for their submissions and pleadings any of the official Swiss languages – German, French, Italian and Romansh. If all parties agree, they may also use English. Parties make use of this option in roughly one-third of the cases.

ii Unitary patent territory Switzerland and Liechtenstein

According to a treaty between Switzerland and Liechtenstein, the two countries constitute one single patent territory. Swiss national patents and European patents designating Switzerland or Liechtenstein are also valid in the respective other country, and can only be invalidated for both countries together.

Nullity actions can be initiated before courts in Switzerland or in Liechtenstein. In both cases, a final appeal is possible to the Swiss Federal Supreme Court. While Switzerland has a specialised patent court (the Swiss Federal Patent Court), the ordinary courts are competent in Liechtenstein.

II TYPES OF PATENT

Switzerland is a signatory to the European Patent Convention, so Swiss national patents and European patents granted by the European Patent Office coexist in Switzerland. The granting authority for Swiss national patents is the Swiss Federal Institute of Intellectual Property (IPI) in Berne, which also maintains the register for Swiss national and the Swiss parts of European patents. Unlike European patents, Swiss national patents are granted without the IPI examining whether the invention is new and inventive in light of the prior art. Despite this difference, a Swiss national patent confers the same rights on its proprietor as the Swiss part of a European patent.

Under Swiss law, supplementary protection certificates (SPCs) for medicinal products and for plant protection products may be granted on the basis of Swiss national and Swiss parts of European patents. The Swiss regime for SPCs closely follows the corresponding
Switzerland

legislation of the European Union. However, because Switzerland is not a member of the European Union, judgments of the European Court of Justice on the interpretation and application of the EU legislation on SPCs are not binding in Switzerland. A Swiss SPC’s maximum term of protection is five years.

Swiss lawmakers also partially followed the EU’s endeavours to improve the health of children by incentivising pharmaceutical companies to perform paediatric tests for their drugs by extending already granted SPCs by an additional six months (Paediatric Extensions).9 The Swiss legislator, however, went one step further and decided to not only grant the benefit of an additional six months’ exclusivity period to those who have already been granted an SPC, but also to those who, for whatever reason, have not previously obtained an ordinary SPC (Paediatric Certificate).10 The IPI is presently implementing the regulations for the Paediatric Extensions and the novel Paediatric Certificates, and the respective provisions are expected to come into force in 2019.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Patent enforcement actions

In Switzerland, the Federal Patent Court has exclusive jurisdiction for patent enforcement actions. An enforcement action is initiated with the filing of a written and substantiated statement of claim and payment of an advance on court costs, which is followed by the written statement of defence. In the statement of defence, the defendant may either file a counterclaim on invalidity or simply raise the invalidity of the patent in suit as a defence. In the case of a counterclaim, the Federal Patent Court declares the patent invalid with erga omnes effect if it finds that the challenge has merit, while in the case of a successful invalidity defence the infringement claim is dismissed without the court revoking the patent. Challenging the validity of a patent is usually not considered a reason for staying infringement proceedings.

Swiss courts have a long tradition of actively facilitating and promoting settlements. The Federal Patent Court is faithful to this tradition. The procedural step that serves this purpose is the preparatory or settlement hearing, to which the parties are typically summoned after the first exchange of submissions. At the preparatory hearing, a court delegation typically consisting of a legal and a technical judge provide their preliminary opinions on how they would decide the case in light of the submissions and evidence produced so far. Because at this stage the fact-finding has not been concluded and only the opinions of two out of three to five judges that would render a final judgment are given, this preliminary assessment does not prejudice the final outcome of the case. In order to reinforce the preliminary nature of their opinions, the opinions are only provided orally, and the parties are prohibited from referring to them in their subsequent submissions and pleadings. The preliminary opinions of the judges serve as starting point for subsequent settlement discussions with the involvement of the court delegation. Statistically, the majority of patent disputes is settled at this stage.

The further course of the litigation depends on whether the case is settled at the preparatory hearing or not. If no settlement is achieved, the plaintiff is given the opportunity to submit the statement of reply, followed by defendant’s statement of rejoinder. After the double exchange of briefs has been completed, a technical judge provides a written opinion

that is then provided to the parties for commenting. The final step is a hearing that is the first and last opportunity for the parties to directly address the full panel of judges. While the parties are precluded from introducing new facts at this stage, they typically use this opportunity to emphasise certain points and summarise their view in particular on the technical judge’s opinion. The court then renders its judgment on infringement and, if relevant, the invalidity counterclaim, typically within around 18 months of commencement of the action.

In the case of infringement actions, it is standard practice in Switzerland to request the court to decide on the infringement or liability first, to then order the defendant to provide information on his or her sales and profits and to decide on the quantum only thereafter. This course of action is called ‘action by stages’.

Under Swiss law, the owner of a patent as well as any person who holds an exclusive licence under the respective patent is entitled to bring an infringement action, irrespective of whether the licence is registered in the patent register.\(^{11}\)

The following table provides an overview of the steps and the timing of a typical infringement action before the Federal Patent Court.

<table>
<thead>
<tr>
<th>Plaintiff</th>
<th>Federal Patent Court</th>
<th>Defendant</th>
<th>Timeline (tentative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement of claim</td>
<td></td>
<td></td>
<td>Day 0</td>
</tr>
<tr>
<td>1st advance on court costs</td>
<td></td>
<td>Statement of defence (invalidity counterclaim or invalidity defence possible)</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Instruction/settlement hearing. Litigation terminates if there is a settlement. If no settlement is reached, litigation continues</td>
<td></td>
<td></td>
<td>8 weeks</td>
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<tr>
<td>2nd advance on court costs</td>
<td></td>
<td></td>
<td>3 weeks</td>
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<tr>
<td>Reply</td>
<td></td>
<td></td>
<td>6 weeks</td>
</tr>
<tr>
<td>Rejoinder</td>
<td></td>
<td></td>
<td>6 weeks</td>
</tr>
<tr>
<td>Comments on new allegations in rejoinder</td>
<td></td>
<td>Written opinion of technical judge</td>
<td>10 days</td>
</tr>
<tr>
<td>Comments on written opinion of technical judge</td>
<td></td>
<td>Comments on written opinion of technical judge</td>
<td></td>
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<tr>
<td>Main hearing</td>
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<tr>
<td>Judgment</td>
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<tr>
<td>Appeal proceedings at Federal Supreme Court</td>
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</tbody>
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\(^{11}\) Article 75 Patent Act.
ii Invalidity actions

Invalidity actions follow the same structure and are typically also decided within around 18 months of the filing of the action. Exclusive jurisdiction for invalidity actions is with the Federal Patent Court.

Pursuant to the Swiss Patent Act, anyone with a proven interest may bring an invalidity action. An invalidity action may be brought despite pending proceedings before the European Patent Office, but the Patent Act provides that the Federal Patent Court may stay its action pending a final decision of the patent office. In practice, the Federal Patent Court only makes very reluctant use of this option. Rather than staying an invalidity action, the Federal Patent Court prefers to invite the European Patent Office to accelerate its proceedings.

Whenever the validity of a patent is challenged, be it in an invalidity action or in the case of a counterclaim in infringement proceedings, the patentee is free to amend the patent claims in the court proceedings. The patent may be limited by deleting patent claims altogether, by combining an independent claim with one or more dependent claims, or otherwise, provided the restricted claim still relates to the same invention and defines an embodiment that is included in the specification of the published patent and in the version of the application that determined the date of filing.

iii Interim relief

Anybody who has standing to bring an infringement action is entitled to interim relief, in particular in the form of a preliminary injunction, if he or she provides prima facie evidence:

a. that the defendant has committed or intends to commit an act of infringement; and

b. that he or she is threatened by a loss that is not easily reparable.

Such requests are decided in inter partes proceedings, unless the urgency is so great that hearing the defendant prior to ordering measures is not warranted, in particular because it would frustrate the very purpose of the requested measure. If an interim measure is ordered ex parte, it needs to be confirmed inter partes.

For inter partes interim relief, immediate urgency is not an independent requirement. According to case law, a claim for preliminary relief is forfeited if the petitioner, after having learned about the infringement, files the request for preliminary relief so late that a decision on this request may no longer be expected to issue sooner than a judgment in an ordinary proceedings initiated immediately after the petitioner had learned about the infringement would have issued. This is called the concept of ‘relative urgency’.

As in proceedings on the merit, the defendant can raise invalidity of the asserted patent as a defence.

The Federal Patent Court may, upon request or ex officio, make an interim measure conditional on the payment of security by the applicant if it is anticipated that the interim measures may cause loss or damage to the alleged infringer.
A party expecting a patentee to file an *ex parte* request for interim measures can deposit a protective letter explaining to the Federal Patent Court the reasons why such a request should be dismissed, or at least not decided *ex parte*. The patentee is only informed of the protective letter after having filed a request for interim measures.

Interim relief proceedings before the Federal Patent Court typically take between three and nine months, depending on the number of asserted patents and the complexity of the issues raised by the parties.

The applicant is liable for any loss or damage caused by unjustified interim measures. An action for damages must be substantiated and proven in a separate lawsuit. Where the exact value of the loss or damage cannot be quantified, the court may estimate the amount, provided the claimant has sufficiently substantiated the factors required for the estimation. On the other hand, the court may reduce the damages or entirely release the applicant from liability if the latter proves that he or she applied for the interim measure in good faith. Whether full or any damages are awarded therefore depends on whether the applicant is found to have applied for the interim measure for legitimate reasons and has conducted the proceedings in good faith.

**Means of evidence**

Patent actions are largely based on written evidence such as written prior art, evidence in writing for the skilled person's general knowledge, drawings and photographs of the allegedly infringing embodiment, correspondence between the parties and the like. Other means of evidence are used much less frequently; witnesses are rarely heard, affidavits and private expert opinions do not qualify as means of evidence, and because the Federal Patent Court usually finds the required expertise among its judges, it does not need to rely on the opinion of external experts.

**SUBSTANTIVE LAW**

**Infringement**

The infringement analysis necessarily begins with claim interpretation. The starting point is the wording of the patent claims, whereby in case of a European patent the wording of the claim in the respective procedural language is binding, even if this is English. Pursuant to Article 69 of the European Patent Convention and the parallel provision in the Swiss Patent Act, the description and the drawings must be used to interpret the patent claims.

Rather than providing a conclusive list of infringing activities, the Swiss Patent Act, in a general manner, states that the patent confers on its proprietor the right to prohibit others from commercially using the invention. By way of example, ‘using the invention’

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17 Article 270 Code of Civil Procedure.
19 Article 168 Code of Civil Procedure. This does not prevent a party from submitting affidavits and private expert opinions. Even if they do not have evidential value in a strict sense, they may still provide guidance to the judges of the Federal Patent Court and cast doubt on findings of the technical judge in his or her technical opinion.
21 Article 8 Patent Act: ‘The patent confers on its proprietor the right to prohibit others from commercially using the invention.’
includes manufacturing, storage, offering, placing on the market, importing, exporting and carrying in transit, as well as possession for any of these purposes. If the invention concerns a manufacturing process, the effects of the patent also extend to the products directly obtained by that process.\textsuperscript{22}

With respect to transit, the Patent Act clarifies that carrying in transit may only be prohibited if the proprietor of the patent is permitted to prohibit importation into the country of destination.\textsuperscript{23}

The Patent Act further states that ‘imitation is also deemed to constitute use’.\textsuperscript{24} This provision served as basis for a long chain of case law that ultimately evolved in today’s doctrine of equivalence. According to recent case law,\textsuperscript{25} a method or device that does not literally fulfil one or more claim features but employs replacing features is considered an ‘imitation’ if from the following three questions the first two may be answered in the affirmative and the third in the negative:

\begin{itemize}
  \item[a] Does the replacing feature in conjunction with the other technical features of the patent claim objectively fulfil the same function as the claimed feature (‘same effect’)?
  \item[b] Is the same effect obvious to the person skilled in the art from an objective point of view, taking into account the teaching of the patent, when the features are exchanged (‘accessibility’)?
  \item[c] Does the person skilled in the art, upon objective reading of the patent specification, come to the conclusion that the patentee has formulated the claim – for whatever reason – so narrowly that he or she does not claim protection for an embodiment with the same effect that is accessible (‘equal value’)?
\end{itemize}

Furthermore, the Patent Act holds that not only the direct infringer may be held liable, but also ‘any person who abets any [direct infringement], participates in them, or aids or facilitates the performance of any of these acts’.\textsuperscript{26} Illicit contributory infringement, therefore, requires that the person in question contributes to an act that qualifies as direct infringement under the Swiss Patent Act. From this requirement of accessoriness, Swiss courts have concluded that a person may be liable as contributory infringer only if the direct infringement to which he or she contributes takes place in Switzerland. On the other hand, Swiss courts have also decided that it does not matter from where the contributory infringer contributes to a direct infringement in Switzerland. A person may, therefore, be liable as contributory infringer under Swiss law if this person contributes to a direct infringement in Switzerland either from within Switzerland or from abroad.\textsuperscript{27} A further requirement derived from the statutory requirement of accessoriness is that there must be a sufficiently close causal connection between the contributory action and the direct infringement.\textsuperscript{28} This is the case if, for example, means are explicitly offered for an infringing use or if means may only be used in such a manner.

\textsuperscript{22} Article 8a Patent Act.
\textsuperscript{23} Article 8 Paragraph 3 Patent Act.
\textsuperscript{24} Article 66 letter (a) Patent Act.
\textsuperscript{25} Summarised in Federal Patent Court judgment S2018_006 of 8 February 2019.
\textsuperscript{26} Article 66 letter (d) Patent Act.
\textsuperscript{27} Federal Supreme Court judgment 129 III 25 of 7 October 2002, consideration 2.2.
\textsuperscript{28} Federal Supreme Court judgment 129 III 588 of 21 July 2003, consideration 4.1.
ii  Invalidity and other defences

Swiss national patents and European patents are presumed to be valid. Upon request of an interested third party, a Swiss national and a Swiss part of a European patent may, however, be declared completely or partially invalid if the subject-matter of the patent is not patentable – in other words:

a if what is claimed is not novel, not inventive, lacks industrial applicability or relates to unpatentable subject matter;29
b if the invention is not described in the specification in a manner sufficiently clear and precise for it to be carried out by a person skilled in the art;

c if the subject matter of the patent goes beyond the content of the patent application in the version that determined the filing date; or
d if the proprietor of the patent is neither the inventor nor his or her successor in title, nor has a right to the grant of the patent on other legal grounds.30

The novelty test is strict. An invention only lacks novelty if it is anticipated in a single piece of prior art or by prior use. While both the Federal Patent Court as well as the Federal Supreme Court have repeatedly stated that there is no single test for assessing inventive step, both courts predominantly apply a modified form of the problem-solution approach initially developed by the European Patent Office.31

Defences to infringement claims include a private use exemption, an experimental use exemption, a Bolar-type exemption and a prior user right.32 Two further exceptions, doctor’s and a pharmacist’s exceptions, enter into force in 2019. Furthermore, the Patent Act contains a quite detailed provision on exhaustion.33 The principle rule is that patent rights exhaust on a Switzerland and EEA-wide basis (the principle of regional exhaustion). Exceptions to this rule are international (global) exhaustion if the patent protection is only of subordinate importance for the functional characteristics of the goods in question, and national (Swiss) exhaustion if the prices of the patented goods are publicly fixed. In a preliminary injunction case, the Federal Patent Court held that a patented cooling system for a turbo charger was only of subordinate importance (i.e., ‘nice to have’) for a car equipped with a combustion engine featuring such a device, and that therefore in that case international exhaustion applied.34

V  FINAL REMEDIES FOR INFRINGEMENT

The standard forward-looking remedy for infringement is a permanent injunction.35 Injunctive relief is granted unconditionally and automatically. In addition, the patentee may demand that the unlawful situation be remedied, for example, by withdrawal of infringing goods from the supply chain or destruction of infringing goods.

29 Namely, methods of treating the human and animal body, plant and animal varieties and essentially biological methods for their creation, inventions contrary to public policy and morality.
31 See, for example, Federal Patent Court judgment S2017_001 of 1 June 2017 ‘Amlodipine and valsartan’.
33 Article 9a Patent Act.
The successful claimant may also ask for compensation for past infringement and alternatively claim damages based on tort law, the infringer’s profits based on the law on the conducting of business without mandate, or a reasonable royalty based on the law on unjust enrichment. While the claim for the infringer’s profits requires that the infringer acted in bad faith, damages are awarded if the defendant infringed the patent negligently or intentionally, and the royalty claim is independent of the defendant’s fault. If the requirements of all claims are fulfilled, the claimant does not need to elect until the taking of evidence has been concluded and the defendant has rendered account.

The damage claim is designed to put the infringed party in the position it would be had the infringement not taken place. The infringed party bears the burden of proof for its damage, which, in the case of lost profits, requires proof of the infringed party’s profit margin.

The infringer’s profits are its turnover minus those costs that are directly attributable to the infringement. The burden of proof for these deductible costs lies with the infringer. However, only that part of the profits must be surrendered that may be attributed to the use of the infringed patent. If the infringer can show that other factors also contributed to the profits, for example, the use of other intellectual property rights such as other patents or trademarks, it is at the court’s discretion to estimate the portion of the infringer’s profits that have to be surrendered to the patentee.

The claim for a reasonable royalty is widely discussed in the literature, but there is no case law available where this method has actually been applied in contradictory proceedings. The reasonable royalty is the royalty that the infringer would reasonably have had to pay if it had obtained the patentee’s consent to use the infringed patent. For determining the relevant reference base and the royalty rate, one usually looks at actual licence agreements relating to the specific patent or similar technologies and then adjusts the terms in light of the specific circumstances of the matter, for example, with respect to the relevance of the patent for the specific product, the remaining term of protection and the level of competition.

A compensation action may only be brought after the patent has been granted. The infringer may, however, be held liable for loss or damage caused from the time when he or she first obtained knowledge of the content of the patent application, but at the latest from the publication of the application.

VI OTHER TYPES OF PATENT PROCEEDING

i Precautionary taking of evidence

Swiss law provides different instruments that allow the taking of evidence before proceedings on the merits are commenced. These instruments have proven to work well and to deliver results quickly.

The Swiss Code of Civil Procedure provides that courts must take evidence at any time before a case on the merits becomes pending if the requesting party has an ‘interest worthy of protection’. According to now established case law, one such interest justifying the taking of evidence prior to the filing of an action on the merits is the requesting party’s interest in being better able to assess the chances of success of a potential civil claim. This tool is, in other

38 Article 158 Code of Civil Procedure.
words, designed to help avoid unnecessary proceedings. It has proved to be helpful in cases
where a party requires information that is in the hands of the opponent in order to decide
whether initiating a litigation is warranted or not.

The patent act, on the other hand, introduced a new tool that in the literature has
been denominated *saisie helvétique*. In order to not only preserve but establish evidence, the
Federal Patent Court can be requested to order the exact description of an allegedly infringing
process, of allegedly infringing products or of the means used for producing such products.39

In practice, delineating the two tools is not easy and they are often combined to obtain
clarity with respect to a 'missing link'. As a requirement, the requesting party must provide
*prima facie* evidence that the patent is infringed should the missing link be established.
Typically, such requests are decided on in a couple of days, and the description is then
conducted by a member of the Federal Patent Court without prior warning of the presumed
infringer. In order to protect the confidentiality interests of the affected party, the law provides
that the Federal Patent Court must give the affected party the opportunity to comment
on the findings before they are handed over to the requesting party, and that the court in
general shall take the necessary precautions to protect the affected party’s legitimate interests.
In particular, the Federal Patent Court typically excludes the requesting party from the
description proceedings but allows their legal or patent attorneys to attend the description.

ii Further actions before the Federal Patent Court

Swiss law provides for the possibility of positive declaratory actions (e.g., declaration that
a certain patent is valid) and of negative declaratory actions (e.g., declaration that a certain
patent is not infringed).40 Declaratory actions are only accepted if the plaintiff substantiates
(1) an uncertainty regarding a legal relationship; (2) that the uncertainty cannot be reasonably
tolerated by the plaintiff any longer; and (3) that the plaintiff has no other option to remedy
that uncertainty, in particular that there is no option to bring an action for performance
against the defendant to remedy the intolerable uncertainty.

The Federal Patent Court is further competent to hear applications for the grant of
compulsory licences and entitlement actions.

iii Further measures not involving the Federal Patent Court

Acts of wilful patent infringement are criminal offences under Swiss law.41 The maximum
penalty is a custodial sentence not exceeding five years or a monetary penalty of up to slightly
more than 1 million Swiss francs, or both.

The Swiss patent act also provides for border measures that can be put in place upon
request of the proprietor of a patent.42 Request forms can be downloaded from the website
of Stop Piracy, a Swiss association that includes members from the private sector, authorities
and consumer representatives.43

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43 www.stop-piracy.ch/was-tun/infos-fur-produzenten/?lang=en-US.

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VII APPEAL

As a court of first instance, decisions of the Federal Patent Court may be appealed. Such appeals are made directly to the Federal Supreme Court, which is the final court of appeals for all decisions rendered by the Federal Patent Court. The Federal Supreme Court only has very limited competence to review facts, and its decision-making processes are impressively efficient. Presently, appeal proceedings before the Federal Supreme Court usually take around six months.

VIII THE YEAR IN REVIEW

In the past 18 months, the Federal Patent Court and the Federal Supreme Court rendered a few landmark judgments on substantive patent matters and numerous judgments clarifying requirements for the issuance of preliminary injunctions.

A true landmark decision is the Federal Supreme Court’s judgment on the validity of Gilead’s Swiss SPC for the combination of tenofovir disoproxil fumarate and emtricitabine. The SPC had been granted by the Swiss Federal Institute of Intellectual Property applying the infringement test, which the Federal Supreme Court had found to be relevant for assessing whether a product is protected by a patent in its Fosinopril judgment of 1998. Mepha, a Swiss Teva group company, challenged the validity of the SPC, arguing that in light of the development in the EU, Switzerland should give up the infringement test. Considering that the SPC’s basic patent, EP 915 894, did not claim the combination of the SPC, Mepha argued that the SPC should be declared invalid under the CJEU’s Medeva case law. The Federal Supreme Court agreed that going forward, the infringement test should no longer apply, but that SPCs that have been granted prior to the judgment (i.e., prior to 11 June 2018), should remain subject to the infringement test because a new interpretation of the same statutory provision should not retroactively invalidate property rights that had been formally granted by Swiss authorities under the previous interpretation of the highest court. While the Supreme Court did not go into the details of the test for which it gave up the infringement test, it stated in a general manner that a substance or combination of substances may only be considered protected by a basic patent if all substances are claimed in the respective patent, whereby the criterion is fulfilled either if the claims name the substances or if the claims, construed in light of the description, implicitly, but necessarily and specifically relate to the substances. As in the EU, further guidance by the courts will be inevitable.

In the subsequent judgment on the alleged infringement of the very same SPC, the Federal Patent Court had to decide whether the scope of an SPC that specifically denotes one salt form also extends to other salt forms of the same compound. Gilead’s Swiss SPC had been specifically granted for tenofovir disoproxil fumarate and emtricitabine, while Mepha’s generic contained tenofovir disoproxil in the phosphate form. The Federal Patent Court first reminded that according to the Swiss Patent Act, the protection of an SPC extends, within the limits of the scope of protection conferred by the patent, to any use of the product for which the SPC has been granted that has been authorised before the expiry of the SPC. It

was undisputed that Mepha’s generic had been authorised prior to the expiration of the SPC and that its combination of active ingredients fell within the scope of the basic patent. The decisive question, therefore, was whether the combination of tenofovir disoproxil phosphate and emtricitabine was to be considered the same product as the combination of tenofovir disoproxil fumarate and emtricitabine. The Federal Patent Court considered that the meaning of the term ‘product’ used in the law on SPCs must be aligned with the Therapeutic Products Act. Under that act, different salt forms and other derivatives are considered the same active substance if they do not differ significantly in their properties with regard to safety or efficacy, or both. Considering that Mepha’s generic had been authorised in simplified approval proceedings precisely because it has the same pharmacological effects as Gilead’s drug comprising tenofovir disoproxil fumarate, Mepha’s generic was held to fall within the scope of protection of Gilead’s SPC.

In a series of judgments, the Federal Patent Court clarified how long after commencement of a patent infringement a patentee may file a preliminary injunction request. The general principle established by the Federal Patent Court is that a preliminary injunction request may be filed within 14 months after the patentee actually learned or should have learned of the infringement.47 With respect to the question regarding what circumstances a patentee is considered to have or should have known of the infringement, the court held that the patentee is under no obligation to acquire and destroy potentially infringing embodiments in order to find out whether they indeed infringe or not.48

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Chapter 23

TAIWAN

Yu-Li Tsai

I OVERVIEW

According to the Department of Statistics of the Taiwan Judicial Yuan, details of civil cases decided through the first instance of the Intellectual Property Court (IP Court) are as follows:

a 2015: 113 patent civil cases. Of these, 86 cases were either withdrawn or dismissed, and 27 cases (23.9 per cent) were won, partly won and partly dismissed, settled or mediated.

b 2016: 100 patent civil cases. Of these, 72 cases were either withdrawn or dismissed, and 28 cases (28 per cent) were won, partly won and partly dismissed, settled or mediated.

c 2017: 107 patent civil cases. Of these, 78 cases were either withdrawn or dismissed, and 29 cases (27 per cent) were won, partly won and partly dismissed, settled or mediated.

d 2018: 124 patent civil cases. Of these, 102 cases were either withdrawn or dismissed, and 22 cases (18 per cent) were won, partly won and partly dismissed, settled or mediated.

It can be inferred from the above statistics that the rate of unfavourable results for patent civil cases is getting higher in 2018, so this might show that the IP Court has not been as friendly to patent rights owners as before.

The IP Court has made some internal reforms regarding case judgments because it received a lot of complaints about the success rate for plaintiffs in patent infringement litigation being too low (i.e., in the range of 10 to 20 per cent). One of the most notable changes is that the percentage holding that a patent was deemed as invalid was reduced from 60 per cent to 30 per cent. This is good news for patentees because it gives them more of a chance to win a civil lawsuit and be awarded damages. However, from the record of 2018, it seems to me that these changes of court did not really affect the judges’ long-term conservative attitudes in judging patent infringement.

II TYPES OF PATENT

Types of patent include invention patents, utility model patents and design patents. An invention patent covers exclusive rights to inventions based on technical ideas using natural laws. A utility model patent covers exclusive rights for devices based on technical ideas using
natural laws, in connection with the creation of a shape, structure or combination of both. A design patent covers exclusive rights for a shape, pattern, colour or combination of these, for an aesthetic item.

The durations of rights granted to an invention, utility model and design patent are respectively 20 years, 10 years and 12 years from the date of actual filing rather than the priority date.

All patents should be filed at the Taiwan Intellectual Property Office (TIPO) for examination or registration. Invention and design patents are required to go through substantive examination by the TIPO to ensure that they meet legal requirements regarding statutory subject matter, enablement, written description, industrial applicability, novelty, non-obviousness and unity. However, utility model patents are only required to go through formal examination, where enablement, industrial applicability, novelty and non-obviousness are generally not examined.

Where regulatory approval is obtained in accordance with applicable laws and regulations for the exploitation of an invention patent involving a pharmaceutical or agrichemical, or the manufacturing process thereof, if such regulatory approval is obtained after publication of the invention patent, the patentee may apply for one and only one extension of the patent term of said invention patent based on the first regulatory approval. The regulatory approval is allowed to be used only once for seeking patent term extension, and the granted patent term extension is five years at most.

III  PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

Disputes or contentions of infringement on patent rights can be brought to the district court located in the district where the defendant resides, where the infringing acts occurred. Or they can be directly brought to the IP Court, which was established to specialise in resolving IP-related disputes.

The invalidation proceedings should first be brought to the TIPO, which is the exclusive administrative authority before a case enters into the judicial remedy system. If a defendant in a civil proceeding for patent infringement would not like to initiate the lengthy invalidation proceedings through the TIPO, he or she may just raise the issue of the invalidity as a defence in the civil proceedings. The judges’ decision on the issue of the invalidity, however, will not have res judicata; that is, the patent is still valid even though the judges hold the patent at issue invalid in the civil proceedings. However, the judged invalidity issue may still have an effect of issue preclusion for other cases involving the same parties.

Although any party can institute the invalidity claim before the TIPO, only the patentee or the exclusive licensee has a standing to bring an infringement claim to prevent or exclude others from exploiting the invention, utility model or design patent.

As to limitation periods, the right to claim patent infringement becomes extinguished if not exercised within two years after the patentee has become aware of the damage and the person liable for damages. The rights to claim also become extinguished if they are not exercised within 10 years after the time of infringement.

While anyone may bring an invalidity claim before the TIPO, if the ground of the invalidation is that the patentee is not the owner of rights to apply for the patent, an invalidity claim can only be filed by the interested party. In addition, there is no specific limitation period for bringing an invalidity claim.
The proceedings of the patent infringement start after the plaintiff submits a complaint to the court. When the defendant receives the complaint, he or she can submit counter-briefs to the court. The court generally will assign one judge (or a commissioned judge in the second instance) to conduct the preparatory proceedings for clarifying the implications involved in the action or in some specific circumstances, and conduct early evidence collection and investigation. After these procedures, the evidence investigation and oral argument proceedings start when the evidence may be obtained from examination of witnesses, expert testimony, documentary evidence, document inspection, interrogation of interested parties, etc. Finally, at the appropriate decision-making time, the court will render the judgment.

Where it is likely that evidence may be destroyed or its deposition in court may be difficult, or where consent has been received from the opposing party, a party may move the court for preservation of such evidence. Where no action has been initiated, a motion for preservation of evidence shall be made to the court where the action is to be brought. When the action has been initiated, such motion shall be made to the court where the action is pending. The court may inspect, examine or preserve documentary evidence when preservation of evidence is ordered. The level of proof is preponderance of evidence standard. There is no strict discovery proceedings here, as in the applicable US laws. Neither is there standard saisie-contrefaçon in Taiwan as under the French laws, as the criminal provisions were abolished in 2003.

The invalidation proceedings start when the opponent files a petition before the TIPO. When the patentee receives the relevant documents, he or she may submit arguments to the TIPO. There are generally no oral argument proceedings in the invalidation proceedings, and the TIPO will examine ex officio the case on the basis of the written arguments submitted by two parties. When the time for decision discretionarily arrives, the TIPO will render a decision.

The amendments of a patent may be made during the patent invalidity proceedings as long as it is pending before the TIPO. The patent can only be amended:

\[\begin{align*}
& a \quad \text{to delete claims;} \\
& b \quad \text{to narrow down the scope of the claim;} \\
& c \quad \text{to correct errors or translation errors; or} \\
& d \quad \text{to clarify ambiguous statements.}
\end{align*}\]

A defendant may challenge validity as a defence in infringement proceedings. The invalidity challenges generally cannot stay the proceedings for infringement. Therefore, if the judge holds that the patent has not been infringed in any way and the action is thus mature for decision, the court may render a judgment dismissing the plaintiff’s claims because of non-infringement, leaving the issue of invalidity unaddressed because it does not affect the results of judgment. Similarly, if the judge holds that the patent is invalid and the action is thus mature for decision, the court may render a judgment dismissing the plaintiff’s claims because of the invalidity without making any mention of the issue of infringement.

In general, a patent infringement case will take six to 12 months for each instance, and its cost may be around NT$300,000 for an average case.

Patent invalidity proceedings before the TIPO may take one to two years. If, however, the patent invalidity proceedings are derived from the patent infringement proceedings, it will take much longer because the TIPO tends to intentionally, though not necessarily, wait and make their decision after the patent infringement proceedings irrevocably end. The initial cost for the proceedings before the TIPO may be around NT$100,000 for an average case.
The plaintiff can move for an injunction maintaining the temporary status quo before the infringement proceedings. The plaintiff shall explain why it is necessary to prevent material harm or imminent danger or other similar circumstances through such motion. The practical standards may be understood as those implemented in the United States – in other words:

- that there is a likelihood of irreparable harm with no adequate remedy at law;
- that the balance of harm favours the movant;
- that there is a likelihood of success on the merits of the case; and
- that public interest favours the granting of the injunction.

The court dismisses the motion if the explanation is insufficient. In addition, even when the grounds of motion for an injunction maintaining the temporary status quo are sufficient, the court may still order the applicant to provide a security for granting the injunction.

Although no specialised term is used for ‘protective letter’ in this jurisdiction, such a letter is theoretically possible because it has the nature of a provisional measure. Furthermore, a declaratory judgment for declaring a patent is invalid is justified. In addition, under current practices, before an injunction maintaining the temporary status quo is granted, the court shall accord all parties an opportunity to appear in the hearing.

When the court later revokes an injunction maintaining the temporary status quo because such order is not justified ab initio, or such revocation is moved by the creditor, or a regular action is not initiated within the court-specified time period, the movant of the injunction shall indemnify losses suffered by the opposing party.

According to Article 45 of Taiwan Fair Trade Act, ‘no provision of this Act shall apply to any proper conduct in connection with the exercise of rights pursuant to the provisions of the…Patent Act.’ This rule is further addressed in Judicial Yuan Interpretation No. 548 by Justices of the Constitutional Court. This Judicial Yuan Interpretation opines that the proper conduct in connection with the exercise of rights includes:

- if the rights owner has obtained the court’s first-instance decision or identification report from a fair and objective appraisal body, and notified the manufacturers in advance that the owner’s rights appear infringed when the rights owner disseminates a warning letter of infringement; and
- if a warning letter is disseminated without attaching the above-mentioned court’s decision or identification report, but the rights owner faithfully describes specific contents and scopes of the rights and specific facts of the infringement, and does not violate prohibition provisions of the Fair Trade Act.

That is, it is a fundamental principle that although the patent law grants the patent rights owner the rights to exclude and prevent infringement by others, the rights may not be abused. If the rights owner violates this fundamental principle, he or she is not worth protection and may be charged under the Fair Trade Act.

**IV SUBSTANTIVE LAW**

**Infringement**

For a product invention, utility model or design patent, an exploiting act means the act of making, offering for sale, selling, using or importing that product for the aforementioned purposes. For a process invention patent, an exploiting act means:
a using the process; or

b using, offering for sale, selling or importing for the aforementioned purposes the product obtained directly by that process.

The exclusive patent rights are only enforceable within Taiwan’s jurisdiction, and no extraterritorial jurisdiction is, therefore, available.

Where there is a person who has not yet committed an actual infringement but has completed preparatory acts for infringement, the patentee may petition to prevent the person from the acts of patent infringement in order to strengthen the protection of the patent rights. For example, if the person has purchased the machine and raw materials, and has prepared to manufacture and sell products embodying the patented invention, these preparatory acts are likely to eventually infringe the patent rights. Under these circumstances, the patentee does not have to wait for the actual infringement before requesting the infringer to remove the infringement, and the patentee may petition to stop or prevent the preparatory acts from maturing into the occurrence of eventual actual infringement as long as he or she demonstrates the possibility of infringement.

In Taiwan, the Patent Act does not specifically provide joint liability, so the application of joint liability should be supplemented by Civil Code and judicial precedents. Paragraph 1 of Article 185 of Taiwan Civil Code stipulates: ‘[i]f several persons have wrongfully damaged the rights of another jointly, they are jointly liable for the damages arising therefrom’. In addition, one of the most common acts of joint infringement is the joint tort act, and there are basically three requirements to establish the joint tort, as follows:

a there are multiple actors (not all of the actors need to personally implement the tort act). For example, if several persons collude together and implement the tort act by a part of them, the person who takes or recognises the others’ acts as his or her own act is also an actor;

b every actor needs to meet the requirements of general infringement acts; and

c a connection of intent is not required among the actors – only jointly associated acts are required. ‘Jointly associated acts’ means that any of the actors’ negligent acts is a common cause of the damage.

Directors of infringing companies may normally be held liable for infringement under Paragraph 1 of Article 185 of the Taiwan Civil Code, or similar rules related to vicarious infringements, such as Article 188 of the Taiwan Civil Code and Article 23 of the Taiwan Company Act.

The application of the divided infringement under Paragraph 1 of Article 185 of the Taiwan Civil Code is much more uncertain. In a Supreme Court case of 1989 in Taiwan, the Court held that, within the purpose of joint infringement, the tort implementers sharing in a part of the infringement act and mutually taking advantages of the others’ acts to achieve the purpose are also joint infringement actors and are jointly liable for the damages arising therefrom. Therefore, it seems that divided infringement where each tort implementer performs a portion of steps to complete an infringement act may be applied in the general civil law regime in Taiwan. Common purpose or direct or control relationships between the actors may be required to prove divided infringement.

Foreign suppliers or accessories may be held liable for infringement under Paragraph 2 of Article 185 of the Taiwan Civil Code, which provides that instigators and accomplices are deemed to be joint tortfeasors. In addition, the court’s decision usually holds that instigators’ or accomplices’ knowledge of the infringement is required for them to be liable.
The scope of a patented invention shall be determined by the claim, and descriptions and drawings may be considered as a reference, but not a limitation, when interpreting the claim. Claims should be interpreted in a reasonable, rather than the broadest, way. The intrinsic evidence (e.g., specification, claims, drawings and file wrapper, and relevant or corresponding cases) and extrinsic evidence (e.g., professional dictionaries, reference books, textbooks, encyclopedias and expert testimonies) may be used as a reference to interpret the claims and the order as intrinsic evidence is applied prior to extrinsic evidence.

The all elements rule must be satisfied when applying either literal infringement or doctrine of equivalents, where the element does not necessarily mean the physical element but the technical feature of the claim. When an accused product or process was literally read on a claim, it is literally infringing on the claim. When the accused product or process was not literally read on a claim but was substantially identical to the claimed invention in aspects of their ways, functions, and results, it still constitutes infringement under the doctrine of equivalents. There are, however, some limitations against the doctrine of equivalents, such as the prosecution history estoppel, prior art defence and donation principle.

A prior arts defence means that when determining whether or not to apply the doctrine of equivalents, if all the technical features of the accused object are the same as a previous single prior art, or a simple combination of a single prior art and the common knowledge of the technical field at the time of filing, then the doctrine of equivalents is not applicable and the accused object does not constitute infringement.

The donation principle means that if a technical feature is disclosed in the specification or drawings of the patent at issue, but is not covered or recited in the claims, the technical feature shall be construed as a contribution to the public, and the patentee cannot claim the doctrine of equivalents on the technical feature that he or she could have claimed but did not claim during the prosecution.

Invalidity and other defences

At the very least, the bases for bringing an invalidity claim include violation of one of the following legal requirements for a patent:

a statutory subject matter;
b an invention or design should not be:
   • animals, plants, or essential biological processes for the production of animals or plants, except for processes for producing microorganisms;
   • diagnostic, therapeutic or surgical methods for treatment of humans or animals;
   or
   • inventions or designs contrary to public order or morality;
c the enablement requirement;
d the written description requirement;
e industrial applicability;
f novelty;
g non-obviousness;
h the first-to-file principle;
i the double patenting bar;
j the invention or design extending beyond disclosure of the original application; and
k the applicant being not entitled to file the patent application.

There is no best mode or method requirement.
Defences to infringement claims include the following:

- **a** non-infringement;
- **b** acts done privately and for non-commercial purposes;
- **c** necessary acts to exploit the invention for research or experimental purposes;
- **d** right of prior use. However, this rule does not apply if the person has known about the invention from the patent applicant for less than 12 months and the patent applicant has made a statement reserving his or her right to a patent being granted;
- **e** a vehicle merely passing through the territory of this country, or any device of such vehicle;
- **f** international exhaustion of owner’s rights;
- **g** an expired limitation (where the right to prevent and exclude infringement will become extinguished if not exercised within two years after the patentee has become aware of the damage and the person liable for damages, or become extinguished if it is not exercised within 10 years after the acts of infringement);
- **h** licence;
- **i** upon suing an instigator or accomplice under Paragraph 2 of Article 185 of the Taiwan Civil Code, lack of instigator’s or accomplice’s knowledge; and
- **j** upon suing divided infringer under Paragraph 1 of Article 185 of the Taiwan Civil Code, lack of common purpose or direct or control relationship between the actors of the divided infringement.

## V FINAL REMEDIES FOR INFRINGEMENT

A patentee may demand that a person who infringes or is likely to infringe their patent rights must stop or prevent such infringement from happening. When making such a demand, the patentee may request the destruction of infringing articles or materials or implements used in the infringing act, or request another necessary disposal. If patent infringement occurs as a result of intentional act or negligence, the patentee may claim for damages suffered therefrom.

The damages claimed may be calculated according to any of the following methods:

- **a** damages suffered and lost profits;
- **b** if no method of proof can be produced to prove suffered damages, a patentee may claim damages based on the difference between the profit earned through patent exploitation after infringement and the profit normally expected through exploitation of the same patent;
- **c** the profit earned by the infringer as a result of patent infringement; or
- **d** the amount calculated on the basis of reasonable royalties that may be collected from exploiting the patent being licensed.

In addition, where the infringement is found to be intentionally committed, the court may, upon request and on the basis of the severity of the infringement, award damages greater than the loss suffered but not exceeding three times the proven loss.

The plaintiff can move for an injunction maintaining the temporary status quo (preliminary injunction) before or in the regular infringement proceedings. In addition, once the plaintiff prevails in the motion for the preliminary injunction, the injunction will become effective until the injunction is revoked by the appeal court during an interlocutory appeal protesting the ruling for the motion. After trial on all issues, normally in or with
the decision rendered by the court and favourable to the plaintiff, the court makes the final injunction. The ease of obtaining a final injunction depends on its necessity to justify the case situation. If such necessity is affirmed, the court decision is always accompanied by a final injunction. Upon making the final injunction, however, the court will ease its own burden of such decision by requiring the plaintiff’s deposit of a bond generally equivalent to one third of the economic or assessed value of the claim, while allowing the lifting of such final injunction with submission of the defendant’s bond equivalent to the full economic or assessed claim value. The preliminary injunction may be stayed by the same court under the doctrine of change of circumstances through submission of relevant evidence from both parties, while the final injunction may be stayed by a higher court also under the doctrine of change of circumstances. In practice, when stayed, it is possible to appeal the injunction just like one does for the regular court decision. The effective scope of any injunction is commensurate with what is described therein, which in turn depends on what the judge finds in the case. The preliminary injunction is good until there is a final injunction or a court decision ruling its removal, while the final injunction is binding until the cause therein disappears or it is removed by a higher court.

VI OTHER TYPES OF PATENT PROCEEDING

A declaratory proceeding before the court for declaring non-infringement is possible. It is an action normally instituted by a possibly alleged infringer. For a patent matter, the IP Court may be the tribunal selected by the relevant party. Criminal provisions in the Patent Act were abolished in 2003.

In response to a national emergency or other circumstances of extreme urgency, the TIPO shall, in accordance with an emergency order or upon notice from the central government authorities in charge of the business, grant compulsory licensing of a patent that is required, and notify the patentee as soon as reasonably practicable. In addition, the TIPO may, upon request, grant compulsory licensing of a patent under any of the following circumstances for which it is deemed necessary:

a) where a patented invention is to be exploited non-commercially for the enhancement of public interest;

b) where a later invention or utility model patent cannot be exploited without infringing upon a prior invention or utility model patent, and where the later invention or utility model patent involves an important technical advancement of considerable economic significance in relation to the prior invention or utility model patent;

c) where a patentee has committed acts restricting competition or has committed unfair competition acts, for which a judgment has been made by a court of law or a decision has been rendered by the Fair Trade Commission of the Executive Yuan.

Request for compulsory licensing of a patent involving semiconductor technology shall be filed based on the grounds set forth in item (a) or (c) above. Request for compulsory licensing of a patent made pursuant to item (a) or (b) may only be approved if the requestor has made efforts to obtain authorisation from the rights holder on reasonable commercial terms and conditions, and that such efforts have not been successful within a reasonable time period. Where a request for compulsory licensing of a patent is made pursuant to item (b), the owner of the prior patent may propose reasonable terms and conditions and seek grant of compulsory licensing of the later patent owned by the requestor.
An interested party may initiate an invalidation proceeding before the TIPO when the patentee is not the owner of rights, to apply for a patent.

A patentee may request that the Customs Office detain the imported articles that are suspected of infringing the patent right or rights. The request should be made in writing, accompanied by a *prima facie* showing of facts of infringement and a security amounting to the duty-paid price of the imported articles, as assessed by Customs, or its equivalent collateral. Customs shall immediately notify the detention requester upon its acceptance, and shall notify in writing both the detention requester and the owner of detained articles when executing the detention. By providing a security amounting to two times of the security or its equivalent collateral, the owner of detained articles may request that Customs lift the detention.

Customs shall repeal the detention for any of the following reasons:

a. Customs has not been notified by the detention requester, within 12 days of the date of Customs’ acceptance of the request, that a litigation claiming that the detained articles infringe patent rights has been initiated;
b. a litigation initiated by the detention requester claiming that the detained articles infringe the patent rights has been dismissed by a final and binding court judgment;
c. a court of law, in a final and binding judgment, has held that the detained articles do not infringe patent rights;
d. the detention requester has requested the repeal of detention; or
e. the owner of the detained articles has shown to the satisfaction of Customs that they should lift the detention.

VII APPEAL

Disputes or contentions of infringement on patent rights may generally be resolved in the IP Court and Supreme Court. There are three instances, two of which are in the IP Court, and a final instance in the Supreme Court.

The appeal rate is relatively high in Taiwan. This is mainly because the attorney fees for litigation payable by local clients are relatively low, so each party is typically willing to exhaust the appeal proceedings to pursue any possibility of obtaining a more satisfactory decision. If a party decides to appeal the decision of the first instance, it shall be made within 20 days of service of the first instance decision. The judges of the second instance try not only legal issues but also factual issues, such as facts that were not clarified or correctly presented because of the violation of the first instance or other proper cause, facts that occur following the end of the oral arguments, facts that shall be investigated *ex officio* by the court, etc. Accordingly, new evidence may be adduced in the second instance. As long as a decisive legal issue or factual issue exists that was not properly tried in the first instance, the likelihood of overturning a decision is appealing. Although the laws require that any decisive legal or factual issue must be debated in the oral proceedings, written briefs or documents play a critical role.

As mentioned above, each instance may have a time frame spanning from six months to one year, and it may cost around NT$300,000 for an average case in either infringement or invalidity proceedings.

If the party decides to appeal the decision of the second instance to the third instance, it should appeal within 20 days after service of the second instance decision. For infringement cases, this may be possible only if the petitioner’s interests are no less than NT$1.65 million. The judges of the third instance may try only legal issues, so the grounds for appeal shall be
based on arguments regarding how the decision of the second instance violates the laws. For example, the grounds might demonstrate that the decision fails to apply or improperly applies any applicable law, that the original decision fails to comply with statutory procedures, or that the decision was not reasonable or was arrived at through contradictory reasons.

The invalidation proceedings should be made to the TIPO first. The appeal process may be summarised as follows. The applicant shall first appeal the unsatisfied examination decision to the Petitions and Appeals Committee (PAC). If the applicant is not satisfied with the PAC’s decision again, it may further appeal to the IP Court. There are two possible outcomes in the IP Court. If the applicant is not satisfied with the IP Court’s decision, it may further appeal to the Supreme Administrative Court to pursue a final decision.

VIII THE YEAR IN REVIEW

On 23 March 2019, the IP Court handed down a Civil-Patent No. 36, 2015 judgment on *Entegris, Inc. v. Gudeng Precision Industrial Co Ltd*. The court held the defendant shall compensate the plaintiff for the full amount of NT$978,870,000. The patent involved in this case was Taiwan Invention Patent No. I317967.

It is understood that the IP Court recorded the largest amount ever of compensation from the infringer in Taiwan’s semiconductor industry, and the amount is also the second highest record of all the awarded compensation amounts in the history of IP Court’s judgments, and will affect the supply reality of wafer cassettes supplied to wafer foundries, such as Taiwan Semiconductor Manufacturing Company (TSMC). It has a sound impact and implication in the wafer supply for the Taiwan semiconductor industry.

IX OUTLOOK

From the overall atmosphere of the court practices and decisions mentioned in Sections I and VIII, it is believed that Taiwan will become a jurisdiction that is much friendlier to the patent owner. Therefore, I believe that the practices of claiming monetary remedies and calculating damages or compensation, which are sometimes described as the last mile for realising the value of a patent, will become hot topics in Taiwan in the future.
Chapter 24

TURKEY

Mehmet Nazim Aydin Deriş, Okan Çan, Muazzez Korutürk and Oya Yalvaç

I  OVERVIEW

Geographically positioned between Europe and Asia, Turkey is a very important strategic country with a population of 82 million, including a large youth population compared to the EU. Turkey, a G20 country, aims to position itself in the global value chain and to strengthen its exportation platform by focusing on high-tech patents, including electronic machinery and equipment, automotive spare parts, railroad and maritime transportation, as well as energy generation and efficiency projects. In addition, as a natural hub for transportation, Turkey is a transitional trade platform to and from Europe and Asia, which significantly increases the importance of IP rights protection in Turkey.

Although an attractive market due to its size and geographical location, Turkey suffers from a counterfeiting problem, as mentioned in some reports. In the OECD-EUIPO study ‘Mapping the Real Routes of Trade in Fake Goods’, Turkey is cited as one of the source countries for counterfeit goods. Another report on EU customs enforcement of intellectual property rights mentions Turkey among the top three countries of provenance by value of detained counterfeit goods.

An important development regarding the patent legislation and litigation landscape was the entry into force of the Industrial Property Code 6769 (IP Code) on 10 January 2017, which is set to profoundly change IP in Turkey as it affects the legislative, administrative and professional components thereof.

The IP Code made wide-ranging structural changes at:

a the legislative level – regarding the establishment, prosecution, maintenance and enforcement of IP rights;

b the administrative level – regarding the administrative structure and function of the Patent and Trademark Office (previously known as the Turkish Patent Institute);

c the professional level – with new rules regarding the organisation and activities of patent and trademark attorneys, especially from a disciplinary standpoint; and

d the judiciary level – concerning the Patent and Trademark Office’s judicial competences, such as the cancellation of trademark registrations on the ground of non-use.

The new IP Code repeals the following decree-laws with an act of Parliament:

a Decree-Law 551 on patents and utility models;

b Decree-Law 554 on designs;

c Decree-Law 6769 on industrial designs.

1 Mehmet Nazim Aydin Deriş is founding partner, Okan Çan is partner and Muazzez Korutürk is senior associate at Deriş Attorney-At-Law Partnership, and Oya Yalvaç is partner at Deriş Patent and Trademark Agency AS.
The IP Code, enabling the patentee to use legal means harmonised with the EU legislation and with international agreements such as the Paris Convention and TRIPs, provides effective legal means for enhanced patent enforcement capabilities.

According to the statistics, the average number of patent litigation cases filed per year between 2015 and 2018 was 225. Most of the patent litigation cases are handled before the specialised IP Courts in Istanbul, Ankara and Izmir.

II TYPES OF PATENT

Although the new IP Code provides exclusive rights for two types of models, namely patents and utility models, there are currently three types of exclusive rights regarding the patents which are subject to enforcement remedies.

National patents are patents filed in Turkey and registered by the Turkish Patent and Trademark Office (TurkPatent) for 20 years. It is possible to oppose national patents within six months upon the publication of the grant decision in the official patent bulletin of TurkPatent.

International patents that designate Turkey are deemed national Turkish patents valid for 20 years from the application date.

Utility models require the existence of novelty and industrial applicability but do not require the criterion of inventive step for grant. The term of utility models is 10 years starting from the filing date.

Short-term patents are patents granted without undergoing substantive examination for a period of seven years as per the repealed Decree-Law 551 on the protection of patents. Despite the fact that all provisions with regard to short-term patents have been abolished by the IP Code, patents that were granted according to the former Decree-Law are still alive and enforceable.

Supplementary protection certificates (SPCs) are not afforded protection in Turkey.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Tribunals

There are specialist criminal and civil courts of intellectual and industrial property rights established in Istanbul, Ankara and Izmir, which have jurisdiction in all IP matters, including patent disputes. Other cities have specific first instance courts that are designated as specialist IP courts. These specialist courts are composed of one judge, who does not have a scientific or technical background but is knowledgeable and experienced in IP disputes. The following rules for forum selection apply:

a all challenges to administrative decisions of TurkPatent are heard by the Civil Court of Intellectual and Industrial Rights of Ankara;

b infringement and unfair competition actions should be heard in the court of the locality where the plaintiff resides, or where the wrongful act was committed in, or otherwise where the effects of that act have been observed;

c invalidity and declaration of non-infringement actions should be heard in the court of the locality where the defendant IP holder resides;

actions brought by non-resident IP holders should be heard either by the court where the agent registered for the IP right before TurkPatent is located, or the specialist court of Ankara; and

forum selection by agreement between the parties is permitted, subject to a signed agreement.

In practice, Istanbul is the city in which the highest number of patent litigation matters is filed, as it is the city where the highest number of agents of foreign IP right holders are domiciled and the central city for most industrial activities. Istanbul IP Courts have been involved in the most complex patent disputes and have given decisions shaping the patent litigation environment.

Are there any criminal sanctions for acts of patent infringement?

Patent infringement is not a criminal offence so the new IP code does not provide criminal sanctions against acts of patent infringement; only civil remedies are available.

Who can institute infringement and invalidity actions?

Turkish Civil Procedural Law requires the legal interest in an infringement action for the patentee to be entitled to institute patent infringement actions against third parties for determining, preventing and ceasing the infringement.

The IP Code stipulates special conditions for licensees to file infringement actions. The exclusive licensee of a patent has all legal remedies pursuant to the IP Code available against infringing third parties unless it is agreed to the contrary in the licence agreement.

The non-exclusive licensee is required to notify the right holder under special conditions. In the case of serious risk of damage, the licensee has the right to request the court to order for preliminary injunction while subjecting the licensee to notify the right holder of the infringement by asking him or her to file an action against the infringement.

Can the infringement claim be based on a patent that has not yet been granted?

An infringement claim needs to be based on a granted patent (either a national patent or a patent validated through the European patent or the Patent Cooperation Treaty (PCT)). However, the infringement claims can also be put forward upon the publication of the patent claims in the official bulletin of TurkPatent or even before the publication of the patent claims, provided that the infringing third party is notified with the patent application and its scope of protection. In such cases where the infringement is based on a patent application, the court stays the final ruling until the grant of the patent.

It should also be stressed that if the patentee wants to enforce a European patent that has not yet been validated in Turkey, it is possible to obtain provisional protection in accordance with Article 67 of the European Patent Convention (EPC). In such case, the translation of the claims for asserting the patent should be published in the official bulletin of TurkPatent.

Limitation period

The limitation period for claims of infringement is stipulated according to the general provisions of the Turkish Law of Obligations, which is two years upon becoming aware of the infringement and 10 years in any event. In cases where the infringement is ongoing, the limitation period will be deemed continuously refreshed.
The invalidity of a patent can be claimed during the protection period of the patent or within five years upon the expiration of the patent term against the patent right holder recorded in the Patent Registry by a person who has a legal interest in the invalidity of the patent, by public prosecutors or by relevant public authorities.

vi Procedure in patent enforcement and invalidity actions

Alternative dispute resolution means, such as arbitration and mediation, are available to the parties in lieu of an outright infringement and invalidation action. The procedure before the civil courts has four main stages, which are valid for both patent enforcement and invalidity actions: the mediation phase; the initial examination phase; the experts’ examination; and the decision phase.

Mediation phase

As of 1 January 2019, Law No. 7155 stipulates that a party claiming compensation shall apply to mediation proceedings before filing a court action with compensation claims. It is important to note that the application for mediation has become a mandatory pre-condition for filing a court action. Therefore, should the plaintiff decide to claim compensation besides the claims of infringement or invalidity, they will need to contact the defendant for an amicable settlement under the mediation procedure first. There is no mandatory mediation requirement for patent infringement or invalidity action where there is no compensation claim.

Initial examination phase

When a dispute is brought before a Civil Court of First Instance, the court serves the writ of summons to the defendant. After receiving the writ of summons, the defendant must submit its replies within two weeks of the notification. After the defendant’s replies, both parties have one more exchange of petitions to submit to the court. The parties are entitled to ask for an extension of time for providing their responses to each other in this phase. After completion, the court proceeds with the preliminary examination stage. In this stage, the judge examines whether the procedural requirements have been fulfilled by the parties and determines the subject matter of the dispute.

The experts’ examination

Examination of the merits of the dispute starts at this stage. The court appoints a panel of experts – usually consisting of one Turkish patent attorney or European patent attorney and two technical experts in accordance with the field of technology. The experts submit their reports and parties have the chance to object to the report findings. Should the court find the objections of the parties sufficient, then the court may refer the file to the same panel of experts for an additional experts’ report in the light of the objections or appoint a new panel of experts for the issuance of another experts’ report. Should the experts’ reports submitted by the second panels contradict the first set, then the judge may decide to conduct a further round of experts’ examination. Calculation of the amount of compensation (if claimed by the plaintiff) requires further experts’ examination by a financial expert or experts.
**Decision phase**

The judge ends the experts’ examination phase and schedules a day for hearing the final arguments of the parties, if it decides that the matter has been examined sufficiently and the information at hand is enough to rule on the matter. After the oral proceedings, the Court renders its reasoned decision.

Detailed information on the procedures with regard to the appeal phase may be found in Section VII.

**vii  Process for obtaining and presenting material to the court**

According to Turkish procedural law, all parties are obliged to file documents evidencing their claims or defences, or both. In cases where there is a risk of loss, parties with legal interest may ask the Court for the determination of evidence. Such determination may be requested either prior to filing the main civil proceedings or within the context of a pending action for securing the evidences (if it is at risk of being concealed or lost).

As determination of evidence is also regulated under the IP Code on the basis of Article 150/3 the patentee may ask the Court to order to the infringer to submit documents in relation to the use of the patent for determining the damages for a possible claim of compensation.

The patentee during the proceedings is also entitled to ask public authorities, such as TurkPatent, Customs or any related regulatory body or bodies, to submit information in their possession for evidentiary purposes through the court.

**viii  Amendment of patents in the course of court proceedings**

It is possible to amend the claims during the post-grant opposition proceedings before TurkPatent, which is a major structural change introduced with the new IP Code as of 2017, (Article 99(4) IPC).

During an invalidity court action, where the grounds for invalidity concern only part of a patent, a partial invalidity of this patent shall be ruled by cancellation of the claims pertaining to such part. A claim may not be partially invalidated (Article 138(4) IPC). In other words, a claim may not be amended, but may be cancelled as a whole.

On the other hand, a European patent validated in Turkey may be limited by amending the claims in proceedings before the competent court or authority relating to the validity of the European patent according to Article 138(3) EPC. The patent as thus limited shall form the basis of the proceedings.

Cancellation of an independent claim causes the cancellation of the dependent claim or claims with the proviso that each of the dependent claims, on its own, does not meet the patentability criteria. Accordingly the dependent claims meeting the patentability criteria, independently from each other, shall survive (Article 138/4).

In this regard, it is important to note that the new IP Code does not provide the possibility to amend the claims by bringing them together to overcome their cancellation. This stance conforms to the practice of the courts in retaining or cancelling the claims in their entirety.
Invalidity as a counterclaim

Turkey has no bifurcated system in patent matters. An invalidity claim can be put forward within the context of the infringement action as a counterclaim or separately in a separate action. Here are two possible scenarios in case the defendant files an invalidity action:

a. where party A files an infringement action, the adverse party B may file a counteraction claiming invalidity within the context of the infringement action. In such case, the court would examine these two claims at the same time.

b. where A files an infringement action, the adverse party B may file a separate invalidity action before a different competent court. In such case:
   • the court before which the invalidity action is filed may decide to consolidate the file with the earlier infringement action on its own discretion. In such case, the invalidity and the infringement actions will proceed simultaneously under the same action; or,
   • the court competent for the infringement action may decide to stay the proceedings until the invalidity action is concluded.

There is no provision or consistent practice concerning the acceptance of a pending opposition, especially if an opposition is filed before the EPO, which has been accepted as a dilatory issue. Such defence is evaluated as per the specific circumstances of each case. In two relatively recent Supreme Court decisions, it was stated that the Court should check the status of the European patent that was opposed before rendering a decision in a pending patent litigation matter.²

Timing and cost

Turkey has a three-instance court system and civil procedure, consisting of the Court of First Instance, the Regional Appellate Court and the Supreme Court in the third instance. Depending on the complexity of the matter and the rounds of expert examination by the panel of experts during the proceedings, a patent litigation suit takes around 18 to 30 months from the filing of the action up to the Court of First Instance’s decision.

The official fees and expenses for a patent litigation suit, whether for an infringement or for an invalidity action, and where there is no compensation claim, depend on the rounds of examination by the court-appointed panel of experts. The expenses and official fees in a straightforward lawsuit with one round of examination would be around US$2,000. In either infringement or invalidity procedures, the official fees would increase depending on the amount of the compensation to be claimed.

The Court does not rule on the effective attorney fees spent for the prosecution of the file through an attorney-at-law. The Court will only rule to a fixed attorney fee, which is determined by the Turkish Bar Association (around US$250), and the reimbursement of the official fees paid by the winning party at the end of a patent litigation suit either for infringement or invalidity where there is no compensation award. If the Court has awarded the plaintiff compensation, the reimbursed attorney fee may increase depending on the

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amount of awarded compensation. For instance, if the Court has awarded US$1,000, the winning party will be entitled to ask for 12 per cent of such amount as an attorney fee, in addition to fixed attorney fees.

xi Preliminary relief

The patentee is entitled to obtain a preliminary relief order in the following situations: within the context of the main infringement action; within the context of the evidential action; or independently.

In each case, preliminary relief may be requested and carried out ex parte or inter partes, subject to the discretionary competence of the Court. It is to be noted that in practice the courts are quite conservative in granting ex parte preliminary relief.

A preliminary relief request may be refreshed at any stage of the action when there is a new development on the matter and a change in the conditions, such as the issuance of a favourable expert report, etc.

Preliminary relief requests are deemed to be urgent matters to be handled according to Turkish procedural law. The most important requirement is to submit substantial evidence attesting a prima facie infringement in order to convince the judge that there is risk of an infringement. Another requirement would be to deposit a guarantee payment before the Court (on discretion of the judge) for the execution of the preliminary relief order once the decision is rendered by the Court. It is important to note that the guarantee payment and the request of execution of the preliminary relief order shall be done within one week of the issuance of the preliminary relief order by the Court. Failure in depositing the guarantee payment and in the execution of the order within one week results in the release of the preliminary relief order.

The amount of the guarantee payment depends on the discretion of the Court in view of the value of the dispute, (i.e., the commercial value of the patent).

Finally, the Turkish IP Courts can also reverse preliminary relief orders upon the deposit of the guarantee payment by the defendant. In such case, the Court may order a preliminary relief that will prevent the patent holder from enforcing its patent rights against the defendant parties.

There are no practice and legal grounds for protective letter in Turkish procedural law.

xii Liability for threatening infringement

The general provisions of Turkish law seeks and protects the interest of a person who puts forward claims against third parties. Should a patentee threaten third parties with a patent infringement action in bad faith knowing that a third party does not infringe the subject patent, and threatens the third party with the cease of its commercial activities in case it continues to carry them out, this patentee would face liability based on the general provisions of the Turkish Civil Law. Besides, such actions would also incur liability based on unfair competition claims.

The Turkish Commercial Law reads that the following actions constitute unfair competition:

a discrediting others or their goods, their activities, or the products of their work or their commercial affairs by means of wrong, deceitful or uselessly offensive statements;
giving wrong or deceitful information regarding one’s own situation, goods and the products of one’s work, one’s commercial activity or commercial affairs of acting in the same manner regarding third persons or putting them in a situation above their competitors; and

acting as if one had obtained a distinction, degree or reward without having obtained the same, thus trying to create the impression that one has exceptional capacities, or using false titles or professional names that are liable to create such impression.

Accordingly, anyone threatening third parties with patent infringement based on deceitful information shall face unfair competition claims.

**IV SUBSTANTIVE LAW**

i **Infringement**

The commercial use of a patented invention and its embodiments are defined as infringing activities in the IP Code, which stipulates that the partial or complete imitation of products embodying the patented invention is an act of infringement against the patent rights of the patentee.

The IP Code specifies infringing parties as persons who know or should have known that the products in question are imitations. By doing so, end users and consumers are excluded from the acts of infringement. Two elements, the commercial purpose and benefit of third parties, are sought in an infringement. This being said, the IP Code provides that the following actions constitute acts of infringement:

- distribution, sales, importation or the commercialisation in any other way of products embodying the patented invention;
- keeping such products in possession for commercial purposes;
- use of the patented product by means of making the patented invention applicable; and
- making proposals to establish an agreement related to a patented product.

The IP Code introduces a separate provision with regard to the acts of infringement against process patents. The following actions of third parties who know or should have known that the process is being used without the consent of the patentee are deemed to be infringing:

- the use of the patented method;
- the sale, distribution, importation or commercialisation in any other way of the products obtained directly by the patented method;
- keeping products obtained directly by the patented method in possession for commercial purposes;
- the use of the patented method by means of making the patented invention applicable; and
- making proposals to establish an agreement related to a patented method.

Moreover, the IP Code continues to consider the following actions as infringement:

- the usurpation of a patent; and
- expansion or transfer of rights granted by the patentee through a contractual or compulsory licence agreement without the consent of the right holder.
As indicated above, preparatory acts, such as making proposals, are also deemed to be infringing actions. However, the preparatory actions should be evidenced by substantial documents in order to constitute a serious basis for infringement claims.

Any party taking part in the commercialisation of the patented product in Turkey is liable for infringement. Importers and exporters of infringing goods, suppliers and any person who provides parts of the patented product in a way to apply the patented invention can be held liable for infringement.

Should the infringing party be a legal person, the Turkish Commercial Code requires fault and bad faith to hold the directors or the members of the entity’s executive bodies, or both, liable. However, the liability would rest only on the legal entity in case of an infringement. This is a problem in the execution of the court decision for the payment of the compensation if the infringing entity goes bankrupt or liquidates itself upon being sentenced to pay compensation to the patentee.

ii **Doctrine of equivalents**

The claims define the scope of protection of a patent application or a patent, pursuant to the IP code. The IP Code rules that the claims are construed in the light of the applicant’s declarations and statements during the examination proceedings and the validation of the patent. In patent infringement proceedings, the court will also take into account the doctrine of equivalents. In that regard, the construction of the claims is not limited to the literal meaning of the words used in the claims. An alleged patent infringement is first examined by comparing the properties of the product or process with the literal meaning of the words used in the claim. If that does not reveal an infringement, the court will evaluate whether the alleged product or process performs substantially the same function, in the same way, leading to the same result, as the claim – the purpose of the claims of the patent being to provide a reasonable degree of certainty to third parties and applicants, while also protecting the patentee. In that regard, the IP Code provides that claims should not be expanded to cover ideas that the inventor had conceived of but which were not included in the claims, and that the claims should cover the features expected to emerge from the reading of the description and drawings by a person skilled in the art.

**Contributory infringement**

Article 86 of the IP Code, regarding contributory infringement, reads as follows:

> (1) The right holder of a patent is entitled to prevent third parties, from handing over to persons unauthorised to work with the patented invention, elements and means related to an essential part of the invention, subject matter of the patent, and rendering that which renders possible the implementation of the patented invention possible. In order that this provision may apply, the concerned third parties have to know, that such elements and means are sufficient for putting the invention to use and that they know, that they will be used to such effect or that the circumstances render such situation sufficiently evident.

> (2) The provisions under Paragraph one of this present Article shall not apply, when the elements or means referred to in Paragraph one of this present Article are products commonly to be found on the market, unless third parties incite the unauthorised persons concerned to commit such (prohibited) acts.'
First, two conditions are to be met according to Paragraph 1, the offered ‘means and elements’ must be essential features of the invention for infringement to be made out. Second, for liability to be established, third parties that offer these elements and means should be aware that they render possible the implementation of the invention.

In respect of ‘means and elements’ mentioned in Paragraph 1, which are ‘commonly to be found in the market’, Paragraph 2 introduces a third condition in that third parties have to have incited the unauthorised person to commit infringement.

**Process patents**

The protection provided by a process claim extends to the products directly obtained by the process. The sales, use or importation of such products is a patent infringement.

**Burden of proof in process patents**

Where the patent concerns a process for the production or preparation of a product or a substance, the Court may require the defendant to show that the alleged product has been produced without infringing the patented process.

Where the patented invention covers the process for the production or preparation of a new product or substance, the defendant is deemed to have produced the alleged product with the patented process. The burden of proof rests on the defendant to show that the product concerned has been produced by a different process than the patented one.

**iii Invalidity and other defences**

**Invalidity**

Besides lack of novelty, inventive steps and industrial applicability, patents can be invalid on the following grounds:

- Lack of sufficiency: the description, claims, and the drawings referenced in the description or the claims, do not explain the patent in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;
- Added subject-matter: the subject-matter extends beyond the scope of the application as filed or beyond the scope of the earliest application, where the patent has been granted on a divisional application filed pursuant to Article 91 or on a new application filed pursuant to Article 110 (after the Court’s final decision ruling that the applicant does not have the right to claim a patent); and
- Subject-matter that is not patent eligible: if the subject-matter of the patent falls within several categories defined by Article 82 of the IP Code, as not being regarded as inventions:
  - discoveries, scientific theories and mathematical methods;
  - plans, rules or methods regarding mental activities, business activities or games;
  - computer programs ‘as such’ (but computer-implemented inventions in the sense of the EPC are patentable in Turkey.); and
  - aesthetic works, literary and artistic works, as well as scientific works; and presentation of information.

In addition, Article 82(3) of the IP Code excludes the following inventions as not patentable:
a inventions against public order or morality (although the prohibition of the commercial use of inventions by means of legislation does not mean that it is against public order or morality);
b plant or animal varieties or essentially biological processes (meaning the production of plants or animals consisting entirely of natural phenomena such as crossing or selection) to produce plants or animals, excluding microbiological processes (meaning any process involving or performed upon or resulting in microbiological material) or the products thereof;
c all therapeutic diagnostic and surgical methods to be applied to the human or animal body (this exception for therapeutic, diagnostic and surgical methods does not apply to products, particularly substances and compositions used in these methods);
d the human body, including the human body at the various stages of its formation and development and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;
e processes for cloning human beings,
f processes for modifying the germ line genetic identity of human beings;
g uses of human embryos for industrial or commercial purposes; and
h processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Compulsory licence

According to the IP Code, compulsory licences should be granted in the following circumstances:
a for the export of pharmaceutical products to address public health needs in other countries (the basis of this requirement is the Protocol amending the TRIPs Agreement – Additional Article 31 bis);
b where it is not possible to develop a new plant variety without infringing a patent;
c where actions have resulted in a limitation or violation of competition rules (Article 129/1e) (under Article 93 of the repealed Decree-Law No 551 mention was made of ‘unfair competition’), the request for the compulsory licence can be made to the courts, or in the case of limitation or violation of competition rules, to the competition board;
d where the use of the patent is not sufficient to satisfy the requirements of the national markets;
e the failure to use the patent within the statutory time period of three years from the publication of the grant decision or four years from the date of request, whichever is later; and
f the discontinuance of use of the patent without a justifiable reason for an uninterrupted period of three years.’

Bolar exemption

Article 85 of the IP Code on the scope and limits of a patent right provide under Paragraph 3 that ‘activities for trial purposes involving a patented invention, including registration of the pharmaceutical as well as tests and trials required for registration’ are exempted from patent protection.
The motivation of this provision explains that this enables the generic drug providers to launch their products just after the expiration of the patent term without waiting for the regulatory proceedings.

Precedent decisions ruled that filing an application for obtaining a marketing authorisation is deemed within the scope of the *Bolar* exemption and would not constitute patent infringement.

**Preparation of a prescription**
The use of medicines prepared in pharmacies without mass production for the preparation of a prescription and actions related to such medicines is exempted from patent infringement.

**Use of breeder’s rights for new plant varieties**
The use of the propagating material of the harvest obtained by planting a patented product sold by the patent holder upon his or her consent or acquired in another commercial way by a small farmer is stipulated not to infringe the patent rights.

**Use of animal breeding or other reproductive material**
Farmers can use animal breeding or other animal reproductive material sold by the patent holder, or upon his or her consent, or otherwise acquired in another commercial way, for agricultural purposes. This right extends to the use of animals or other animal reproductive material for the purpose of maintaining the farmer’s own agricultural activity. Procedures and principles with regard to the use of such right have been laid down in the implementing regulation.

According to Article 118 of the Implementing Regulation of the IP Code, the main aim for such a use should be for the continuation of the farmers’ agricultural activity and not in the sense of any commercialisation of the reproductive cells, semen or embryo of the patented animal. The milk and meat production from the patented animal are not deemed to be the commercialisation of the patented animal but as the produce of agricultural activity of the farmer. Thus, the reproduction of the patented animal on the farm for the use of the farmer is also not deemed to be commercialisation of the patented animal.

**Exhaustion of rights**
The patent rights of a patentee are exhausted once they are put on the market by the right holder. The former contradiction between the law and jurisprudence was removed by the IP Code, which introduced the principle of international exhaustion of rights.

**V FINAL REMEDIES FOR INFRINGEMENT**
The IP Code provides several legal remedies to the patentee enabling the patentee to protect and enforce patent rights against infringing activities. One remedy of the IP Code is that it enables the patentee to request the prevention of an infringement in case of a serious risk of infringement.
i  **Evidential action for determination of act of infringement**

It is possible to file a non-adversarial action, that may proceed *ex parte* subject to the Court’s discretionary competence, for the determination of the act of infringement or evidence, or both. A positive outcome of this action serves as official evidence and as the determination of the infringing act and evidence within the context of the subsequently filed main civil action.

Moreover, the patentee may request the determination of the production capacity and the process of production for the facilitation of calculation of the damages in the next stages of the proceedings.

ii  **Permanent injunction**

The IP Code enables the patentee to request simultaneously the ‘determination and prevention of infringement’ from the court as a part of the permanent injunction order.

iii  **Compensation of material and moral damages**

The patentee is entitled to ask for material and moral compensation. The calculation of the material compensation is based on the loss of profit.

Article 151, Paragraph 1 reads that the damages suffered by the patentee cover both the actual loss and the loss of profit. The loss of profit can be calculated according to one of the below methods preferred by the right holder:

a. probable income that may be earned by the right holder if the competition of the infringer did not exist;

b. net income earned by the infringer of the industrial property right; and

c. the licence fee required to be paid in case the infringer of the industrial property right used such right by means of a licence agreement as required by law.

The IP Code stipulates that factors, such as the nature and extent of infringement, particularly the economic importance of the industrial property right or the number, term and type of licences related to the patent in dispute and at the time of infringement, shall be taken into consideration when calculating the loss of profit.

A patentee who prefers the method of calculation in points (a) or (b) above may request to add an appropriate amount to the calculated compensation in case the patent has a determinant role in the demand for the infringing product in the market.

In addition, the patentee is entitled to ask for moral and reputational compensation, where the reputation of the patent right suffers damage, in the event the products or services forming the subject of the right were used or produced in an inferior manner or where such products are launched in the market or made available in an improper manner.

iv  **Confiscation of infringing products and the devices and machines used in the production of such products**

The patentee is entitled to ask for moral and material compensation and the seizure of the infringing products and devices and equipment used for their production to the extent these devices and equipment are not used in the production of other products produced by the adverse party.
Measures to prevent the continuation of infringement
The patentee may also request the destruction of the infringing products, devices and machines used for their production if this is inevitable for prevention of the infringement or may ask for the change of the shape of the infringing products, devices and machines used for their production at the expense of the infringing third party, especially to prevent the continuation of the infringement.

Requesting the assignment of the infringing products and manufacturing devices
It is possible to request the assignment of the property rights on confiscated infringing products, on devices and machines used in the production of such infringing products, and the deduction of the value of such products, devices and machines from the total amount of the compensation determined by the Court.

Publication of the court decision in daily newspapers or by means of similar mediums in whole or in summary
The patentee may request the publication of the finalised verdict, in whole or in summary, in daily newspapers or by other means, or the notification of the parties having interest in the legal proceedings at the expense of the adverse party.

Execution and suspensive effect of the decision
The final injunctions can be executed upon the finalisation of the Court’s decision. The finalisation of the Court’s decision matures upon the exhaustion of all legal routes, such as the appeal before the Regional Appellate Court and the Supreme Court, or in the lack of an appeal by the parties.

On the other hand, preliminary relief orders remain valid until the finalisation of the Court decision unless the Court renders a decision for the removal.

As to the suspensive effect of the appeal, the general rule according to the Civil Procedural Law is that the appeal does not have suspensive effect as of Article 367, Paragraph 1, but it does have a suspensive effect as of Article 367, Paragraph 2 for cases involving the ‘right of persons, families, real estate’. The case law rules that the infringement of IP rights considered as acts of unfair competition are deemed to be closely related to ‘personal rights’. For all such cases, the appeal has suspensive effect.

Article 162 of the IP Code rules that in all actions instituted against the decisions of TurkPatent and in invalidity actions the decision of the court is not executable until it becomes final.

OTHER TYPES OF PATENT PROCEEDING

Declaration of non-infringement
Actions can be brought for declarations of non-infringement of a patent against the patentee, but these actions cannot be filed by a party against whom an infringement action has already been filed.
VII APPEAL

Since 2016, the decisions of the first-instance courts are appealed to the regional appellate courts, and then to the Supreme Court of Cassation.

The Regional Appellate Courts have panels composed of three non-technical judges, who may either uphold the first instance decision, or quash the decision and render a new one. The regional appellate court may hold hearings during the appeal and refer the file to a new panel of experts, if it is thought that the matter needs further examination.

The decision of the regional Appellate courts are appealed before the Supreme Court, which has a special chamber for IP matters composed of a panel of five non-technical judges. Unlike the regional appellate court, appeals to the Supreme Court are limited to matters of substantive or procedural law. Decisions of the Supreme Court are final and cannot be appealed. If a decision is reversed by the Supreme Court, the case file is referred to the court of first instance or the Regional Appellate Court (whichever rendered the reversed decision).

According to Turkish procedural law, parties have the right to appeal, with no need to seek prior clearance.

Proceedings before the regional appellate courts take between 15 to 20 months. Appeals before the Supreme Court take around 15 to 18 months.

VIII THE YEAR IN REVIEW

The most important development in IP litigation in Turkey is the post-grant opposition introduced by the IP Code, which applies to national patents filed after 10 January 2017. The post-grant opposition procedures are expected to develop as of the end of 2019 or during 2020, after the patents filed after 10 January 2017 are granted. It is expected to have a significant impact on patent litigation before IP courts in Turkey.

IX OUTLOOK

As mentioned above, the new IP Code substantially impacted the IP landscape in Turkey. Some issues that were vague according to the former Decree Law on patents received solutions increasing legal certainty, such as the burden of proof in process patents or whether a third party needs to notify the patentee before filing a declaratory non-infringement action. Some new questions have arisen with the new IP Code as well.

In particular, Article 82 provides that ‘biotechnical inventions’ are non-patentable, but this term is not defined in the IP Code and will have to be defined by case law. New rules on compulsory licences are also likely to give rise to disputes, and employee inventions, which is an area that requires more legal and operational certainty.

Another hot topic will be the patentability of computer-implemented inventions and AI technologies in Turkey in the coming years.
I OVERVIEW

Although the number of cases concerning patent validity and infringement that get to full trial in the UK, around 20 or so each year, and constituting some 10 to 20 per cent of the actions that are commenced, is not in itself that large, the speed with which patent actions can be taken to trial to provide decisions as to both infringement and validity, and the well-reasoned nature of such judgments, means that the English courts play a significant role in most major patent disputes in Europe. This, coupled with the preparedness of the English courts to adjudicate on the validity of the UK designations of European patents even though these may be under opposition at the European Patent Office (EPO), and the relative ease of establishing standing to seek declarations of non-infringement, means that English courts are often the first in Europe to provide a decision in such disputes.

There are two significant first-instance courts in the UK for patent matters – the Patents Court and the Intellectual Property Enterprise Court. Although certain courts in Scotland and Northern Ireland also have jurisdiction over UK patents, very few patent cases are brought in these jurisdictions.

II TYPES OF PATENT

UK national patents (prosecuted via the UK Intellectual Property Office (UKIPO)) and European patents that designate the UK (prosecuted via the EPO) both have effect in the UK. The same substantive law applies to each, and once granted, both are subject to the same patent litigation procedure, except that European patents are also subject to central revocation at the EPO instituted within nine months of grant. The UK has no utility model or similar protection, but there is no need for any as the grant of UK national patents can be secured relatively quickly and, unlike some European national patents, provides the benefit of pre-grant examination.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

Patent actions in the UK are usually brought in either the Patents Court or the Intellectual Property Enterprise Court, both of which are specialist courts and part of the High Court of England and Wales. Both have jurisdiction in relation to both infringement and validity, and it is common in infringement proceedings for the defendant to counterclaim seeking

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to revoke the patent in suit. Certain types of patent dispute may also be brought in the UK IPO, but in most cases these will be transferred to a suitable specialist court if one or other party so requests. Although their procedures differ somewhat, the jurisdiction of the two English courts is the same, and both can grant injunctions, but the Intellectual Property Enterprise Court (which is intended for smaller intellectual property disputes and for small- and medium-sized enterprises and limits the degree of cost shifting) can only award financial relief of up to £500,000. Transfer between the two courts is possible but is rare, a major consideration being the protection that the cap on costs shifting regime in the Intellectual Property Enterprise Court provides to small- and medium-sized enterprises, although the Court has also heard smaller disputes between large enterprises. In each court, only a single judge will hear matters, but in the Patents Court this judge will be chosen from one of a small number of specialist judges, or in less demanding cases, one of several other designated judges of the Chancery Division. Deputy judges, who will typically be barristers drawn from the Patent Bar but are now also drawn from the solicitors profession, also sit in both courts.

In infringement actions, it is usual to bifurcate the issues of liability and financial relief, so there is no evidence directed to financial relief in the initial liability phase of the proceedings.

In the Patents Court, actions proceed by the service of a claim form and the subsequent exchange of statements of case, which are relatively brief as they should identify the issues between the parties (and the areas of agreement between them) rather than set out any argument. At a case management conference (CMC), the schedule through to trial and the date for trial will be set – typically about a year after the action has been started, although in suitable cases this can be much less if the court orders an expedited trial. An order will be made as to the number of expert witnesses that the parties can call (it is rare for this to exceed two on each side), and whether or not either party should provide further information to the other or respond to requests for admissions as to any matters in issue in advance of the exchange of evidence. An order will also be made as to whether or not there is to be any disclosure of documents relating to the matters in issue and, if so, its scope. Although the default position in the Patents Court is for disclosure as to validity to cover a four-year period centred on the earliest priority date, in recent years the Patents Court has become increasingly prepared not to order this. As an alternative to disclosure, regarding infringement (where this is in issue), the defendant may provide a product or process description. Either party may make applications to the court at any time for further such procedural orders, such as applications for further disclosure or to amend a statement of case.

Expert reports, (as well as any statements of any witnesses of fact and Civil Evidence Act notices) are exchanged on the date fixed at the CMC, typically several weeks before trial, and usually attract expert reports in reply that are also exchanged on the date fixed at the CMC. However, such evidence cannot be relied on unless the other side has had an opportunity to cross-examine those who have given it at trial. Detailed briefs (misleadingly called ‘skeleton arguments’) setting out the respective parties’ arguments are then exchanged shortly before trial. At the trial itself, which can take up to several days, it is usual for the patentee to ‘open’ by explaining its view of the case by reference to its skeleton argument, and then to offer its experts and any witnesses of fact up for cross-examination. The defendant will then offer

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its experts and any witnesses of fact up for cross-examination. It will then explain its view of the case by reference to its own skeleton argument, supplemented by reference to the cross-examination, and the patentee will then respond in like manner.

A written judgment is then delivered, usually within a few weeks of the end of trial, which is first shared in confidence with the parties for corrections to be suggested, before it is made public. A further short hearing then takes place to make orders consequential on the judgment, such as to whether to discount the award of its legal costs made in favour of the winning party to take account of any specific issues on which it did not win, whether or not to grant the losing party leave to appeal and, where the validity of the patent has been upheld in amended form, as to its amendment. Where the patentee succeeds in an infringement action, the Court will usually also order an injunction, and whether or not to stay this pending the outcome of any appeal. It will also order an enquiry as to damages or the taking of an account of the defendant’s profits, and as to any preliminary financial disclosure directed to providing the patentee with sufficient information to make an informed election between the two. If a patent is held to be invalid, the Court will make an order for its revocation, suspended pending the outcome of any appeal.

Procedure in the Intellectual Property Enterprise Court differs from that in the Patents Court in that the statements of case should be more detailed and should set out the arguments of the parties. The default position, unless otherwise ordered at the CMC, is for no disclosure and for no oral testimony or cross-examination at trial, which should usually take no more than one day and at most no more than two.

In each court, the winner will recover a large proportion of its legal and court costs, subject to reduction to take account of those issues on which it failed. In the Patents Court this will have the effect of exposing the loser to paying the other side costs of the order of several hundred thousand pounds, and in heavy cases even more, in addition to having to meet its own costs. In the Intellectual Property Enterprise Court, costs recovery is capped at £50,000 for the liability phase and £25,000 for the damages phase, unless the behaviour of the losing party is such as to amount to an abuse of process.

In either court, a patentee is able to seek an interim injunction against infringement pending full trial on the merits. However, to succeed in such an application it must show that damages until trial would not be an adequate remedy and that it would suffer more damage pending trial if no interim injunction is granted than would the defendant were one to be granted. In extreme situations, interim injunctions may be sought without notice to the defendant. Evidence directed to the respective strengths of the parties’ cases on the merits is not relevant on such applications as long as the action is not so weak that it can be struck out summarily. Because of the speed to trial on the merits (and the power of the court to order an expedited trial), it is rare for interim injunctions to be sought or granted in patent infringement cases. One exception concerns the entry into the market of generic pharmaceuticals, as the damage caused by the precipitate and irreversible price drop associated with such market entry is not generally regarded as capable of ready compensation in damages, which is why generic entrants will generally seek to ‘clear the path’ in advance of the launch of patents that are likely to be asserted against them. A condition of the grant of an interim injunction is that the patentee must provide a cross-undertaking in damages in

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4 See, for example, Warner-Lambert Company Llc v. Teva UK Ltd & Ors [2011] EWHC 1691 (Pat).
the event that it loses at the trial on the merits.\(^5\) In addition to the enjoined party, others may seek a similar cross-undertaking if the interim injunction is likely to affect them, an especial issue for the UK National Health Services with interim injunctions against generic entrants.\(^6\)

A defendant may, and usually will, challenge validity by way of counterclaim in infringement proceedings, but may also initiate revocation proceedings at any time. Standing is not required, so anyone can seek to revoke a granted patent. Those who, although they are not threatened with infringement proceedings, wish to seek a declaration of non-infringement can provide to the owner of a patent of concern details of what it is they propose to do, which suffices to establish standing in the event that the patentee does not respond confirming that such activity does not infringe. A patentee may counterclaim for infringement in proceedings for revocation, always assuming that the party bringing the revocation proceedings is actually doing something that can be regarded as infringement and is not simply ‘clearing the path’ in advance of doing so.

Regarding opposition at the EPO to a patent, the subject of English litigation is not usually regarded as providing a basis for staying English revocation proceedings as these can be brought to a conclusion much more quickly than an EPO opposition and its subsequent appeal, unless the EPO proceedings are already far advanced at the time.\(^7\)

A party that fails to pursue a matter that could have been raised at trial on the merits will, in general, not be able to pursue it subsequently. Thus, a patentee should apply to make any amendments to its patent before the trial on the merits, so that the court can hear such application at the same time and determine the allowability of the amendments and whether these suffice to meet the validity attack. In general, the court will not allow such amendments to be made after trial, treating such an attempt as an abuse of process.\(^8\)

Certain types of threat of patent infringement proceedings expose those who so threaten liability in an action that can only be countered by a successful counterclaim for patent infringement. The old law as to what threats gave rise to such potential liability was recognised to be unsatisfactory, and new provisions that are more readily complied with entered into force on 1 October 2017.\(^9\)

\(^{5}\) For an example of an assessment of damages payable under a cross-undertaking in damages given on the grant of an interim injunction, after the patentee had lost on the merits, see AstraZeneca AB & Anor v. KKKA del Novo Mesto & Anor [2014] EWHC 84 (Ch); [2015] EWCA Civ 484.

\(^{6}\) Under Paragraph 10 of the Patents Court Guide 2019 ‘[w]here a party seeks an interim injunction which would affect dealings in a pharmaceutical product or medical device purchased by the National Health Service (‘NHS’), the Court will consider whether the applicant should give such an undertaking in favour of the NHS. The applicant must notify the Department of Health … of (i) the application when it is made and (ii) any order made following the application as soon as practicable.’

\(^{7}\) IPCom GmbH v. HTC Europe Co Ltd [2013] EWCA Civ 1496.


IV SUBSTANTIVE LAW

i Infringement

Infringement may be either direct (e.g., making, selling or importing an infringing product, using an infringing process or importing into the UK the direct product of such a process) or indirect (e.g., supplying or offering to supply in the UK means relating to an essential element of the invention, for putting the invention into effect knowing, or it being obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the UK). Moreover, a party that does not itself infringe may be liable for infringement as a joint tortfeasor with another party that has undertaken infringing acts, where such acts were done pursuant to a common design and the party that did not itself undertake such acts has made them its own.

In practice, most controversies as to infringement concern whether or not the activity in issue falls within the scope of the claim. In *Eli Lilly v. Actavis UK Ltd & Ors* [2017] UKSC 48, the UK Supreme Court reinterpreted Article 69 of the European Patent Convention and the Protocol on its interpretation, and in so doing established a more liberal test for infringement in the UK than was previously the case, widening the scope for infringement by equivalence but permitting, at least in theory, some reliance on patent prosecution history in litigation. Under the new approach, it is first necessary to establish whether the activity in issue infringes the claim as a matter of ‘normal’ interpretation. If not, then the scope of protection in relation to a variant over what is literally required by the claim is summarised as follows:

1. Notwithstanding that it is not within the literal [i.e. contextual] meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?
2. Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
3. Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

These three questions are a reformulated version of those first set out in *Improver Corporation v. Remington Consumer Products Ltd* [1990] FSR 181 at [189], and subsequently regularly applied by the English courts until they fell out of favour in the light of certain observations made by the House of Lords in *Kirin-Amgen Inc & Ors v. Hoechst Marion Roussel Ltd & Ors* [2004] UKHL 46, the previous leading UK authority on infringement. The effect of repurposing these questions as a test for equivalence rather than one of construction, and of their reformulation, in particular as to the second question, is such as strongly to favour a finding of infringement, as is made clear by the analysis of this approach and its application.

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10 The effect of this can be best seen for the reformulated third question when applied to numerical limitations in claims. As part of the construction analysis the third question when applied to such limitations used generally to be answered in the affirmative. As part of an equivalence analysis it is likely to be answered in the negative, as in *Rogen Lab SA v. Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat).

11 The reformulated second question differs especially from its earlier version in providing for a variant to infringe even if the skilled addressee did not know in advance, and it was not obvious, that it would work,
in *Icescape Ltd v. Ice-World International BV & Ors* [2018] EWCA Civ 2219. The courts have yet to address the consequences of the accused product or process being held to be an equivalent, even though such equivalent would also have lacked novelty or inventive step over the prior art at the priority date. Is the accused product or process deemed to fall outside the scope of the claim in such cases, thus providing a defence to infringement?\(^\text{12}\)

Patent prosecution history is not generally an admissible aid to construction in the UK, although in *Eli Lilly*, the UK Supreme Court, while discouraging its use, accepts that it is:

\[\ldots\text{A]ppropriate where (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored [an example of which would be] a case where the patentee had made it clear to the [Patent Office] that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.\]

In practice, these conditions impose a considerable constraint on reliance on prosecution history with the result that, as in *Actavis* itself, in none of the post-*Actavis* caselaw has reliance successfully been placed on it.

ii  Invalidity and other defences

Although questions of patent validity arise during prosecution, it is in the context of challenges to the validity of granted patents that such issues are most fully and authoritatively developed. The only grounds on which the validity of a granted patent having effect in the UK can be challenged are excluded subject matter (e.g., a business method), lack of industrial applicability,\(^\text{13}\) anticipation (lack of novelty),\(^\text{14}\) obviousness (lack of inventive step), insufficiency, added matter (i.e., subject matter has been added in the course of prosecution)\(^\text{15}\) or that the protection has been extended by post-grant amendment. In all these areas, with the exception of excluded subject matter and obviousness, courts in the UK do not regard their case law as being materially different from that of the EPO Technical Boards of Appeal, and will refer to such case law, where appropriate, in addition to their own. Where, as is typical, the patent in suit claims priority from an earlier application and there is prior art that becomes relevant if validity is lost, such claim is often challenged, either on technical grounds or, as has become increasingly common, on the basis that those who claimed priority lacked the right so to do when the filing that claimed priority was made.

As to excluded subject matter, in *Aerotel Ltd v. Telco Holdings Ltd; Macrossan's Patent Application* [2006] EWCA Civ 1371, the English court criticised the EPO approach in

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\(^{12}\) See the discussion in *Technetix BV & Ors v. Teleste Ltd* [2019] EWHC 126 (IPEC) at [85] to [99].


\(^{15}\) See *Novartis AG & Ors v. Focus Pharmaceuticals UK Ltd & Ors* [2016] EWCA Civ 1295 at [52] to [76].
this area, in particular as to computer programs providing a technical effect and so being addressed as part of an inventive step analysis, and instead recommended that courts adopt the following four-step approach:

a. properly construe the claim;
b. identify the actual contribution;
c. ask whether it falls solely within the excluded subject matter; and
d. check whether the actual or alleged contribution is actually technical in nature.

This remains the law in the UK, 16 and although the English courts, if asked, would probably disagree, the view of most practitioners is that the effect in practice of this approach has been to make it more difficult to secure protection in the UK for computer-implemented inventions than in the EPO.

The approach of the English courts to obviousness is the ‘structured approach’, as set out in Pozzoli Spa v. BDMO SA & Anor [2007] EWCA Civ 588:

1. (a) Identify the notional ‘person skilled in the art’ and (b) Identify the relevant common general knowledge of that person;
2. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
3. Identify what, if any, differences exist between the matter cited as forming part of the ‘state of the art’ and the inventive concept of the claim or the claim as construed;
4. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

This differs from the ‘problem and solution’ approach of the EPO, but neither approach provides an answer to the ultimate question of whether or not the claimed invention is obvious. Both are instead intended to put the court or tribunal in the correct frame of mind in which to answer such question. On those occasions on which they have considered the matter, the English Patents Court has not concluded that the two different approaches should result in any difference in outcome. 17

As to insufficiency, the UK Supreme Court observed in Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) & Ors [2018] UKSC 56 at [23] and [25] that:

… The Technical Board of Appeal treats the condition of sufficiency under EPC article 83 as satisfied if it is possible to work the invention across the scope of the claim from the information in the specification, interpreted in the light of common general knowledge at the priority date. It addresses the broader question whether the disclosed contribution to the art is commensurate with the monopoly claimed under EPC article 56, in the context of inventive step…. 


17 For a critique of the Problem and Solution Approach see Actavis UK Ltd v. Novartis AG [2010] EWCA Civ 82 at [25] to [41].
English law diverges from this approach, although the divergence is more a question of labels than of substance. It distinguishes between so-called ‘classical insufficiency’ (where the skilled person is unable to perform the invention from the information disclosed in the specification) and so-called Biogen insufficiency (where the claim is said to be too broad, because it exceeds the disclosed contribution to the art).

Accordingly, insufficiency has been used in the past in the UK as a ground of challenge in ‘claim breadth’ cases whereas in the EPO and other jurisdictions, the same challenge would be formulated as one of lack of inventive step as failing plausibly to solve the objective technical problem, although English courts are now starting to analyse matters first in terms of ‘lack of technical contribution’ obviousness and then finding that claim breadth insufficiency stands or falls with it. In Warner-Lambert, the UK Supreme Court upheld decisions of lower courts that had found those claims to uses of a pharmaceutical for the treatment of certain types of pain that were broad enough to cover central neuropathic pain to be insufficient because there was no basis in the specification or the common general knowledge for saying that it was plausible that the pharmaceutical would be effective for such pain. However, the UK Supreme Court has evidently more to say about ‘Biogen’ insufficiency as it has granted leave to appeal from the decision of the Court of Appeal in Regeneron Pharmaceuticals, Inc v. Kymab Ltd & Anor [2018] EWCA Civ 671, which had reversed a finding at first instance that the patent in suit was insufficient.

It is rare in practice for UK patent litigation to involve one of the specific defences to infringement that are available – for example, as to private and non-commercial use, use for experimental purposes relating to the subject matter of the invention, and personal prior use. However, certain such defences, when pleaded by a defendant, may be a suitable subject of a preliminary hearing, for example, as to the existence and scope of an express or implied licence (which may be determinative in favour of the defendant), or as to whether or not a defence based on competition law can be struck out as unarguable (as otherwise leaving it to be determined at trial would massively expand the scope of such hearing and the nature of the discovery to be given and evidence adduced). Lack of knowledge on the part of the defendant is not a defence to an allegation of direct infringement, although it may be to one of indirect infringement, and can also provide a basis for seeking to limit damages in the case of direct infringement.

V FINAL REMEDIES FOR INFRINGEMENT

A patentee that succeeds in establishing that its patent is valid and has been infringed will be able to secure damages,\(^{18}\) or at its option, an account of the profits made by the defendants by reason of such infringement. It will also almost always be able to secure a permanent injunction against further infringement, although this will typically be stayed, on the same principles as those that apply to the grant of interim injunctions, as discussed above, until there is no further prospect of appeal.\(^ {19}\)

\(^{18}\) For a summary of the principles applicable to such an assessment see Ultraframe (UK) Ltd v. Eurocell Building Plastics Ltd & Anor [2006] EWHC 1344 (Pat).

\(^{19}\) The Court will in certain special cases exercise its discretion to qualify an injunction, for example, so as not to apply to supplies of an infringing medical device for implanting in patients for whom this is the only such device that is suitable, as in Edwards Lifesciences LLC v. Boston Scientific Scimed Inc [2018] EWHC 1256 (Pat).
In the case of patents that have been declared to be essential to a technical standard, an injunction can be avoided as the law stands only by taking a global licence on terms established by the court. However, absent doing so, an injunction will be granted notwithstanding that the patent in issue is essential to a standard.20

VI  OTHER TYPES OF PATENT PROCEEDING

English courts show considerable flexibility in terms of the types of proceeding that may be brought in them, as demonstrated by their preparedness to grant declarations of non-essentiality in relation to patents declared to a standards setting organisation as essential to a technical standard,21 and more recently, by making declarations that certain activities were anticipated or obvious as at certain dates, notwithstanding that there were no longer any patents in existence in the UK that claimed such activities.22

More traditionally, the Patents Act 1977 expressly provides for proceedings for declarations of non-infringement to be brought when a patentee has failed to acknowledge that an adequately described product or process does not infringe. Proceedings may also be initiated to challenge title to a patent, or by employee or former employee inventors seeking compensation for inventions that have proven to be of outstanding benefit to the employer.

VII  APPEAL

Appeal from the UK Intellectual Property Office lies to the Patents Court. Appeals from the Patents Court and, in patent matters, the Intellectual Property Enterprise Court lie to the English Court of Appeal, but only with the leave of either the lower court or the Court of Appeal.23 The Court of Appeal will typically hear appeals some 18 months after the decision at first instance, although in urgent cases this period can be truncated considerably. The panel in the Court of Appeal consists of three judges – at least one, but possibly two, of whom will have had experience of patent proceedings as specialist judges at first instance. Further appeal lies to the UK Supreme Court, but only with its leave, which used to be only rarely given, with the result that in some years the UK Supreme Court, which until this past year had no judges with specialist experience of them, may hear no patent actions. The panel in the Supreme Court consists of at least five judges and now has, for the first time, as a member of its panel a judge with experience of patent proceedings as a specialist judge at first instance.

Appeals are conducted on the basis of the papers that were before the court at first instance and the transcripts of any cross-examination of witnesses and experts in such court. There is no real scope to introduce new evidence on appeal, as it is hardly ever the case that such evidence could not have been secured before the hearing at first instance. Nor, as the appeal should be limited to matters of law, is there any real scope to challenge on appeal findings of fact at first instance unless these are obviously wrong. It is also extremely hard to

23 The considerations to be taken account of in determining whether or not to grant such leave were reviewed in Teva UK Ltd v. Boehringer Ingelheim Pharma Gmbh & Co KG [2016] EWCA Civ 1296.
challenge assessments at first instance of the evidence and findings based on these. Issues of patent claim construction do, however, provide a relatively fertile basis for appeal, as these rarely turn on the evidence.

VIII THE YEAR IN REVIEW

From an international point of view, the most significant recent decision was that of the Court of Appeal in Unwired Planet International Ltd v. Huawei Technologies Co Ltd & Anor [2018] EWCA Civ 2344, upholding the decision at first instance in which the English Patents Court, having found two UK patents to be valid and essential to a mobile telephony standard, determined a fair, reasonable and non-discriminatory (FRAND) royalty for the entire portfolio of which these formed part, not only for the UK but globally, and granted an injunction in respect of the UK patents unless the defendant took such licence. An appeal to the UK Supreme Court against the decision is being heard, on an expedited basis, in October 2019 and its outcome is eagerly awaited.

The decision of the UK Supreme Court in Warner-Lambert Company LLC v. Generics (UK) Limited t/a Mylan v. Warner-Lambert Company LLC [2018] UKSC 56 proved to be something of a disappointment owing to its inability to achieve consensus on the infringement of ‘Swiss form’ claims to new medical uses addressed when such claims present when they are asserted, on a direct infringement theory (as the product of a patented process), against medicinal products that do not have a marketing authorisation for the patented use, but where it can be envisaged that some degree of patented use of such products will take place in practice. The Supreme Court did, however, uphold, the decision of the lower courts as to the threshold of ‘plausibility’ that such a claim must meet if it is not be regarded as insufficient, although it was not unanimous as to precisely where that threshold lay.

IX OUTLOOK

The UK Supreme Court continues to take more of an interest in patent cases than used to be the case, and in this coming year will hear appeals not only from Unwired Planet International Ltd v. Huawei Technologies Co Ltd & Anor [2018] EWCA Civ 2344 but also from Regeneron Pharmaceuticals, Inc v Kymab Ltd & Anor [2018] EWCA Civ 671.

As for Brexit, although the UK patent system and patent litigation (except in so far as jurisdiction is founded on the Brussels I Regulation) will be unaffected, this will have a serious effect on prospects for the Unified Patent Court Agreement (UPCA). This is because although the UK has ratified the UPCA, which would confer jurisdiction on a new Unified Patent Court, concurrent with that of national courts of countries party to the UPCA, and over any European patent designating such country, unless such patent had been opted out before an action was brought in the Unified Patent Court in respect of it, the UPCA is framed on the assumption that all its participants will be EU Member States.
I OVERVIEW

The United States has a highly developed system of patent litigation, largely because of its historic investments in the research and development of technology, coupled with its large and profitable market for products produced both domestically and abroad. US patents are granted based on applications that are examined by the US Patent and Trademark Office (PTO). Those patents can be enforced in the US district courts or at the US International Trade Commission if the infringing products are imported and the patent is used by a domestic industry. All US patents are subject to potential post-grant validity challenges at the PTO. While the volume of patent litigation has varied over time, the need to protect the investments that are necessary to develop new technologies and the profits that are available to competitors suggests that US patent litigation will continue to command significant attention.

II TYPES OF PATENTS

Three types of patents may be obtained in the United States: utility, design and plant. The PTO is responsible for reviewing patent applications and granting patents. Utility patents make up approximately half of the patent applications received and patents granted by the PTO. The grant of a utility patent provides a patentee with the nationwide right to exclude others from making, using, offering for sale, selling or importing any patented invention. The scope of those rights is set forth in one or more patent claims that define the boundary of patent protection and that are the basis for determining patent validity and infringement.

The process of preparing and filing a patent application with the PTO is referred to as patent ‘prosecution’. An applicant may file either a provisional or non-provisional application. A provisional application need only contain a specification and a drawing but no claims, and does not get examined substantively by the PTO. Instead, the provisional application acts as

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1 Thomas L Jarvis and Cyrus T Frelinghuysen are attorneys at Winston & Strawn LLP and Judge Randall R Rader and Benjamin Christoff are partners at the Rader Group PLLC. The following information was accurate as of August 2018.


a kind of placeholder for an applicant who wants to provide evidence of conception no later than the date of the application. An applicant must then file a non-provisional application containing claims within a year.

Examiners at the PTO review patent applications to determine whether the statutory requirements for patentability are satisfied. These include three basic requirements. First, the claimed invention must fall within the statutory subject matter, which covers ‘any ... process, machine, manufacture, or composition of matter, or any new and useful improvement thereof’. In contrast, ‘[l]aws of nature, natural phenomena, and abstract ideas are not patentable.” Second, the invention must be new (novel), meaning the invention was not disclosed to the public either in a printed publication or in any other form prior to the filing date of the claimed invention. Third, the invention must be ‘non-obvious’. An invention may be determined to be ‘obvious’ when a ‘person having ordinary skill in the art’, in other words, someone who is skilled in the general field of the claimed invention, would have been able routinely to come up with the claimed invention based on then-available technology and information.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

The Federal Rules of Civil Procedure, procedural decisional law and any local or judge-specific rules govern civil litigation proceedings, including patent infringement actions. Proceedings in a patent infringement action can be divided into seven phases: due diligence investigations, pleadings, discovery, patent claim interpretation, summary judgment motions, trials and post-trial proceedings.

i Due diligence

The due diligence phase includes review of the client’s patent portfolio to identify patents that appear to be infringed by products that are identified in the market, preparation of infringement claim charts to track the correspondence of each element of the patent claim to features in the apparently infringing products, investigation of defendants to determine the appropriate court for the litigation and estimating the likely monetary awards and injunctive relief that should be awarded. With that information, one may prepare a basic business case for proceeding with litigation.

Selection of patents for litigation should reflect the likely interpretation that will be accorded to each element of the claims, the opportunity to obtain information demonstrating that the accused products meet each of those limitations and optionally an investigation of whether those patents are susceptible to invalidity challenges.

5 Enacted in 2011, the America Invents Act (AIA) had several significant impacts on US patent laws, including shifting the United States from a ‘first-to-invent’ system to a ‘first-inventor-to-file’ system. Under the first-to-invent system, an inventor could obtain a patent upon a showing that he or she was the first to conceive of the claimed invention and reduce it to practice. In contrast, under the AIA’s first-inventor-to-file system, the person who first discloses an invention, namely, through the filing of a provisional or non-provisional application, will be granted a patent, even if someone else were to have previously conceived of the invention.


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Identification of products that are likely to be found to infringe those patents may be possible from simple examination of the product, or might require sophisticated reverse engineering. The preparation of infringement claim charts is a systematic means of evaluating infringement. The claim chart documents the basis for later infringement allegations and satisfies rules in some courts that require the chart as part of a complaint.

US district courts hold original and exclusive jurisdiction over actions arising under the Patent Act.10 There are 89 judicial districts spread across the 50 states, with a total of 94 districts including the territories of the United States. Until recently, patent infringement actions were routinely filed in the judicial district believed to be most favourable to the patent owner’s interests (often the Eastern District of Texas). However, starting in May 2017, patent venue (the proper district for a case) has been changed to benefit defendants. The US Supreme Court narrowly interpreted the first prong of the patent venue statute – which allows suit wherever a corporate defendant ‘resides’ – by interpreting a corporation’s residence to mean its state of incorporation rather than wherever it distributes products.11 Soon thereafter the US Court of Appeals for the Federal Circuit narrowly interpreted the other prong – which allows venue wherever the defendant has committed acts of infringement and has a regular and established place of business – so that the presence of remote employees, without more, does not confer the status of a ‘regular and established place of business’.12 The restriction of the venue laws has dramatically reduced the number of patent infringement cases filed in the Eastern District of Texas, preferred by patent owners, and increased the number filed in Delaware, New York and Illinois, where many companies are incorporated or headquartered. For example, in the first quarter of 2017, the last quarter before the Supreme Court’s decision, 129 patent cases were filed in Delaware, but that number grew to an average of 216 cases for each of the following three quarters.13 In 2018, Delaware is on track to surpass the Eastern District of Texas as the top district for the filing of patent cases.14

ii Pleadings

Patent litigations are initiated by the filing of a complaint. Historically, patent infringement complaints were only required to provide a short and plain statement of the claim, showing that the pleader is entitled to relief – the model form only required an allegation of jurisdiction, that the plaintiff owns the patent, that the defendant has been infringing the patent ‘by making, selling and using [the device] embodying the patent’, that the plaintiff has given the defendant notice of its infringement and a demand for an injunction or monetary damages.15 However, from 1 December 2015, those simple rules were revised in favour of more detailed pleadings. While the new standards continue to evolve, a common interpretation of the new rules requires that the complaint contain an identification of representative claims from each patent, some description of the patented functionality, identification of the accused products

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10 28 U.S.C. § 1331. Except for ancillary issues such as breach of contract claims arising from the sale of a patent, as a general matter state courts do not have jurisdiction to enforce patents.
12 In re Cray Inc., 871 F.3d 1355, 1366 (Fed. Cir. 2017).
14 DocketNavigator Analytics, 2017 Most Active Courts (showing 467 cases filed in Delaware and 289 filed in the Eastern District of Texas as of July 2018).
15 McZeli v. Sprint Nextel Corp., 501 F.3d 1354, 1357 (Fed. Cir. 2007); see also Fed. R. Civ. P. 8(a)(2) and 84, and Form 18.
and a description of corresponding functionality in such products. A few courts require more, such as alleging element-by-element that the patent claims are used in the accused products. When a court finds that a complaint lacks sufficient detail, there are generally opportunities for amending or submitting a wholly new complaint with additional details. The patent owner must file the complaint with the appropriate court and serve a copy of the complaint upon the defendants. A defendant served with a complaint must respond within 21 days (plus any extensions of time). If the complaint is defective due to lack of jurisdiction, failure to state a recognised claim, failure to name all necessary parties, or other reasons, the defendant may file a motion to dismiss. Absent a motion to dismiss, the defendant must file an answer to the complaint. Answers are issue-by-issue admissions, denials, or denials based on lack of information. Failure to deny any allegation in the complaint, except for the amount of damages, can constitute an admission of that allegation. Answers must also include any affirmative defences, which are reasons why the defendant should not be subject to any claim for relief even if the allegations in the complaint are proven true. Common affirmative defences include unreasonably delayed claims, defendant’s licence under the patent, past payment or resolution of the dispute in a prior litigation. Any affirmative defences that are not included in the answer may be found waived. In some courts, the complainant must respond to the affirmative defences. Failure to respond to a complaint in a timely manner can result in a default judgment where the court rules in favour of the plaintiff without further proceedings. However, in many instances, the courts have exercised discretion to permit late responses in order to avoid a default. Depending upon the complexity of the issues, the court may allow submission of later discovered information that was not available when the original complaint or answer were filed, or even allow amendments to the complaint and answer later in the litigation.

iii Discovery

The discovery phase of US civil litigations involves the exchange of information between the parties and, if necessary, obtaining information from third parties, that might later be used as evidence at trial. After service of the complaint is completed, the parties must prepare a proposed discovery plan for submission to the court. Within 14 days after the discovery plan, all parties must make initial disclosures (without awaiting discovery requests) that identify the names and contact information for likely witnesses, copies of documents upon which the party will use to support its claims or defences, a calculation of damages and any insurance agreements. In most circumstances, the court will hold a scheduling

16 See, for example, *Uniloc USA Inc. v. Avaya Inc.*, No. 6:15-cv-1168, slip op. at 7 2016 WL 7042236 at *5 (E.D. Tex. 13 May 2016).
18 See Fed. R. Civ. P. 12(a)(1)(A). The defendant’s waiver of service can extend the time to 60 days and a foreign defendant may be entitled to 90 days to respond.
22 See Fed. R. Civ. P. 12(b), (b).
conference within 90 days of service of the complaint and as soon as practicable the court will issue a scheduling order that limits the time to join other parties, amend the pleadings, complete discovery and file motions. The period for conducting discovery varies widely, but in complex patent infringement cases, fact discovery may last for about a year and expert discovery for an additional six months. Fact discovery includes the exchange of documents and inspection of equipment, interrogatories (written answers to questions from the opposing party), and depositions (out-of-court sworn oral testimony of a witness that is transcribed by a court reporter for possible later use at trial). Expert discovery includes the exchange of written reports disclosing all facts and opinions that an expert witness intends to rely upon at trial, followed by deposition of the experts. Discovery is often the most expensive phase of patent litigation. Parties may move for a protective order limiting discovery requests that are irrelevant or where the burden or expense of producing the evidence outweighs its likely benefit. Parties also sometimes agree to forego certain types of discovery owing to expense.

iv Patent claim interpretation

In 1996, the Supreme Court held in Markman v. Westview that the interpretation of patent claims is a legal issue for judges to decide and does not require jury consideration. Many judges now conduct Markman hearings early in the procedural schedule. Following the US Court of Appeals for the Federal Circuit’s guidance, trial courts consider the evidence of proper claim interpretation in the following order of importance: first, the intrinsic evidence, including the claims, specification and the prosecution history and, then (optionally), extrinsic sources such as dictionaries and expert testimony. Based on the hearing, the judge may issue an order construing (interpreting) the patent claims at issue. The resolution of patent claim interpretation disputes relatively early in the proceedings often provides a basis for settlement or summary motions regarding infringement or validity issues.

v Summary judgment motions

Any party may file a motion for summary judgment on issues where the facts are not in dispute and the judge can resolve the issue as a matter of law. After issuance of a Markman claim interpretation, infringement and invalidity issues may be ripe for summary motions. The success rates for summary motions are highly variable depending on the district. In 2017, patent owners obtained summary judgment 27 per cent of the time, while motions against patent owners were granted 25 per cent of the time. Since July 2014, 36 per cent of motions
for summary judgment of invalidity for lack of patentability under 35 U.S.C. Section 101 have been successful in light of the Supreme Court's 2014 Alice ruling that ‘abstract ideas’ are not patentable.35

vi Trial

Although about 4,600 patent infringement complaints were filed in 2017, typically only about 3 per cent of those complaints culminate in a trial.36 Many cases are settled, some are resolved by summary judgment and others are withdrawn owing to lack of interest or litigation resources.

The median time to trial for patent cases in the US district courts is about 30 months.37 While some courts like the Eastern District of Virginia routinely proceed to trial in 12 months, most courts are slower and many individual cases are delayed (stayed) pending inter partes review (IPR) of the validity of the patent at the PTO. Courts vary widely in the rate at which they exercise their discretion to stay patent litigations pending an IPR; however, some studies indicate that up to 70–80 per cent of patent cases with a co-pending IPR validity challenge are stayed pending completion of the IPR proceeding.38

Plaintiffs and defendants have a constitutionally guaranteed right to a jury trial, but upon agreement of both, a judge can decide in lieu of a jury. While a well-educated and experienced judge might more easily comprehend the complex technology at issue in many patent cases, about 80 per cent of patent infringement cases that go to trial are tried to a jury, probably because plaintiffs have generally obtained higher success rates and larger monetary damages before juries instead of judges.39

Trials are formal hearings where witness testimony, documents and physical evidence are examined to resolve disputed issues of fact. The jury is then instructed by the judge on the applicable law in order to reach a verdict on the issues – typically, whether the patent is infringed by the accused device, whether the patent is valid and the appropriate monetary damages. Counsel for the parties play an active role in presenting evidence, including questioning the witnesses. Trials typically begin with counsel providing opening statements to foreshadow the evidence that will be presented, followed by testimony from fact and expert witnesses and typically ending with counsel providing a closing argument on how the evidence should be interpreted. The average duration of patent infringement trials is eight days.40

35 DocketNavigator Analytics, Motion Success, Unpatentable Subject Matter (July 2014–July 2018); Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).
36 DocketNavigator Analytics, New Patent Cases and Trials (2008–2018). For example, in 2017, 4,548 cases were initiated, but there were just 122 trials during the same time frame (2.7 per cent).
United States

vii Post-trial proceedings

Jury verdicts can be challenged by motions for judgment as a matter of law (JMOL). Those motions ask the judge to consider whether the evidentiary record is sufficient to support the verdict of the jury. And if a defendant made a pre-verdict JMOL motion on damages, then that motion can be reasserted after the verdict. 41 JMOL motions are often coupled with motions for a new trial and can result in significant reductions in damage liability.

The complexity of the technology and legal issues has led many judges and judicial districts to adopt special procedural rules for patent litigations – rules that are often further tailored for the special circumstances of individual cases.

IV SUBSTANTIVE LAW

i Infringement

A patent holder can bring an action for ‘direct’ infringement against anyone who makes, uses, offers to sell, sells or imports into the United States a patented invention or a product that is made by a patented process. 42 Absent special circumstances, liability for infringement attaches to companies found to have engaged in the specified prohibited acts, not their specific employees, officers or directors.

A patent holder may also bring a claim for ‘indirect’ infringement against anyone who actively induces or contributes to direct infringement, as long as there is a showing of direct infringement. 43 Liability for inducement attaches when a party knows about a patent and actively takes actions that encourage others to infringe the patent, knowing that such actions constitute inducement. 44 A defendant’s good faith belief in a patent’s invalidity is not a defence against a claim of induced infringement. 45 Liability for contributory infringement attaches when a party sells, offers to sell or imports into the United States a component of a patented invention that constitutes a material part of the invention rather than a commodity-type article suitable for substantial non-infringing uses, knowing that the component was made or adapted for use in an infringing manner. 46 In addition, a party may be liable for infringement if it exports for assembly abroad all or substantially all of the components of a patented invention, 47 or if it exports for assembly abroad a component of a patented invention that constitutes a material part of the invention rather than a commodity-type article suitable for substantial non-infringing uses, knowing that the component will be combined outside the United States in an infringing manner. 48 A patent holder has the burden of proving infringement by a preponderance of the evidence. 49 The determination as to patent infringement is a two-step process. 50 First, a court construes the claims of the patent,

42 35 U.S.C. § 271(a) and (g).
43 35 U.S.C. § 271(b)–(c).
49 Centricut LLC v. Esab Grp., 390 F.3d 1361, 1367 (Fed. Cir. 2004). This standard may be understood to mean that infringement is more likely than not.
namely, the court determines what the claims mean. Claim interpretation is a question of law for the court to rule upon.\(^{51}\) Second, the accused product or process is compared to the properly-construed claims. This step is a question of fact\(^{52}\) and therefore usually determined by a jury. Infringement will be found when an accused product or process includes every element ('limitation') of a claim.\(^{53}\) ‘Literal infringement’ exists when each and every element in a claim ‘reads on’, or is found in, an accused product or process.\(^{54}\)

In addition to literal infringement, infringement under the ‘doctrine of equivalents’ exists even if one or more of the claim limitations are not literally present in the accused product or process, as long as the equivalents of those limitations are present.\(^{55}\) In other words, to find infringement under the doctrine of equivalents, any differences between the claimed invention and the accused product must be insubstantial.\(^{56}\) A determination of infringement under the doctrine of equivalents is subject to two major limitations. First, ‘prosecution history estoppel’ limits the range of equivalents available to a patent holder by preventing recapture of subject matter that the patent holder surrendered through narrowing amendments during prosecution of the patent.\(^{57}\) Second, under the ‘all elements’ rule, the doctrine of equivalents does not apply if applying the doctrine would vitiate an entire claim limitation.\(^{58}\)

ii. Invalidity and other defences

There are multiple defences available to a party accused of infringement. The most commonly-raised defences include non-infringement, invalidity and unenforceability.

**Non-infringement**

With respect to non-infringement, an accused infringer may argue that a patent holder has failed to establish infringement either literally or under the doctrine of equivalents. As the burden of proof rests with the patent holder, an accused infringer may defeat a claim of infringement by showing that an accused product or process fails to meet just a single limitation of a claim.

**Invalidity**

The validity of a patent may be challenged on multiple grounds, including but not limited to the grounds described below, and a defendant bears the burden of proving invalidity by clear and convincing evidence.\(^{59}\) First, an accused infringer may take the position that a patent is invalid for the reasons described below.

\(^{51}\) id.  
\(^{52}\) id.  
\(^{53}\) id.  
\(^{54}\) *Allen Eng’g v. Bartell Indus.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002).  
\(^{55}\) See *Allen Eng’g v. Bartell Indus.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002).  
\(^{56}\) *VirnetX, Inc. v. Cisco Sys.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014).  
\(^{57}\) *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1377 (Fed. Cir. 2007) (citation omitted).  
\(^{58}\) *Seachange Int’l v. C-COR Inc.*, 413 F.3d 1361, 1378 (Fed. Cir. 2005).  
\(^{59}\) *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011). The ‘clear and convincing’ standard is a higher standard of proof than the ‘preponderance of the evidence’ standard necessary to prove infringement and has been described by the US Supreme Court as a ‘heavy burden.’ See id. at 104.
directed to ineligible subject matter, in other words, laws of nature, natural phenomena and abstract ideas. The US Supreme Court has articulated a two-step framework for determining patent eligibility:

\[ a \] determine whether the claims are directed to one of the aforementioned patent-ineligible concepts; and

\[ b \] if so, consider the elements of the claims – both individually and as ordered combinations – to assess whether the additional elements transform the nature of the claims into a patent-eligible application of the concept.\(^{60}\)

Second, a patent may be found invalid for failure to satisfy what is known as the ‘utility requirement’. In short, the utility requirement demands that an invention actually work as claimed. For example, an invention that is ‘inoperative’, in the sense that it does not operate to produce the results claimed, is not a ‘useful’ invention for the purposes of meeting the utility requirement.\(^{61}\)

Third, an accused infringer may argue that an invention lacks ‘novelty’, meaning it is anticipated by the prior art. ‘Prior art’ refers to any information or other evidence that was publicly known prior to a certain date.\(^{62}\) Prior art references may include, for example, patents, patent applications, books, articles, advertisements or even pre-existing products. A patent is anticipated when a single prior art reference describes every limitation of the claimed invention.\(^{63}\)

Fourth, a patent may be rendered invalid as being ‘obvious’. This means a particular invention would have been obvious to a person of ordinary skill in the art at the time of the invention. For example, an invention may be obvious if someone working in the relevant technical field could have routinely and easily come up with the invention by combining certain prior art references. The obviousness analysis entails several basic factual inquiries:

\[ a \] determining the scope and content of the prior art;

\[ b \] ascertaining the differences between the prior art and the claims at issue; and

\[ c \] evaluating the level of ordinary skill in the pertinent art.\(^{65}\)

In addition, the obviousness analysis must take into account secondary evidence that supports a finding that an invention is not obvious. Such evidence includes whether:

\[ a \] the invention was commercially successful or widely licensed;

\[ b \] there was a long-felt but unresolved need for the invention;

\[ c \] others failed to come up with the invention; and

\[ d \] the invention yielded unexpected results.

Fifth, under the ‘written description’ and ‘enablement’ requirements, a patent may be found invalid if it lacks a description of the invention sufficient to enable one of ordinary skill in

\(^{60}\) See Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2355 (2014).


\(^{62}\) After the passage of the AIA, any information or evidence disclosed before an inventor files a patent application will be considered prior art.

\(^{63}\) Net MoneyIN Inc. v. VeriSign Inc., 545 F.3d 1359, 1369 (Fed. Cir. 2008).

\(^{64}\) The phrase ‘person of ordinary skill in the art’ refers to a hypothetical person who is presumed to have an average level of skill in the relevant technical field at the time of the invention.

the art to make and use the invention. 66 A patent’s specification must describe the invention in full, clear, concise and exact terms. 67 The written description requirement is met where there is sufficient information in the specification to show that the inventor possessed the invention at the time of the original filing. 68 The enablement requirement is met where one skilled in the art, having read the patent’s specification, could practise the invention without undue experimentation. 69

Sixth, a patent may be found invalid to the extent the claims are not ‘definite’. A patent specification must conclude with claims particularly pointing out and distinctly claiming the subject matter of the claimed invention. 70 If the scope of a claim, when read in light of the specification and prosecution history, is not clear to a person of ordinary skill in the art, it may be found indefinite. 71

Unenforceability

Even when a defendant cannot prove invalidity, a patent may nonetheless be found unenforceable for a variety of reasons, including inequitable conduct or patent misuse. Inequitable conduct occurs when an inventor breaches the duty of candour and good faith owed to the PTO while applying for a patent. For example, either a misstatement or misrepresentation to the PTO can lead to a finding of inequitable conduct, if it was material in nature and done with an intent to deceive. 72 Inequitable conduct can render all claims of a patent unenforceable.

A patent may also be found unenforceable owing to misuse. Misuse occurs when a patent holder attempts to impermissibly broaden the physical or temporal scope of the patent grant in a way that has anticompetitive effects. 73 For example, in the licensing context, one common form of misuse is when a patentee requires the purchase of an unpatented product as a condition for obtaining a licence to the patent. 74 Another type of misuse would be charging royalties for a patent after the patent has expired. Misuse renders the patent unenforceable during the period of the misuse.

Particular unenforceability issues arise in the context of standard-essential patents (SEPs). First a brief overview of SEPs may be appropriate. In recent decades international corporations have increasingly collaborated in standardising technologies to achieve interoperability of products. (One simple example is the standardised USB ports included in various manufacturers’ computers.) The companies that participate in standard-setting attend meetings hosted by standard-setting organisations (SSOs), where they propose and vet technological solutions. The agreed-upon result is often a long technical standard that specifies the requirements for each component of a complex technology. Before participating, companies must often sign an agreement with the SSO, which obligates them to disclose any patents relevant to the standard and to license them to implementers on fair, reasonable

69 Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1288 (Fed. Cir. 2012). Various factors must be considered when determining whether a disclosure requires undue experimentation. See id.
72 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011)
74 See id.
and non-discriminatory (FRAND) terms. After all, one factor in choosing the best technical solution to adopt into the standard may be whether additional patent royalties would be required for practicing the solution. If so, the participating companies may prefer to adopt another technology that is free to use.

Against this backdrop, a new body of unenforceability case law has emerged owing to increased SEP litigation. Generally speaking, failure to comply with a SSO’s policies regarding the disclosure of relevant patents or the licensing of SEPs on FRAND terms may prevent a patent owner from enforcing its patents. For example, in a noteworthy decision from 2008, the Federal Circuit upheld a finding that Qualcomm breached its duty to disclose certain patents to a SSO, which rendered those patents unenforceable against any standard-compliant products.\(^75\) In a more recent case, the Federal Circuit provided clarification regarding implied waiver owing to a breach of a duty to disclose information to a SSO.\(^76\) Nokia was the original assignee of the patent-at-issue, which it did not disclose at the time Nokia’s technical proposal was not adopted by the SSO. Nokia ended up disclosing the patent to the SSO four years later. The district court rejected the argument that Nokia had waived its right to enforce the patent by breaching its obligation to disclose the patent to the SSO. On appeal, the Federal Circuit did not find the patent unenforceable but remanded the case to the district court for further proceedings, explaining that implied waiver may render a patent unenforceable when a patentee’s conduct results in an unfair benefit or is so egregious as to justify unenforceability. This case underscores the need for companies that actively participate in SSO activities to be wary of the potential negative consequences of failing to meet the obligations imposed by the SSO’s policies.

Additional defences

Additional defences that may be raised to counter a claim of infringement include licence, patent exhaustion and equitable estoppel. An accused infringer may rely on an express or implied licence to practise the patented invention. When an express licence defence is involved, there is typically a licence agreement that exists between the parties that must be interpreted. In contrast, an implied licence may arise in certain unique circumstances when the grant of a licence can be inferred.\(^77\) For example, when a patent holder sells a patented product, the sale carries with it an implied licence to engage in conduct that would otherwise constitute infringement.\(^78\)

A concept closely related to this form of implied licence is what is known as ‘patent exhaustion’. Under the doctrine of patent exhaustion, the authorised sale of a patented product gives the buyer, or any subsequent purchaser, a right to use or resell that product.\(^79\) In 2017, the Supreme Court found that patent exhaustion applies even with respect to foreign sales.\(^80\)

\(^{75}\) See Qualcomm Inc. v. Broadcom Corp., 548 F.3d 1004, 1027 (Fed. Cir. 2008).
\(^{77}\) Monsanto Co. v. Scruggs, 459 F.3d 1328, 1336 (Fed. Cir. 2006).
\(^{79}\) Bowman v. Monsanto Co., 133 S. Ct. 1761, 1764 (2013).
\(^{80}\) Impression Prods., Inc. v. Lexmark Int'l, Inc., 581 U.S. __ (2017).
Finally, the defence of equitable estoppel is available to accused infringers. To prevail on an estoppel defence, there must be a showing that the patent holder’s misleading statement or conduct led the alleged infringer to reasonably infer that the patent holder did not intend to enforce its patent.81

V FINAL REMEDIES FOR INFRINGEMENT

There are two remedies for infringement: monetary damages and injunctive relief.

i Monetary damages

The Patent Act provides for the award of damages ‘adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use of the invention made by the infringer’.82 The courts have recognised multiple grounds for calculating the appropriate compensation, but lost profits and reasonable royalties are the two most common grounds. Lost profits typically result in larger damage awards and may be available if the patent owner can establish that, but for the infringement, it would have made the infringer’s sales.83 Proof of lost profits often includes evidence:

- that the patented invention was in demand;
- that no non-infringing substitutes were available;
- that the patent owner was capable of fulfilling the demand; and
- of the profits the patent owner would have received.84

If lost profits cannot be established, then the courts can award reasonable royalties. Reasonable royalties are most often determined by the rate a reasonable and willing patent owner and a reasonable and willing licensee would have hypothetically negotiated at the time the infringement began. Courts consider many factors in the hypothetical negotiation, including:

- royalties paid by other licensees of the infringed or similar patents;
- nature and scope of the licence;
- whether the patent owner previously sought enforcement or licence of its patents;
- whether the parties are competitors;
- possibility of convoyed sales;
- remaining term of the patent;
- profitability of products covered by the patent;
- advantages of the patent product over alternative products; and
- the portion of profits that derive from patented components of a commercial product.85

81 Hynix Semiconductor Inc. v. Rambus Inc., 645 F.3d 1336, 1347 (Fed. Cir. 2011).
84 Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.3d 1275 (Fed. Cir. 2017).
Injunctive relief

Injunctive relief may be available under 35 U.S.C. Section 283, which provides that:

[i]he several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

Until about a decade ago, injunctions were routinely granted to most prevailing patent owners upon request. However, the Supreme Court’s 2006 eBay, Inc v. MercExchange decision restricted the issuance of injunctive relief to patent owners that satisfied the traditional equitable test that:

a. absent an injunction, irreparable injury will occur;

b. monetary damages are inadequate to compensate for that injury;

c. the balance of hardships between the patent owner and the infringer favour injunctive relief; and

d. the public interest does not preclude an injunction.86

Following the eBay decision, trial courts have rarely granted permanent injunctions to patent assertion entities (only 16 per cent of the time), but have awarded permanent injunctions to all other patentees, including practising entities and universities, at a rate of about 80 per cent.87

Standard-essential patent remedies

SEPs raise unique remedies issues. Because technical standards are international (unlike the patent laws), foreign countries’ various policies of setting royalties for use of standard-essential patents can influence US damages awards. Determining a reasonable royalty under US patent law often involves looking to comparable licence agreements – and in some cases, the most comparable licences may be those reached under a foreign country’s SEP licensing regime. The Japan Patent Office (JPO), for example, recently issued guidelines for setting fair and reasonable royalties for use of SEPs.88 Commentators have observed that the JPO has engaged in a praiseworthy effort to balance the interests of patent owners and standard implementers,89 but balance is not necessarily the norm throughout the world.

Further, while there is no per se rule against awarding injunctions for infringement of SEPs, courts are often hesitant to do so. As an initial matter, if the patent owner agreed to license on FRAND terms, then the patent owner could be deemed as waiving its argument that remedies at law (i.e., money damages) are inadequate to compensate for the infringement (as required for an injunction). A patent owner’s best chance of securing an injunction generally arises where the implementer has unreasonably delayed negotiations or unilaterally

refused to accept a reasonable licence offer.\textsuperscript{90} However, in the ITC, where injunctive relief is the only remedy available, FRAND obligations are generally examined in the public interest context after a violation has been found.\textsuperscript{91}

VI OTHER TYPES OF PATENT PROCEEDINGS

\textit{i} Section 337 investigations at the US International Trade Commission

The US International Trade Commission (ITC) is authorised to exclude from importation into the United States articles that infringe a US patent that protects a domestic industry (19 U.S.C. Section 337). Although Section 337 is technically a government investigation, patent owners and importers largely drive the proceedings. The adoption of free trade policies, the relocation of manufacturing industries into Asia and the dominance of globally traded products has increased the number and importance of patent infringement cases at the ITC. Although sometimes criticised as a tool of protectionist trade policies, about one-third of all Section 337 complaints are filed by non-US based companies.\textsuperscript{92}

\textbf{Jurisdiction}

The ITC has jurisdiction over parties that sell for importation into the United States, import or sell after importation into the United States (collectively, ‘importers’).\textsuperscript{93} Like US district courts, the ITC can exercise personal jurisdiction over persons and companies that have at least some minimal level of contact with the United States, or that appear and defend in a Section 337 investigation. However, in addition, the ITC also has \textit{in rem} jurisdiction over all products imported into the United States.\textsuperscript{94} In order to attain economies of scale, most industries depend on the large and lucrative markets available in the United States and therefore are subject to Section 337 investigations.

To establish a violation of Section 337, a patent owner must establish by a preponderance of the evidence that (1) a valid and enforceable US patent is infringed (2) by products imported into the United States and (3) that there are significant investments in a US domestic industry that exploits the patent.\textsuperscript{95}

\textbf{Patent infringement}

With a few exceptions, the ITC generally applies the same patent law as the US district courts. Because Section 337 applies to the ‘importation... of articles that infringe’, direct infringement is determined as of the moment of importation. Thus, at the ITC there is typically no direct infringement of method claims and claims covering systems that are not

\textsuperscript{90} See \textit{Apple Inc. v. Motorola, Inc.}, 757 F.3d 1286, 1332 (Fed. Cir. 2014).
\textsuperscript{93} 19 U.S.C. § 1337(a)(1)(B).
\textsuperscript{95} 19 U.S.C. § 1337(a)(1)(B) and § 1337(a)(2)-(d).
assembled until after importation – however, an importer of those articles can be found to be indirectly infringing by contributing to or inducing a direct infringement by its customers. Liability for contributory infringement arises when an importer:

[O]ffers to sell or sells ... a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practising a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.\(^ {96} \)

Liability for induced infringement arises when an importer ‘induces infringement of a patent’, \(^ {97} \) which the courts have interpreted as requiring both knowledge (or at least no wilful blindness) of the asserted patent and that its actions would lead another to directly infringe the patent.\(^ {98} \) This ‘infringing at the moment of importation’ test has had a substantial impact in the electronics industries where patents are often directed to methods of operation and components are often imported for assembly into infringing systems within the United States.

**Importation**

The Section 337 importation requirement is met when at least one unit of the allegedly infringing product is imported into the United States. The ITC takes an expansive view to find importation in each of the following circumstances:

- foreign manufacturers that sell products to trading companies with knowledge that the trading company would import the product into the United States;\(^ {99} \)
- foreign manufacturers accepting purchase orders for delivery and installation of the product in the United States;\(^ {100} \)
- foreign manufacturers that ship to the United States disk drives that include magnetic disk components that had earlier been made by an infringing process in the United States;\(^ {101} \) and
- importation of a single unit for use at a trade show.\(^ {102} \)

**Domestic industry**

Section 337 requires (1) significant investments in plant, equipment, labour and capital; or (2) substantial investments in research, development, engineering or operating a licensing business, that exploit at least one claim of each asserted patent.\(^ {103} \) Complainants must establish both the economic prong of domestic industry (the amount of the investment, considered in the context of the industry) and the technical prong (practice of the patent by either the complainant or its licensees). Historically, investments sufficient to manufacture

\(^ {96} \) 35 U.S.C. § 271(c).
\(^ {97} \) 35 U.S.C. § 271(b).
\(^ {100} \) Certain Variable Speed Wind Turbines, Inv. No. 337-TA-376, Order No. 11 (19 October 1995).
\(^ {102} \) Certain Abrasive Products, Inv. No. 337-TA-449, Initial Determination at 6 (8 Feb 2002).
\(^ {103} \) 19 U.S.C. § 1337(a)(2)-(3).
in the United States a product that practises a patent is deemed a ‘significant’ investment. As investments in research, development, engineering or licensing may not result in a product, those investments must have a nexus to the claims of the asserted patent. Complainants may rely upon their own investments, as well as the investments of their corporate affiliates, investments made by their licensees under the patent and investments made by their contractors.

Section 337 procedures

Section 337 investigations are governed by the ITC’s Rules of Practice and Procedure. Owners of US patents file with the ITC a complaint containing detailed allegations of the facts that, if later proven true, would constitute a violation of Section 337 and typically support those allegations with voluminous exhibits. The ITC institutes an investigation in nearly all cases and issues a notice of investigation defining the investigation’s scope ‘in such plain language as to make explicit what accused products or category of accused products’ will be investigated.

The procedures in Section 337 investigations are similar to those in district court patent infringement cases in several ways: Section 337 provides the full gamut of discovery tools; motions are available to resolve discovery disputes; motions for summary disposition are available (although less frequently granted than in district court); and formal trials are held. However, there are important procedural differences. Section 337 patent infringement investigations are typically completed in about 16 months, whereas comparable cases in the district courts average about 30 months. Section 337 investigations often involve extensive foreign discovery, complex technology (about 70 per cent of the cases involve the electronics industry), voluminous briefs and written testimony and high demand trials that are compressed into very short time periods. While only about 3 per cent of district court patent infringement cases proceed to trial, about 40 per cent of Section 337 investigations proceed to trial. The ITC’s dedicated administrative law judges preside over discovery and a trial and they issue an initial determination (ID) on all issues that bear on whether the

105 Certain Liquid Crystal Display Devices and Products Containing the Same, Inv. No. 337-TA-631, Order No. 18 (23 Sept. 2008).
112 See 19 C.F.R. § 210.18.
importers have violated Section 337 – all within about 12 months. The ITC commissioners then take over the case for the final four months during which they can review and modify the findings in the ID and then rule on remedy, bonding and public interest issues.

Section 337 investigations can be terminated based on withdrawal of the complaint, settlement, dispositive decisions on motions for summary determination, or a final determination on the merits by the ITC. Of the investigations that went to a final determination during the period 2011–Q1 of 2018, complainants won in about 56 per cent of those cases.\(^{117}\) When a complainant wins, unless contrary to the public interest, the ITC must issue an exclusion order that directs US Customs and Border Protection to stop further importations of infringing products.\(^{118}\) If the importers who were found in violation have commercially significant inventories of infringing products, the ITC has the discretion to also issue a cease-and-desist order prohibiting certain enumerated commercial activities involving that inventory.\(^{119}\)

Section 337 remedial orders are immediately effective, but subject to a 60-day review period during which the president can disapprove the remedy for policy reasons.\(^{120}\) During that period, importations can continue if the importers post a bond that is ultimately forfeited to the complainant unless the President disapproves the orders or the decision is reversed on appeal.\(^{121}\) Losing parties in Section 337 investigations can appeal for modification of the decision by the Court of Appeals for the Federal Circuit.\(^{122}\) In the event an importer is found to violate a cease-and-desist-order, the ITC is authorised to impose civil penalties in the amount of US$100,000 per violation day or alternatively up to twice the domestic value of the products.\(^{123}\)

\[\text{ii \hspace{1cm} Inter partes review at the US Patent and Trademark Office}\] An IPR is a proceeding before the Patent Trial and Appeal Board (PTAB), a branch of the PTO that is authorised to review the validity of a patent.\(^{125}\) Any US patent that was issued on or after 16 September 2012 is eligible for IPR.

Anyone other than the owner of a patent may petition the PTAB to institute an IPR.\(^{126}\) During the first two years that IPRs were available, about 80 per cent of IPR petitions were directed to patents in pending litigations.\(^{127}\) IPR petitions are subject to detailed requirements, including: the identification of all real parties in interest; identification with particularity of


\(^{118}\) 19 U.S.C. § 1337(d).

\(^{119}\) 19 U.S.C. § 1337(f).

\(^{120}\) 19 U.S.C. § 1337(j). Presidential review is now delegated to the US Trade Representative.

\(^{121}\) 19 U.S.C. § 1337(j)(3).

\(^{122}\) 19 U.S.C. § 1337(c).


\(^{124}\) The AIA was signed into law on 16 September 2011. The AIA created three types of post-grant review proceedings: inter partes review (discussed herein) and the less commonly used post-grant review and covered business method review, each of which became effective 16 September 2012.


\(^{126}\) 35 U.S.C. § 311(a); 37 C.F.R. § 42.101.

each patent claim challenged; the proper interpretation of the claim; and the legal grounds and evidence supporting the challenge. Patent owners have the option of responding to the petition prior to the PTAB’s determination of whether to institute an IPR.

The PTAB will institute an IPR no later than six months after filing of the petition if there is a ‘reasonable likelihood that the petitioner will prevail’ with respect to at least one of the challenged patent claims. IPR proceedings are called trials, but have limited procedures for discovery and submission of testimony and are often decided on written submissions without an in-person hearing. The PTAB must issue a final written decision no more than 12 months after institution of an IPR. IPRs have had two significant impacts on patent litigation:

a. many district courts (but not the ITC) often stay infringement proceedings on patents that are undergoing IPR until the conclusion of the IPR proceeding; and

b. IPRs that proceed to a final written decision invalidate all claims at issue in about 64 per cent of the cases, some of the claims in about 16 per cent of the cases and none of the claims in about 19 per cent of the cases.

In May 2018, the PTO under new leadership proposed changing the PTAB’s claim interpretation standard from ‘broadest reasonable interpretation’ to match the standard used by district courts, which seeks to ascertain a skilled artisan’s understanding of the claim language in dispute. The rule change is not expected to significantly impact the PTAB’s patent invalidation rate, but rather is designed to prevent patent challengers from strategically arguing for a narrow interpretation in district court to avoid infringement while also arguing for a different, broader interpretation before the PTAB.

VII APPEAL

All appeals of patent-related claims fall within the exclusive jurisdiction of the US Court of Appeals for the Federal Circuit, located in Washington, DC. The Federal Circuit was created to ensure there exists a nationwide uniform authority for patent law. The Federal Circuit takes appeals from decisions of various courts and agencies, including district court patent cases, PTAB decisions and final determinations of the ITC. For district court cases, the losing party must file a notice of appeal with the district court within 30 days after the court has entered judgment. For PTAB proceedings, a notice of appeal must be filed with the PTO no later than 63 days after the PTAB’s final decision. Finally, for ITC investigations, a losing party must file an appeal with the Federal Circuit no later than 60 days after the ITC’s final determination.

128 35 U.S.C. § 312(a); 37 C.F.R. § 42.104.
130 35 U.S.C. § 314(b); 37 C.F.R. § 1.923.
131 See 37 C.F.R. §§ 42.51-74.
135 37 C.F.R. § 90.3.
After an appeal is docketed with the Federal Circuit, the parties submit a series of briefs setting forth their arguments why the lower decision should be affirmed or reversed. Generally speaking, the Federal Circuit will only review materials already in the record below and will not consider new evidence. After briefing is completed, oral arguments are often held before a panel of three Federal Circuit judges. The panel will issue an opinion, although no opinion may be provided when the panel determines to affirm a district court judgment. The disposition of appeals to the Federal Circuit from the time of docketing an appeal to a decision typically requires a year – and has been rising from 10.5 months in 2015 to 13 months in 2018. In terms of outcomes, for the 12-month period ending 30 September 2017, the Federal Circuit reversed district court judgments for just 11 per cent of the time – that figure was 14 per cent for the ITC and 12 per cent for the PTO. Since the creation of the PTAB in 2011 caused an influx of new cases for the Federal Circuit, the court has increasingly issued summary affirmances with no opinion, whose frequency controversially rose as high as 49 per cent in Q4 2016 and moderated somewhat to 37 per cent for 2017. The most common issue on appeal is claim interpretation, both because of its importance to the outcome in most cases and because the Federal Circuit rarely defers to the lower court’s decision on the issue. In the vast majority of instances, the Federal Circuit’s decision will resolve a case, unless a losing party decides to seek review by the Supreme Court, which only rarely grants requests for review. The cost of an appeal can range from tens of thousands of dollars up to US$1 million, depending on the complexity of the issues.

VIII THE YEAR IN REVIEW

Historically, the Supreme Court rarely reviewed patent cases, leaving it to the Federal Circuit to guide the direction of patent law. Yet in recent years, the Supreme Court has been granting review of more cases and has generally narrowed the scope of protection available under the patent laws. During the past year, the Supreme Court ruled on the following three patent cases.

i Oil States Energy Services LLC v. Greene’s Energy Group LLC

In this widely watched case challenging the constitutionality of IPR proceedings, the Supreme Court upheld IPRs as constitutional. After the PTAB invalidated its patents, Oil States argued on appeal that actions to revoke a patent must be tried in a federal district court before a jury rather than in administrative proceedings. The Federal Circuit rejected this argument. The


140 After a panel reaches a decision, the losing party may also file a petition for rehearing by the panel or the whole Federal Circuit, but the latter is typically only granted if there is an important issue of patent law that the Federal Circuit decides should be addressed.

Supreme Court affirmed the Federal Circuit’s judgment, finding that an IPR ‘involves the same interests as the determination to grant a patent in the first instance’, such that Congress can properly empower the PTO to administer IPRs. The Supreme Court emphasised ‘the narrowness of [its] holding’, remarking that its decision should not be ‘misconstrued as suggesting that patents are not property’ in other legal contexts.

ii  
**SAS Institute Inc. v. Iancu** 142

In this decision issued the same day as Oil States, the Supreme Court held that, if an IPR is instituted, the PTAB must decide the patentability of all claims challenged by a petitioner. The Supreme Court found that the PTAB’s practice of reviewing fewer than all challenged patent claims violated the plain language of the America Invents Act, which requires a ‘yes-or-no choice’ as to whether to institute an IPR. As a result of this decision, petitioners may need to be more selective in choosing which claims to challenge, as the PTAB will reach a final decision on all of them, such that the petitioner cannot challenge them again in district court. There is also a greater likelihood that district courts will stay cases pending the PTAB’s final decision, given that the PTAB will now have to issue a decision on every challenged claim.

iii  
**WesternGeco LLC v. Ion Geophysical Corp.** 143

In its third patent decision of the year, the Supreme Court addressed when a party may recover damages for lost profits outside of the United States. Generally speaking, lost foreign sales are not recoverable for domestic acts of infringement, but this case involved Section 271(f) of the Patent Act, 144 which imposes liability for infringement when a party supplies a patented invention’s components from the United States. The Supreme Court reversed the Federal Circuit’s holding that the patent owner could not recover foreign lost profits caused by patent infringement, finding that, under Section 271(f)(2), the focus is on the act of exporting components from the United States such that damages can include lost foreign profits to fully compensate the patent owner for the infringement.

IX  
**OUTLOOK**

The United States has a long tradition of research and development of new technologies, large markets with high profit margins and a tradition of rewarding intellectual property rights, all of which results in a great deal of patent litigation. With the shift of manufacturing to Asia, Chinese patent infringement proceedings could emerge as viable additions or alternatives to proceedings in the United States. In 2017, a reported 16,010 patent litigations were filed in China, an increase of nearly 30 per cent from the prior year. 145 According to one study, foreign patent owners are as likely to litigate in China as domestic patent owners, and the patent owner ‘win rate’ in China may be as high as 80 per cent. 146 However, there is an array

of challenges that face foreign companies involved in patent litigation in China, including strict limits on discovery, low damages awards and the chance that political considerations may influence the outcome of a case.  

The US patent system remains resilient in the face of obstacles. The PTAB’s IPR proceedings have delayed many patent infringement cases in the district courts and have invalidated many patents involved in those litigations. The US Supreme Court’s *Oil States* decision has resolved the constitutionality of such proceedings for now. It remains to be seen if the number of district court actions will decline significantly as a result. Further, the high cost of thorough discovery in the US may be disproportionate to its benefits and thus could be stifling patent enforcement. Another area where consensus is building in favour of change is patent eligibility under Section 101 of the patent statute, whose ambiguity has visibly harmed innovation in important industries such as medical diagnostics. But history has repeatedly shown that reports of the ‘death’ of patent litigation have been greatly exaggerated.

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Appendix 1

ABOUT THE AUTHORS

NATALIE ACKERMANN-BLOME

_Linklaters LLP_

Natalie Ackermann-Blome is an associate in Linklaters’ German patent litigation practice and is based in Frankfurt. She specialises in intellectual property litigation with a focus on cross-border patent infringement matters. She also represents clients in parallel opposition and nullity proceedings. Furthermore, she advises on competition law in relation to intellectual property rights. Her clients are particularly from the life science, semiconductor, automotive and chemical industries.

Natalie studied law at the University of Mannheim with a focus on intellectual property rights. In 2015, she started working as research assistant for Prof Dr Mary-Rose McGuire at the University of Osnabrück. Additionally, she wrote her PhD thesis in patent law and has published extensively on patent and intellectual property law. Natalie joined Linklaters in 2018.

MARTA ALVES VIEIRA

_Vieira de Almeida_

Marta Alves Vieira is a managing associate at Vieira de Almeida. Marta obtained her law degree from the University of Lisbon, with a university extension in arbitration. She is admitted to the Portuguese Bar Association and also has a proficiency certificate as trainer.

Marta Alves Vieira joined Vieira de Almeida and the intellectual property practice area in 2012, and is now a managing associate, with a strong background in litigation and arbitration and a solid experience as a litigator in the Portuguese courts for approximately 16 years.

In this capacity she has been involved in intellectual property litigation (in particular, pharmaceutical patent litigation), and advising companies in all intellectual property matters.

She recently became a member of several important intellectual property international organisations, such as MARQUES and ECTA, where she is currently a member and the secretary of the design committee.
PRAVIN ANAND

Anand and Anand

Pravin Anand, managing partner of Anand and Anand, completed his law studies in New Delhi in 1979 and has practised as an IP lawyer since then. He has been counsel in several landmark IP cases, including those involving the first António Piller order (HMV), first Mareva injunction order (Philips), first Norwich Pharmacal order (Hollywood Cigarettes), moral rights of artists (Amarnath Sehgal), first order under the Hague Convention (Astra Zeneca) and several significant cases for pharmaceutical clients such as Merck, Novartis, Pfizer and Roche. He received the National Innovation Foundation Award from the Indian government in recognition of pro bono work for rural innovators at the grass roots level.

Mr Anand is co-author of two volumes of Halsbury’s Laws of India on Intellectual Property and author of the India-specific chapter in several renowned guides. He also serves on the editorial board of several international IP journals. He was the first Indian legal practitioner to receive the AIPPI award of merit, and has also received other prominent awards and accolades.

ANTÓNIO ANDRADE

Vieira de Almeida

António is of counsel at Vieira de Almeida. He obtained his law degree from the University of Lisbon and is admitted to the Portuguese Bar Association. He was granted the title of ‘specialist lawyer in intellectual property’ by the Portuguese Bar Association in 2006. He has been a patent, trademark and design attorney since 2007.

He joined the intellectual property practice area of Vieira de Almeida & Associados in 2011.

In this capacity he has been involved in intellectual property litigation, such as in patent (namely pharmaceutical patent), trademark and design litigation, and advising companies in all intellectual property matters.

He is a member of several IP international organisations, including AIPPI (Portuguese group), ECTA, FICPI, INTA, MARQUES and Union-IP. He was the chair of the ECTA Design Committee (2010–2016) and is currently a member of the ECTA Copyright Committee. He is also a member of the Union-IP Litigation Commission.

He has been a speaker and delegate at several conferences, seminars and workshops regarding intellectual property matters and is the author of a number of IP legal opinions published in IP publications and in the press.

DOVEV APEL

S Horowitz & Co

Dovev Apel is a partner at S Horowitz & Co. He specialises in intellectual property, life sciences and health law.

Dovev advises major global and domestic pharmaceutical and technology-based companies on a wide range of intellectual property issues involving patents, trademarks, designs, copyrights, and trade secrets, with a particular strength in the life sciences industry. Dovev regularly appears before the Israel Patents, Designs and Trademarks Office, including in pre-grant patent opposition proceedings, and all levels of Israeli civil courts and arbitration tribunals on IP cases, including cross-border IP proceedings.
Dovev’s non-contentious practice includes advising on the commercial exploitation of intellectual property rights and IP legal due diligence within the context of M&A transactions, as well as the provision of legal opinions in the pharmaceutical field, in particular concerning issues of freedom to operate.

Dovev is recognised by Managing Intellectual Property as a ‘star’ in Israel in the field of patents and trademarks.

Dovev teaches courses on patent law for LLB students at the Academic Centre of Law and Business, Ramat Gan.

ARMANDO ARENAS REYES

Armando Arenas is a partner. His areas of practice are pharmaceutical law, IP litigation and enforcement. He has detailed regulatory expertise regarding health law, and provides strategic advice in complex patent litigation cases and dispute resolutions. Armando's clients and deal experience include all segments of the industry – pharma, biotech, medtech, diagnostics, animal health, vaccines and health services. He also represents life sciences companies before the Mexican courts, and has handled the following relevant cases:

a) restoration of a patent’s life term granted under provisions of Article 12 transitional (pipeline patents);

b) infringement actions of patents covering pharmaceutical products declared final and beyond appeal against generics companies;

c) the first case in Mexico where it was resolved that the revocation of the marketing authorisation of a pharmaceutical product was in violation of a formulation patent listed in the Linkage Gazette;

d) the first case in Mexico of a use patent being effectively enforced in Mexico related to public tender;

e) the unconstitutionality of Article 167 bis of the Health Supplies Regulation, as it does not provide the right of the titleholder of a patent to be heard during the prosecution of the marketing authorisation; and

f) the first case in Mexico enforcing the linkage system in order that the local regulatory agency consider a use patent included in the Linkage Gazette for allopathic medicines.

Armando has a bachelor’s degree from the National Autonomous University of Mexico (1995). His languages are English and Spanish.

DAVID AYLEN

David Aylen is an internationally renowned intellectual property lawyer with extensive experience advising foreign nationals on doing business in Russia and the CIS, as well as helping emerging Russian companies establish and protect their IP rights around the world. David is known for providing timely, responsive service and delivering innovative solutions that achieve results – whenever and wherever a problem arises.

As managing partner of the firm’s Russia/CIS practice, David is a client’s first point of contact to the Russian market. He provides strategic, practical legal advice to help clients understand and access the significant business opportunities available in Russia, as well as overcome any difficulties.
Under David’s management, Gowling WLG’s Russia/CIS practice brings a Western-style approach to legal issues and is consistently ranked as a top-tier IP practice. From IP litigation, patent and trademark prosecution to licensing, domain names, and advertising and marketing law, David makes sure clients receive the best possible service and results.

Having practised in Canada for many years, David is certified as an IP specialist (trademarks, patents and copyright) by the Law Society of Ontario. He is also the only Alternative Dispute Resolution expert certified by the International Trademark Association in Russia.

TAL BAND

S Horowitz & Co

Tal Band is a senior partner, member of the executive board and of the management committee and the chair of the intellectual property practice group at S Horowitz & Co. Tal represents high-profile clients in litigation before the Israeli civil courts and the Patents and Trademarks Office on all matters relating to patents, trademarks and copyright issues. He has particular expertise in complex, multi-jurisdictional disputes and works in close coordination with leading IP litigators in the United States, the United Kingdom and worldwide. Tal has been involved in and responsible for numerous precedent-setting Supreme Court decisions in IP in general, and in patent cases in particular.

Tal has been described by Chambers Global as ‘a fantastic IP trial lawyer who is intelligent and can be counted on for first-class legal work’, as well as being ‘one of, if not the most gifted litigators in the country’, by the World Trademark Review.

Tal was a member of various public committees of experts appointed by the government of Israel to review legislation in various fields, in particular the law revision committees overseeing the Patents Law, the Trademarks Law, application of the TRIPS agreements, practice and legal proceedings before the Patent Office and the Standards Law.

Tal teaches courses on IP at the Tel Aviv University. In recent years, Tal has served as chair of the highest-profile international conferences on IP and business in Israel.

OKAN ÇAN

Deriş

Okan Çan counsels and represents market-leading companies in the protection and enforcement of IP rights. His expertise extends to IP litigation, IP strategy, transactional intellectual property, technology licensing, data privacy and publicity rights. He has achieved notable resolutions and results in complex patent and trademark litigation, technology licensing and transactional IP.

Mr Çan is listed in the IAM Patent 1000, Managing Intellectual Property’s IP Stars, The Legal 500 and the WTR 1000 (2016 through 2018) in the gold tier for litigation and enforcement.
TREVOR COOK
Wilmer Cutler Pickering Hale and Dorr LLP

Trevor Cook, a partner at Wilmer Cutler Pickering Hale and Dorr LLP, is an English solicitor with 40 years’ experience in intellectual property, and notably global patent litigation, who has acted in many of the leading patent infringement cases before the English courts, and also in several leading European cases regarding data exclusivity.

In 2014, Mr Cook joined WilmerHale in New York from Bird & Bird LLP in London, where he had been a partner since 1981. He chairs the British Copyright Council and for several years was president of the UK group of the International Association for the Protection of Intellectual Property. He is on the World Intellectual Property Organization list of arbitrators.


ERWIN CRUZ
Olivares

Erwin Cruz has been a member of Olivares’ life science law group since 2008, helping clients to add value to their businesses and projects in Mexico. He achieves this not only by getting exclusive rights to clients, but also by developing and successfully implementing strategies to enforce exclusive rights and fair trade rules against potential infringers. Erwin provides highly qualified regulatory assistance related to products’ marketing, labelling and advertising.

He has extensive expertise in intellectual property rights and regulatory compliance related to the pharma, agro and software industries. He constantly participates in international and national conferences, and meets key authorities in Mexico for these industries, such as the IMPI, the Healthcare Products Regulatory Agency, the Plant Breeders’ Rights Office and the Bureau of Consumer Protection.

Erwin has written several articles about litigation and regulations for pharmaceuticals, biotechnologies, agribusinesses, food and beverages.
PAULINE DEBRÉ

*Linklaters LLP*

Pauline, a partner at Linklaters LLP, heads the intellectual property practice of Linklaters in Paris. Pauline has considerable experience in handling national and cross-border IP disputes, notably patent litigations, particularly in the healthcare and telecommunications sectors. She has assisted clients in all types of patent proceedings, including preliminary injunctions, seizures (saisie-contrefaçon) and actions on the merits (validity and infringement) in different contexts (parallel litigation in the United States, pending oppositions before the European Patent Office).

Pauline is a member of several associations: AIPPI (member of the Comité Directeur of the French group, co-head of the Patent and Life Science Commission, co-head of the Standing Committee on Patents and Standards), EPLAW, APEB and LES.

Pauline is ranked among France’s best IP lawyers. She is described as a ‘real expert’ who ‘knows IP in depth’ (*Chambers 2017*). According to *The Legal 500* (2019), ‘Linklaters’ ‘intellectual property team is very dedicated to its clients’ and its ‘thoroughly experienced patent specialists’ are led by Pauline Debré, who one client recognises as ‘one of the top patent litigators on the French market’.

CHRISTIAN DEKONINCK

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Christian Dekoninck is a partner in the IP/IT group where his practice covers all aspects of intellectual property law. He focuses on patent litigation, mainly in the pharmaceutical sector. Christian Dekoninck also has significant experience in IP issues specific to the life sciences industry, such as the interface between IP and regulatory issues. Christian is the author of many publications in the field of IP.

MEHMET NAZIM AYDIN DERİŞ

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Mr Deriş has been shareholder and manager of Deriş Patents & Trademarks Agency AS since July 1971, providing the full range of services for IP and industrial property rights. He is currently counsel of Deriş Attorney-At-Law Partnership for court action and transactional matters and has extensive experience in IP litigation and prosecution matters in Turkey and abroad.

He is fluent in French, English, Italian and German and speaks Greek. Mr Deriş is a member of the International Federation of Intellectual Property Attorneys, the International Trademark Association and the Pharmaceutical Trademarks Group. As a European patent attorney, he is a member of the European Patent Practice and Litigation Committees. He was actively involved in establishing the International Association for the Protection of Intellectual Property Turkish National Group in 2007 and served as its first president until 2011.
BOLKO EHLGEN

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Bolko Ehlgen is part of Linklaters’ German patent litigation practice and is based in Frankfurt. He specialises in intellectual property litigation. Bolko is experienced in the enforcement of intellectual property rights and the defence against allegations of infringement, particularly in a cross-border context. His particular area of expertise is patent and utility model litigation. He represents his clients’ position in infringement cases and actively participates in validity proceedings. His clients are mainly from the semiconductor, life sciences, electronics and telecommunications sectors and also include chemical companies and industrials.

Bolko has particular expertise with US proceedings and is also admitted to practice in New York. The coordination of the proceedings that he handles requires close alignment with US counsel and insights into US patent law and proceedings.

Bolko studied law at the Universities of Heidelberg and Cologne and completed an LLM at the University of Pennsylvania in Philadelphia, USA. He started his career at DLA Piper and joined Linklaters in 2015.

LUZ ELENA ELÍAS

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Luz Elena Elías studied law at the National Autonomous University of Mexico (1994). She has an LLM degree from the University of Ottawa in Canada, and a master’s degree in patents, trademarks and copyrights from the University of Alicante in Spain.

She is part of the appeals department of Olivares. She provides legal opinions to clients and is involved in consulting regarding regulatory issues, handling cancellation, nullity and infringement actions before the Mexican Institute of Industrial Property, as well as handling nullity trials before the Federal Court for Administrative Affairs and *amparo* lawsuits before the federal courts.

SOLOMON EZIKE

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Solomon Ezike is a senior associate at G Elias & Co. He holds a degree in law from the University of Calabar, Nigeria. His areas of practice include intellectual property law, media and technology and dispute resolution. He has vast experience in patent litigation. He is a member of the team that represented both Mobile Decisioning in a seminal case for the invalidation of multiple patent grants on an invention and Telco in the 100-billion naira patent infringement claim.

VIDISHA GARG

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Vidisha Garg is a partner of Anand and Anand and has been with the firm since 2004. She is a patent agent and has law degree. Her experience involves patent prosecutions for chemical and pharmaceutical patents. Vidisha also handles patent revocation matters before the IPAB, matters relating to protection of national biodiversity and has worked on complex pharmaceutical patent litigation. Vidisha’s past experience as an academician and a researcher
in synthetic organic chemistry helps her in understanding and deciphering complex chemical inventions. She has authored several articles and papers. She is also the recipient of the prestigious CSIR Research Fellowship and TIFAC Scholarship for training in IPR.

**STEVEN B GARLAND**  
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Steven has over 25 years of trial and appellate experience in all areas of IP. He has litigated on matters relating to patents, trademarks, copyright, industrial designs, trade secrets, breach of confidential information and competition law. In respect of patents, Steven has acted in matters that have involved a wide variety of subjects, including chemical, electrical, biochemical, pharmaceutical, biotechnological, telephony, mechanical and computer or internet.

Steven has appeared as counsel before the Supreme Court of Canada, the Federal Court and Federal Court of Appeal, appellate and trial courts for the provinces of Ontario, British Columbia, Alberta and Nova Scotia, and the Patent Appeal Board and the Trademarks Opposition Board. Steven also acts on behalf of innovator pharmaceutical and biopharmaceutical companies in respect of patent related matters, including patent infringement actions and proceedings under the Patented Medicines (Notice of Compliance) Regulations.

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Licia Garotti has been head of the department of intellectual property and information technology law in Gattai, Minoli, Agostinelli & Partners since 2015. She focuses her activity on intellectual property, copyright and ICT (Information Communication Technology) matters, assisting and representing Italian and foreign clients both in transactions as well as in complex litigations concerning patents, software, trademarks, design and unfair competition, often coordinating multi-jurisdictional cases. She assists clients from different industries, including electronics, telecommunications, chemical, pharmaceutical and biotechnology, mechanical as well as the banking and finance, fashion, luxury and food sectors. Panellist and speaker at several Intellectual Property and ICT Seminars, Ms Garotti has authored various publications in the field of patents, design and trademarks law, 3D printing and disruptive technologies, for both Italian and European legal magazines. She is a member of the International Association for the Protection of Intellectual Property and of the Licensing Executives Society. She graduated in law from the University of Bologna and was admitted to the Italian Bar Association in 2001. She was named Lawyer of the Year in the Trademarks and Patents category at the Legal Community IP & TMT 2018 Awards. Licia has also been recognised by the Legal Community IP&TMT report 2017 as having ‘a deep knowledge of software and connected technical issues’ and for being ‘skilled, capable, headstrong’.
SUE GILCHRIST
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