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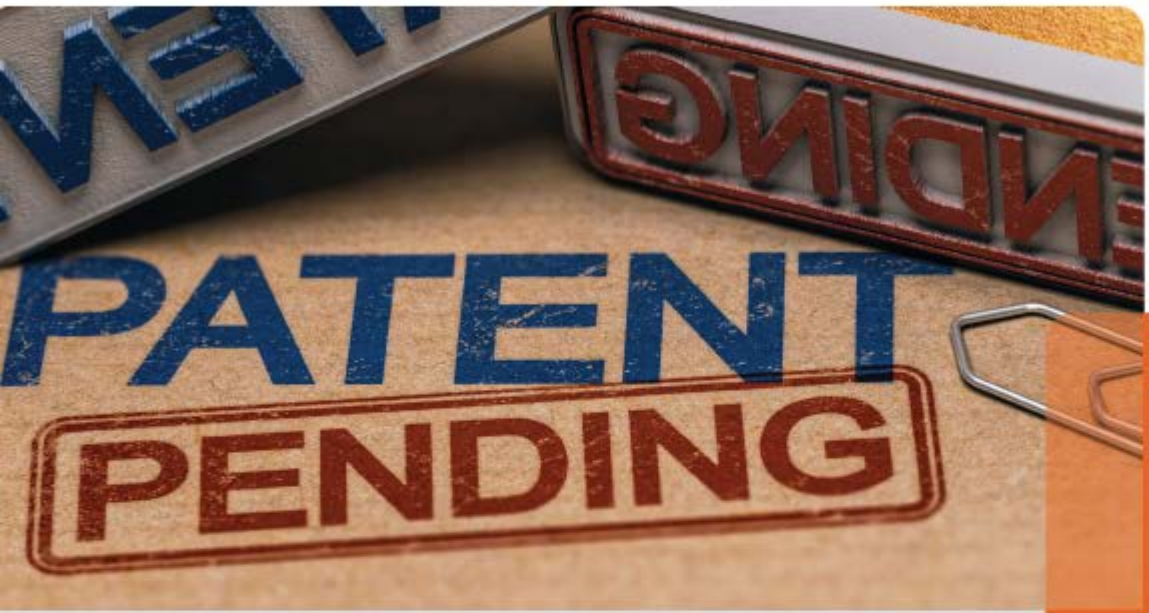

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Recent Developments in SEP Litigation and FRAND Determination


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1 A Busy Year

The last year has been a busy period in the world of Standard Essential Patent ("SEP") litigation, particularly in the UK. The UK is one of the few countries where the courts are willing to determine global Fair, Reasonable and Non-Discriminatory ("FRAND") terms and this year has seen the publication of two enormously long decisions where the judges have sought to do just that. The question of the court's approach to injunctions in SEP cases has also been in the news, with the Supreme Court (the UK's highest court) due to consider the issue in early 2024.

Meanwhile, some countries have considered or are considering guidelines governing SEP licensing negotiations. In April 2023, the European Commission, concerned that if it did not take the initiative it would have to follow developments in other jurisdictions, released a proposal for a Regulation on SEP licensing which, if adopted, would introduce a very different and more centralised approach to both SEP and FRAND disputes within EU Member States.

2 The appropriateness of injunctions for SEPs

A SEP owner, unlike the owner of other patents, must license its patents subject to a FRAND commitment. That is, the SEP owner promises to license any implementer that uses the standard to which the patents are essential on FRAND terms. Where the patent owner and the implementer fail to agree licence terms, the courts, including the Court of Justice of the European Union,[1] have recognised the patent owner's right to seek to enforce its patents, subject to certain conditions that must be fulfilled in order to comply with the FRAND commitment and to prevent an abuse of the patent owner's dominant position.

In 2020, in the *Unwired Planet* and *Conversant* cases against Huawei,[2] the UK Supreme Court held that the court had the power to grant an injunction (referred to as a FRAND injunction) in respect of UK national patents, but it would not take effect if the implementer agreed to enter into a global licence over the patentee's patent portfolio.

In the *Unwired Planet* case, the judge at first instance, Mr Justice Birss (as he then was) handed down his decision determining the FRAND rate and then considered the issue of the FRAND injunction. He put Huawei to an election: take the determined rate; or cease the infringing acts in the UK. This year, in April 2023, the UK Supreme Court indicated it will hear an appeal in the *Apple v Optis* case in which it has been asked whether it is appropriate for an implementer to be put to that election as soon as there is a finding of infringement of an SEP, but before the rate has been determined.

2.1 The Court of Appeal's ruling in *Apple v Optis*: a quick recap

In August 2021, the Court of Appeal[3] upheld the Patent Court's decision that Optis, the SEP owner, was entitled to an injunction in a qualified FRAND form after the patent had been found valid, essential and infringed, even though the trial to set the terms of the appropriate FRAND licence had not yet taken place. This question was considered at first instance by Mr Justice Meade in what was referred to as "Trial F". The practical implication of Mr Justice Meade's decision was that Apple would have to undertake to take a global licence to Optis's portfolio on terms determined to be FRAND by the English Court before the amount had been determined, or face an immediate FRAND injunction.

Both parties appealed the decision. Optis sought an unqualified injunction if Apple would not give the undertaking, on the basis that it had waived its right to a FRAND defence. Apple argued that it was entitled to see the FRAND determination before being put to the election between taking the licence or leaving the UK market.

Lord Justice Arnold, who gave the leading judgment in the Court of Appeal, concluded that Mr Justice Meade was right to find that Optis was entitled to a FRAND injunction, following a finding of patent infringement, and dismissed both parties' appeals.

2.2 Ramifications of the Court of Appeal's decision

The Court of Appeal's ruling was widely welcomed by patent owners in the SEP field. The judgment showed that SEP holders are able to obtain early certainty of whether an English FRAND action will resolve a dispute. This avoids the risk of incurring the costs of a FRAND trial, for an implementer to only then decide that it will not take a licence on FRAND terms. Implementers, on the other hand, usually prefer to wait until the outcome of the FRAND trial before making their decision to see whether the court will decide on FRAND terms that are favourable to them.

2.3 Analysis

The Court of Appeal's decision has very wide applicability, being relevant to nearly all FRAND trials. As a result, the appeal to the Supreme Court is likely to be watched with great interest by SEP holders and implementers alike. SEP holders will, no doubt, hope that the Supreme Court maintains the *status quo*,

while some implementers are likely to hope that the Supreme Court may overturn the lower courts and remove this powerful tool for resolving FRAND disputes in the UK.

One question is whether this appeal is moot, given that a FRAND judgment has now been given (see next section below) and Apple can unequivocally say whether it will take a licence on the Court's determined FRAND terms. However, given the likelihood that the FRAND decision will be appealed, the wider applicability of the point and the number of FRAND disputes currently before the English courts, there seems to be a reasonable chance that the parties will decide to go ahead with the appeal. It will be heard in January 2024, but the decision will not be published until some months later.

3 FRAND determination by the UK courts: two new decisions

This year has seen the publication of two decisions in which the judges at first instance determined FRAND terms. First to be published was *InterDigital v Lenovo*[4] and the second was *Optis v Apple*.[5]

What is of keen interest to all those in this sector, is that the methodology considered suitable by each judge, respectively Mr Justice Mellor and Mr Justice Marcus Smith, was different. The methodologies are both discussed below.

3.1 Context to the UK's FRAND determinations

To date, only the UK courts and the US courts have determined global FRAND terms. In *TCL v Ericsson* (2017),[6] heard with the consent of both parties, the US District Court of Central California set a global portfolio rate for Ericsson's patents. The approach adopted by Judge Selna in calculating a FRAND rate was similar in some respects to the approach used by Mr Justice Birss in the UK *Unwired Planet*[7] case the year before: both used comparable licences to the portfolio as a benchmark and each also used a form of top-down analysis (this is where the patent owner's share of the total aggregate royalty burden is calculated using the patent owner's share of relevant SEPs). However, there were differences in approach at the detailed level, the most important of which was a difference in the total number of patents assumed to be essential to the standards. The differences in detail, controversially, gave rise in the US court to a much lower rate for Ericsson's portfolio. While the UK decision was upheld, the US decision was vacated on appeal before the parties settled.

In China, the Supreme People's Court[8] has decided that the courts are entitled to set global FRAND terms, although a court has yet to do so. There have, however, been decisions on China-only rates, for example, the decision of the Nanjing Intermediate People's Court which used a top-down analysis in *Huawei v Conversant* (2020).[9]

3.2 Overview of the two 2023 decisions

Both judges confirmed that UK courts are willing and able to determine global FRAND terms. They both awarded a lump sum. In *InterDigital v Lenovo*, the judge awarded a total payment (described as the "Royalty" in his Order) of $184.9m for a global 3G/4G/5G licence, i.e. $138.7m plus an additional payment of $46.2m being interest at a rate of 4% per annum compounded quarterly.[10]

In *Optis v Apple*, Apple had to pay $5.13m per annum for a global 4G multi-standard licence covering all future Apple products (including the hypothetical Apple car). The total payable was therefore $56.43m (a five-year licence going forward and a six-year past release). Interest on the past release was payable and the judge stated his "firm but provisional view" that the rate should be 5% compounded annually (the exact rate has been reserved to a future hearing).

3.3 Confidentiality *v* transparency

The decision in *InterDigital v Lenovo* took the judge, Mr Justice Mellor, over a year to write and was initially handed down in March 2023 with an indication that he considered that much of the redacted material should be published. However, following a hearing in which both the parties and some of InterDigital's licensees made submissions as to the confidential nature of such material, only some of it was published in a further copy of the decision in July.

The decision in *Optis v Apple* (referred to as "Trial E") is even more heavily redacted and was handed down in June 2023. As with the *InterDigital v Lenovo* judgment, there will be a hearing at which third parties will have the opportunity to be heard on the issue of confidentiality. Again, the judge, Mr Justice Marcus Smith, indicated that he was of the preliminary view that most or all of the redactions are indefensible.

As discussed below, this drive toward transparency by both judge's chimes with one of the aims of the European Commission when drafting the proposed SEP Regulation. However, it does so in an asymmetric way: rather than lifting the veil on all licensing activity in the industry, it selectively exposes the agreements of some parties, while allowing others to keep theirs confidential. That type of arbitrary and selective transparency, SEP owners argue, distorts rather than facilitates the licensing market; and it does so to the disadvantage of third parties who have assisted the court by consenting to their confidential information being used in the rate-setting case.

3.4 Comparables are the right starting point, but different methodologies were used

The judges were agreed that any determination of a FRAND rate must start with comparables. Mr Justice Mellor made it clear that the comparables analysis was the primary "if not the exclusive indicator of the appropriate financial terms". In *Optis v Apple*, the judge also relied upon comparables, concluding that "the case law makes clear that, even if remote, comparables are one of the best sources for determining excessive prices" and "the comparables are in fact the only real evidence that I have to determine the FRAND question".

Mr Justice Mellor started by considering 20 InterDigital licences (mostly providing for running royalties) but rejected them because Lenovo's total cellular units under consideration were significantly larger than the total units of any of the 20 licensees. He then considered the basket of seven licences with InterDigital's six big licensees. Of these seven licences, the parties both relied upon a licence with LG (Lenovo's expert describing the licence as an "awesome" comparable). The judge nevertheless analysed all seven, determining LG to be the best comparable.

To calculate a rate payable by Lenovo, Mr Justice Mellor took the blended "effective per unit rate" for the LG licence over the entire term of the licence, thus applying the same rate to the past released sales as to the future sales. (By using this figure, the judge rejected InterDigital's case that it applied significant discounts to past sales and therefore the future rates should

be analysed for the purposes of what Lenovo should pay). To the effective per unit rate, the judge then applied a number of scaling factors to adjust for the differences between LG and Lenovo when it came to sales mix and markets, resulting in a single per unit rate of $0.175. When applied to all Lenovo's sales, this resulted in a lump sum of $138.7m which he later increased by including interest for the entire period of the licence to come to a total figure of $184.9m (as mentioned above).

In *Optis v Apple*, the judge used a very different methodology to the one described above. He described his task as pricing the value to Apple of Optis's portfolio. In summary, he held that the approach to be adopted was:

- determine the number of SEPs in the entire applicable "Stack" of SEPs (taken in this case as 22,000 SEPs);
- pro-rata the Stack based on comparable licences indicative of other portfolios, not just the SEP holder's portfolio;
- value the Stack, preferably using a lump sum calculation; and then
- determine the SEP holder's share of the Stack and the resulting payment owed.

When considering which comparables to use, the judge rejected the 14 licences put forward by Optis as being relevant. All were licences to the Optis portfolio (or a portion of it) and as the judge pointed out, this was an advantage since this was the portfolio he was seeking to value to answer the question of what was a FRAND rate. However, he rejected them as being "worse than useless" in helping him, because they were generally with small players with low sales. They also only gave him one reference point to valuing the Stack.

The 14 comparable licences put forward by Apple, some with large counterparties, were not licences over the portfolio the judge had to value. However, he considered that they were more reliable than the Optis licences, and were indicative of multiple patent portfolios giving him some insight into the value of the Stack as a whole. Once unpacked, they gave a range for the value of the entire Stack. The judge excluded some that he considered to be outliers and modified others before averaging the remaining value to come up with a value for the Stack.

The judge found that Optis's share of the total Stack was 0.61%, which he valued at $8.235m. (As an aside, while the value of the Stack as a whole was redacted from the judgment, $8.235m per year for a licence to 0.61% of the Stack, leads to an annual value for the Stack for Apple of $1.35bn, or about half of a percent of its net sales.) For reasons which have been redacted in the judgment, the proportion of the sum payable by Apple was reduced by 0.38% giving a figure of $5.13m per annum.

3.5 Top-down analysis

Both judges declined to rely upon the top-down analysis that was presented to them, unlike Mr Justice Briss who had found it useful as a cross check in the *Unwired Planet* case.

Mr Justice Mellor found there was no value in the top-down analysis because it did not lend support to his analysis of the comparables.

Mr Justice Marcus Smith also rejected the top-down cross-check put forward by Optis. Optis started from an *ad valorem* rate for the Stack of 15%. This was rejected by the judge as a starting point because of the inconsistency with the aggregate rate calculated by Optis when starting from the licences they relied upon with the smaller players.

3.6 Other methodologies rejected in *Optis v Apple*

Scaling from *Unwired Planet* was not an acceptable approach as the facts and evidence were very different.

Apple also contended for a patent-by-patent approach. However, the judge noted that parties undertake infringement and validity proceedings at considerable expense to get to the position that at least one patent is found by a UK court to be infringed, essential and valid. To expect this approach to be applied to a portfolio of any size would be unworkable.

Finally, the judge rejected an argument based on the Smallest Saleable Patent Practising Unit or "SSPPU" (which for cellular SEPs is the baseband chipset). The argument put forward by Apple was that the proportion of the overall cellular declared SEP royalty profits that is allocated to the cellular SEP holders is determined to be no more than the profits of the baseband chipset. The judge described this argument as "indefensible".

3.7 Programme or headline rates

Many of the large SEP owners publish what were referred to as "programme rates" in the *InterDigital* case and "headline rates" in the *Optis* case. Both judges were critical of InterDigital's and Optis's argument that the determination should start from these rates, or licences which embodied (or closely embodied) these rates with the smaller players. As Mr Justice Marcus Smith stated, the question was why did Optis bother with small counterparties like these as the transaction cost dwarfed the revenue? He noted that it was difficult to avoid the conclusion that these licences were agreed to assist Optis in their litigation with Apple.

In *InterDigital v Lenovo*, the court heard evidence that in reaching agreements with licensees, InterDigital applied a number of discounts to its programme rates such as, for example, volume discounts, pre-payment discounts, regional sales mix discounts and time value of money discounts. For some of the largest players, some of the discounts could be sizeable. The judge expressed his view that this had the effect of discriminating against the smaller licensees, which paid sums closer to the programme rates on more of their sales. Mr Justice Mellor did note that some discounts, however, such as the time value of money discount and pre-payment discounts were entirely fair and consistent with FRAND.

3.8 Interest on past sales and limitation periods

One of the interesting points in both judgments is the approach to interest. Whereas Mr Justice Mellor found that royalties (and therefore interest) should be payable for all infringements, even going back beyond the limitation period of six years, Mr Justice Marcus Smith held that royalties should run only from when Optis first asserted its patents, which was six years prior to the judgment. Mr Justice Mellor's rationale was that an award of interest on past royalties is consistent with the relationship of willing licensor and willing licensee because the willing licensee had had the use of the money in the meantime. Therefore, in Mr Justice Mellor's view, limitation periods should have no role in the relationship between the willing licensor and licensee.

3.9 Validity of individual SEPs

In a point only argued in *Optis v Apple,* Apple contended that the validity of each SEP should be considered when FRAND terms are being determined, the argument being that a party may hold alleged SEPs, but if a large proportion of them are invalid then the party should receive a reduced royalty as a result. In this case, the judge decided to use numbers relating to patents declared to ETSI and leave out of consideration whether the patents of a portfolio were valid/essential.

3.10 Looking forward

It is difficult to reconcile the methodologies used in these two decisions. Although in neither case did the judge say that he found the top-down approach useful, Mr Justice Marcus Smith has adopted a form of top-down in his approach to calculating the rate. However, what they do indicate is that the decisions are very much the result of the individual facts in the case and what the judge views as the most reliable evidence. Both decisions are likely to be appealed, possibly by both sides, on multiple grounds; indeed, Mr Justice Mellor has already given permission to appeal certain aspects of his decision.

There are potentially three more FRAND determinations to come hot on the heels of these two. In October 2024, Mr Justice Meade will hear *Nokia v Oppo*. Then in 2025, there are two trials: *Philips v Oppo* and *InterDigital v Oppo*, indicating the UK courts are becoming the go-to jurisdiction for these types of actions.

4 Developments in Europe – Proposal for a SEP Regulation

The EU Commission issued its formal proposal for an EU Regulation on SEPs on 27 April 2023.[11]

The Commission expressed concern about the high transaction costs and long-drawn-out negotiation times, in addition to implementers' uncertainty about the SEP royalty burden to their products.

Consequently, the initiative is aimed at facilitating SEP licensing negotiations and lowering transaction costs for both SEP owners and implementers by: (a) providing more clarity on who owns SEPs and which SEPs are truly essential; (b) providing more clarity on FRAND royalty and other terms and conditions, including awareness raising with regard to licensing in the value chain; and (c) facilitating SEP dispute resolution.

Below is an overview of the proposal and its likely effects if enacted.

4.1 What is proposed?

The Regulation proposes that the EU Intellectual Property Office (EUIPO) is given responsibility for various SEP matters in the EU. (The EUIPO is an EU organisation based in Alicante, Spain, that to date handles EU design and trade mark applications.) In particular, the EUIPO would:

(a) maintain an electronic register of technical standards;
(b) maintain details relating to an aggregate royalty for a technical standard;
(c) maintain an electronic register and database for SEPs;
(d) administer a process for assessment of the essentiality of SEPs;
(e) administer a process for determination of license terms and conditions on FRAND terms; and
(f) manage rosters of evaluators and conciliators.

At this stage it is just a draft and must be passed by both the European Parliament and the European Council before it becomes EU law. Both may amend the draft Regulation and it is possible for the Regulation to be rejected altogether.

4.2 What are the key takeaways from the draft Regulation?

There are a number of key takeaways from the draft Regulation for both SEP holders and implementers, in particular it is intended that:

(a) A SEP may not be enforced until its registration with the EUIPO.
(b) A SEP holder is not entitled to royalties or damages for infringement of a SEP until its registration with the EUIPO.
(c) FRAND determination must be initiated:
  (i) prior to any initiation of a SEP infringement claim in a competent court of a Member State; or
  (ii) prior to any request for the determination or assessment of FRAND terms and conditions of a SEP licence in a competent court of a Member State.
(d) Essentiality checks are conducted on a random selection of SEPs each year, but SEP holders and Implementers may propose a list of SEPs each year.
(e) Aggregate Royalty determination is not mandatory.
(f) The date of registration of a SEP is the date the request is received by the EUIPO.

Each of these issues is considered in more detail below.

4.3 Maintain an electronic register of technical standards (Art 14)

The onus is said to be on "holders of a patent in force in a Member State" to notify to the EUIPO information relating to a Technical Standard. The information comprises: the commercial name of the standard; a list of relevant technical specifications that define the standard; the date of the publication of the latest technical specification; and details of implementations of the standard known to the SEP holder. An "implementer" (a person that implements, or intends to implement, a standard in a product, process, service or system) may also notify the EUIPO. "Stakeholders" (anyone with a "legitimate interest in SEPs") may comment and then the EUIPO publishes the information relating to the standard.

This information is in relation to a standard and no details of any SEPs are required at this stage. Accordingly, who will actually do this and when are interesting questions. Various time limits are given, but no consequences if "holders of a patent in force in a Member State" do not notify the EUIPO of a standard.

4.4 Maintain details relating to Aggregate Royalty for a technical standard (Arts 15–18)

Holders of SEPs "may" notify the EUIPO of an aggregate royalty for the SEPs covering a standard and also may ask the EUIPO to appoint a conciliator to mediate discussions for a joint submission of an aggregate royalty. In the latter case, an opinion is published for all to see. However, neither of these steps is mandatory.

Again, this raises the questions – who will actually do this and when? Various time limits are given but, again, no consequences if the time limits for this voluntary process are not met.

4.5 Maintain an electronic register and database for SEPs (Arts 20–25)

This is where the draft gets interesting. As mentioned above, the EUIPO is to maintain an electronic register and database for SEPs; and the consequences of a SEP holder not registering a SEP with the EUIPO are severe:

(a) A SEP may not be enforced until its registration with the EUIPO.
(b) A SEP holder is not entitled to royalties or damages for infringement of a SEP until the SEP's registration with the EUIPO (Art 24).

The date of registration of a SEP is the date the request is received by the EUIPO (Art 21).

Therefore, registration of a SEP will be mandatory on SEP holders that wish to enforce their SEPs in the EU. The time limits are interesting – within six months of entry of the standard in the register (or six months from grant of the SEP if it was not granted when the standard was entered in the register). Again, there are no consequences in the Regulation if this time limit is not met.

However, a competent court of an EU Member State (national courts of an EU Member State and the Unified Patent Court) that is requested to decide on any issue related to a SEP in force in a Member State "shall verify whether the SEP is registered as part of the decision on admissibility of the action" – therefore, this looks like the courts in the EU may consider an action as inadmissible if the SEP is not registered.

One other point to note is that "the registration fee shall include, in case of medium and large enterprises, the expected costs and fees of the essentiality check" (Art 20(6)). There is no indication, at this point, of the scale of the registration fee, but it will be the SEP holder paying it.

4.6 Administer a system for assessment of the essentiality of SEPs (Arts 28–33)

Essentiality checks will be carried out each year on a sample of SEPs. There is no indication how large this sample will be. SEP holders and implementers can each propose up to 100 SEPs each year to be checked for essentiality. If there has been a decision in an EU court relating to essentiality of a SEP in relation to the standard, then no essentiality check will be carried out by the EUIPO.

SEP holders are informed if one of their SEPs has been selected and may submit a claim chart and any additional technical information that may facilitate the essentiality check. Stakeholders may submit observations concerning the essentiality of the selected SEPs and the SEP holder may comment on these.

An evaluator selected by the EUIPO (and not disclosed to the SEP holder) carries out the essentiality check. If the evaluator considers that the SEP is not essential to the standard, the SEP holder may request a peer evaluation.

The (non-binding) result and reasoned opinion of the essentiality check are published and may be used as evidence before courts, arbitrators, etc.

Who pays for this? As mentioned above, the initial SEP registration fee is planned to cover the expected costs and fees of the essentiality check. However, if a SEP holder or implementer has proposed a SEP to be checked for essentiality then it appears that they pay for the essentiality check (Art 62).

Therefore, an essentiality check is not mandatory and it is open ended when an essentiality check on a SEP will be carried out by the EUIPO. The SEP holder may participate in the essentiality check, although this does not appear to be mandatory. Some SEP holders may decide not to participate to distance themselves from any essentiality check carried out by the EUIPO; who pays is unclear at this time.

4.7 Administer the process for FRAND determination (Arts 34–58)

FRAND determination is the majority of the Regulation. The Regulation says this starts with a "Request and Response" procedure between a Requesting Party and a Responding Party (typically these will be a SEP holder and an implementer as a potential licensee) and that the procedure must be concluded within nine months. This appears to be nine months from the conclusion of the "Request and Response" procedure.

The FRAND determination must be initiated by a SEP holder or an implementer:

(a) *prior to* any initiation of a SEP infringement claim in a competent court of a Member State; or

(b) *prior to* any request for the determination or assessment of FRAND terms and conditions of a SEP licence in a competent court of a Member State (Art 34).

It is not clear from the Regulation whether a SEP infringement claim/request for FRAND determination can be initiated in a competent court of a Member State once the FRAND determination has been "initiated". The recitals to the Regulation appear to suggest that a party should not be exposed to litigation during the time of the FRAND determination; but also, that any party that commits to comply with the outcome of the FRAND determination while the other party fails to do so should be entitled to initiate proceedings before the competent national court pending the FRAND determination.

It is clear from the Regulation that, if one party commits to the FRAND determination but the other party does not, the one party does not have to wait for the outcome of the FRAND determination before initiating court proceedings. However, the position is not so clear in relation to a situation in which neither party commits to the FRAND determination. According to Art 38, this results in termination of the FRAND determination, but the consequences of such termination have not been set out.

The Regulation also states that, where a parallel proceeding has been initiated in a non-EU Member State before or during the FRAND determination, the FRAND determination shall be terminated upon the request of any other party.

In the FRAND determination procedure, a conciliator has around four months to reach an initial recommendation of a determination of FRAND terms and conditions (having engaged with both parties) and then by 45 days from the end of the nine-month period the conciliator must submit a final reasoned proposal for a determination of FRAND terms and conditions to the parties (after both parties have had the opportunity to comment on the initial recommendation).

The EUIPO shall keep confidential the determination of FRAND terms and conditions, any proposals for determination of FRAND terms and conditions submitted during the procedure and any documentary or other evidence disclosed during the FRAND determination, which is not publicly available, unless otherwise provided by the parties.

However, "the methodology and the assessment of the determination of FRAND terms and conditions by the conciliator" is *not* kept confidential.

Who pays for the FRAND determination? The costs are borne equally by the parties, unless they agree otherwise, or the conciliator suggests a different apportionment based on the level of participation of the parties in the FRAND determination (Art 62). Again, there is no indication at this time regarding how much these fees are likely to be.

4.8 Manage rosters of evaluators and conciliators (Arts 26 and 27)

Finally, the EUIPO will need to find a large pool of experts in SEPs to be evaluators and conciliators and how this will work in practice is yet to be seen, as these people tend also to be expert witnesses in court proceedings around the world.

4.9 What next?

One of the UK judges, Lord Justice Arnold, has made no secret of being a long-time advocate of arbitration for resolving FRAND disputes. In the *Optis v Apple* Trial F (relating to the injunction), he added a postscript to his judgment in which he highlighted what he considered to be the "dysfunctional state" of the current system for determining SEP/FRAND disputes. In his view, the only way to put a stop to the attempts to game the system was for ETSI and other standard setting organisations to make arbitration of such disputes legally enforceable through their IPR policies. Although many SEP owners have publicly expressed their willingness to arbitrate disputes, there are significant challenges to implementing a system that compels parties to arbitrate FRAND disputes.

By proposing a new framework in its draft Regulation, the Commission has seized the initiative. Not surprisingly, the big SEP holding companies have expressed significant concerns with the proposal. The feedback to the Commission only closed on 10 August 2023, but the comments, of which there are many, can be viewed on the Commission's website.[12]

Once a Regulation is proposed by the EU Commission, it is considered by the EU Parliament and Council. The process starts with Parliament appointing a committee to consider the Regulation and prepare a report, recommending either amending the Regulation, adopting it without amendments or rejecting it altogether. The Regulation can undergo up to three readings before Parliament and Council.

There is no set time limit by which either Parliament or Council must conclude its first reading. Therefore, it is likely to be some time before we find whether and in what form this Regulation becomes EU law. We wait to see if one of the stated aims of the Regulation comes about:

> "*This Regulation aims at improving the licensing of SEPs, by addressing the causes of inefficient licensing such as insufficient transparency with regard to SEPs, fair, reasonable and non-discriminatory (FRAND) terms and conditions and licensing in the value chain, and limited use of dispute resolution procedures for resolving FRAND disputes.*"

Endnotes

1. Judgment of the Court of Justice of 16 July 2015 in *Huawei Technologies Co. Ltd v ZTE Corp. and ZTE Deutschland GmBH,* C-170/13.
2. *Unwired Planet International Ltd v Huawei Technologies (UK) Co Ltd* [2020] UKSC 37.
3. *Optis Cellular Technology LLC v Apple Retail UK Ltd* [2022] EWCA Civ 1411.
4. *Interdigital Technology Corp v Lenovo Group Ltd* [2023] EWHC 1583 (Pat).
5. *Optis Cellular Technology LLC (and others) v Apple (and others)* [2023] EWHC 1095 (Ch).
6. Decision of the United States District Court for the Central District of California, *TCL v Ericsson*, Case No. 8:14-cv-00341-JVS-DFM.
7. *Unwired Planet International Ltd v Huawei Technologies Co Ltd* [2017] EWHC 711 (Pat).
8. Chinese Supreme Court, ruling of 19 August 2021, *OPPO v Sharp*, Zui Gao Fa Zhi Min Xia Zhong No. 517.
9. *Huawei v Conversant,* Cases no. (2018) Su 01 Min Chu No. 232, 233, 234.
10. *Interdigital Technology Corp v Lenovo Group Ltd* [2023] EWHC 1578 (Pat).
11. Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU) 2017/1001, Brussels 27.4.2023, COM(2023) 232 final, 2023/0133 (COD).
12. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13109-Intellectual-property-new-framework-for-standard-essential-patents_en.

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Unified Patent Court

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This Unified Patent Court (UPC) chapter covers common issues in patent laws and regulations – including enforcement, amendment, licensing and term extension in the UPC.

1 Patent Enforcement

1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

The UPC (or here, the Court), established by the UPC Agreement (UPCA), is a specialist patents court, at both first instance and on appeal, having exclusive jurisdiction over patent litigation and various ancillary matters, currently for 17 European Union (EU) Member States, over European patents which have not been opted out of the UPC system, European patents having unitary effect and Supplementary Protection Certificates (SPCs), the basic patent for which is such a European patent. As a consequence, since the opening of the Court on 1 June 2023, patent litigation within the scope of its jurisdiction can no longer be brought in national courts in the 17 EU Member States that are parties to the UPC – namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, and Sweden (Contracting Member States). Most other EU Member States are also able to join the UPC system, although the only one likely to do so in the near future is Ireland.

The Court is divided into a Court of First Instance and a Court of Appeal. The Court of First Instance consists of a central division (the location of which is currently split between Paris and Munich, depending on the technology in issue, but in due course will be split also with Milan), one regional division (covering Estonia, Latvia, Lithuania and Sweden), one local division in each of Austria, Belgium, Denmark, Finland, France, Italy, the Netherlands, Portugal, Slovenia, and four local divisions in Germany (located in Dusseldorf, Hamburg, Mannheim and Munich). The Court of Appeal is based in Luxembourg.

Revocation actions and actions seeking a declaration of non-infringement must be brought in the central division. Infringement actions may be brought in the local or regional division in which the actual or threatened infringement has occurred or may occur, or in which a defendant has its residence. Where a defendant is resident outside the territory covered by the Court, an infringement action may be brought in the central division, as is also the case where the actual or threatened infringement has occurred or may occur in a Contracting Member State which does not host either a local or a regional division. Where an infringement action is brought in a local or regional division, a counterclaim for revocation may be brought in the same local or regional division as that in which the infringement action has been brought, although the division may transfer the counterclaim or, with the agreement of the parties, the entire action to the central division.

1.2 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

The UPC Rules of Procedure (RoP) do not mandate mediation or arbitration, but provide for the Court, if it is of the opinion that the dispute is suitable for a settlement, to propose that the parties make use of the facilities of the Patent Mediation and Arbitration Centre established under the UPCA in order to settle or to explore a settlement of the dispute. There is nothing, however, to prevent the parties agreeing to submit to arbitration or mediation under the rules of other institutions, such as the WIPO Arbitration and Mediation Center. Although a patent may not be revoked or limited in arbitration proceedings, the result of an arbitration has effect as between the parties.

1.3 Who is permitted to represent parties to a patent dispute in court?

Parties to a patent dispute in the Court must be represented either by lawyers authorised to practise before a court of a Contracting Member State or by European Patent Attorneys who are entitled to act as professional representatives before the European Patent Office (EPO) and who have appropriate qualifications such as a European Patent Litigation Certificate.

1.4 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

Proceedings in the Court are commenced by the lodging of a Statement of claim by the claimant. The fee for commencing an infringement action or for a declaration of non-infringement consists of a fixed fee of €11,000 and an additional value-based fee where the value of the claim is over €500,000. The claimant's initial valuation is subsequently reviewed by the judge-rapporteur in the interim procedure. The value-based fee is calculated on a sliding scale going up to €325,000 where the value of the claim is more than €50 million. The fee for commencing a revocation action is a fixed fee of €20,000, and for a revocation counterclaim the same fee as the infringement action subject to a fee limit of €20,000.

There has, as yet, been no experience of how long it takes in practice to bring a case to trial in the Court, but the RoP envisage the written and the interim procedure which must precede the oral procedure (namely the trial) being completed well within a year after the proceedings are commenced, absent extensions.

1.5 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

Yes. By Rule 192 of the RoP, a party may make an application to preserve evidence either before or after commencing infringement proceedings on the merits, which procedure largely corresponds to the "*saisi*" and its equivalents as provided for by certain national European jurisdictions. Once proceedings are under way, Rule 190 provides that where a party has presented reasonably available and plausible evidence in support of its claims and has, in substantiating those claims, specified evidence which lies in the control of the other party or a third party, the Court may, on a reasoned request by the party specifying such evidence, order that other party or third party to produce such evidence. The Court may order that the evidence be disclosed to certain named persons only and be subject to appropriate terms of non-disclosure in order to protect confidential information. In addition, Rule 191 allows parties to seek an order to communicate certain types of information and Rule 199 allows parties to seek an order for inspection.

1.6 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

The proceedings before the Court of First Instance before the trial (oral procedure) consist of both a written and an interim procedure.

In the written procedure for an action for patent infringement the defendant should serve its statement of defence (and counterclaim for revocation, if applicable) within three months of the service of the Statement of claim on it, after which the judge-rapporteur, after consulting the parties, will set a date and time for any interim conference and set a date for the oral hearing. The claimant should serve its defence to the counterclaim for revocation together with any reply to the Statement of defence and any application to amend the patent, if applicable within two months of service of the statement of defence. Subsequent replies to defences and rejoinders to replies may also be served within the specific time limits set out in the RoP, but are optional.

The purpose of the interim procedure, which ought to be completed with three months of the closure of the written procedure, is for the judge-rapporteur to make all necessary preparations for the oral hearing including, where appropriate, holding an interim conference or conferences with the parties. The aims of the interim conference include, in addition to deciding the value of the action, confirming the date for the oral hearing and making orders as to its conduct: (a) identifying the main issues and determining which relevant facts are in dispute; (b) where appropriate, clarifying the position of the parties as regards those issues and facts; (c) establishing a schedule for the further progress of the proceedings; (d) exploring with the parties the possibilities to settle the dispute; and (e) where appropriate, issuing orders regarding production of further pleadings, documents, experts (including court experts), experiments, inspections, further written evidence, the matters to be the subject of oral evidence and the scope of questions to be put to the witnesses.

1.7 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

The trial (oral hearing) consists of the hearing of the parties' oral submissions and the hearing of witnesses and experts under the control of the presiding judge. The presiding judge and the judges of the panel may provide a preliminary introduction to the action and put questions to the parties, to the parties' representatives and to any witness or expert. Then, under the control of the presiding judge, the parties may put questions to the witness or expert. The presiding judge may prohibit any question which is not designed to adduce admissible evidence. Oral testimony at the oral hearing or at any separate hearing shall be limited to issues identified by the judge-rapporteur or the presiding judge as having to be decided on the basis of oral evidence. The presiding judge may, after consulting the panel, limit a party's oral submissions if the panel is sufficiently informed. The oral hearing and any separate hearing of witnesses shall be open to the public unless the Court decides to make a hearing, to the extent necessary, confidential in the interests of one or both parties or third parties or in the general interests of justice or public order.

A party may at any stage of the proceedings apply to the Court for leave to change its claim or to amend its case, including adding a counterclaim. Any such application shall explain why such change or amendment was not included in the original pleading. Unless the amendment is such as to limit a claim in an action unconditionally, leave to amend shall not be granted if the party seeking the amendment cannot satisfy the Court that the amendment in question could not have been made with reasonable diligence at an earlier stage; and that the amendment will not unreasonably hinder the other party in the conduct of its action.

1.8 How long does the trial generally last and how long is it before a judgment is made available?

The RoP provide that the presiding judge should endeavour to complete the oral hearing within one day. They also provide that the Court should endeavour to issue the decision on the merits in writing within six weeks of the oral hearing.

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

No, there is not.

1.10 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?

The RoP require that decisions and orders made by the Court be published.

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

Although the Court is not obliged to follow precedents from earlier similar cases, it is expected that it will in practice do so

unless there are very good reasons not to do so. This is expected to be especially the case with earlier decisions of the Court of Appeal, once these start to emerge. It is expected that decisions of the courts of major European national patent jurisdictions, especially as to issues of infringement, and as to validity, of the Boards of Appeal of the EPO, and particularly the Enlarged Board of Appeal, whilst not binding, will have persuasive authority.

1.12 Are there specialist judges or hearing officers, and if so, do they have a technical background?

Yes, to both. The Court comprises both legally qualified judges and technically qualified judges. All judges must have proven experience in the field of patent litigation. With the exception of the central division where two legal and one technical judge sit, the Court of First Instance sits in panels of three legally qualified judges, and, if one the parties so requests, an additional appropriately technically qualified judge. The Court of Appeal sits in a panel of five judges, of which three are legally qualified and two are technically qualified in the appropriate field.

1.13 What interest must a party have to bring (i) infringement, (ii) revocation, and (iii) declaratory proceedings?

The claimant in infringement proceedings must be the owner or co-owner of the patent, an exclusive licensee (unless the licensing agreement provides otherwise) or a non-exclusive licensee (but only where expressly permitted by the licence agreement). In the case of actions brought by licensees, the patent proprietor must be given prior notice and is entitled to join the action.

The claimant in revocation proceedings need not have any commercial or other interest.

Proceedings for a declaration of non-infringement may be brought where the patent proprietor or a licensee entitled to bring proceedings has asserted that the act is an infringement, or, if no such assertion has been made by them, if: (a) the potential claimant has applied in writing to the proprietor or licensee for a written acknowledgment to the effect of the declaration claimed, and has provided full particulars in writing of the act in question; and (b) the proprietor or licensee has refused or failed to give any such acknowledgment within one month.

1.14 If declarations are available, can they (i) address non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?

Yes, as to declarations of non-infringement. Although the RoP do not refer to "declarations of non-essentiality" to a technical standard, there would not appear to be any reason why a request for a declaration of non-essentiality could not be formulated as a request for declaration of non-infringement of products complying with that standard.

1.15 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of, but not all of, the infringing product or process?

Yes. A third party infringes a patent where, without the consent of the owner of that patent, it supplies or offers to supply, within the territory of the Contracting Member States within which that patent has effect, any person other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention when the third party knows, or should have known, that those means are suitable and intended for putting that invention into effect. There is an exception where the means are staple commercial products, except where the third party induces the person supplied to perform any infringing acts. Case law of the national courts of the Contracting Member States as to the corresponding provision in their national laws will inform the position adopted by the Court to the interpretation of terms such as "means" and "staple commercial product". It is, however, well established that knowledge of the patent, actual or constructive, is not a pre-requisite for such infringement; rather, knowledge of the intended product or process is required. It is also well established that knowledge of the intention of the ultimate user is also not required, it being sufficient that it would be obvious that some ultimate users would use the essential element so as to infringe.

1.16 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?

Yes. It is an infringement of a process claim to import any product obtained directly by means of the process claimed. The meaning of "obtained directly by means of the process" has been considered by some of the national courts of the Contracting Member States on a number of occasions when considering the corresponding provision in their national laws, and it is expected that such case law will inform the position adopted by the Court.

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

The Court has, as yet, no case law on the subject, but given Article 69 of the European Patent Convention (EPC) and the Protocol on its Interpretation and the position of the courts of Contracting Member States, such as Germany, it is expected that the scope of protection of a patent claim will extend to equivalents in the context of infringement.

1.18 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

Validity can be put in issue by means of a counterclaim for revocation, without restriction. Where the infringement proceeding has been brought in a local or regional division, the Court has the discretion either to: (a) proceed with both the action for infringement and with the counterclaim for revocation (adding a suitably technically qualified judge to the panel); (b) refer the counterclaim for revocation to the central division and suspend or proceed with the action for infringement; or (c) with the agreement of the parties, refer the case for decision to the central division. It is expected that in most cases the action for infringement and with the counterclaim for revocation will be heard together.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the "*Formstein* defence")?

The Court has, as yet, no case law on the subject, but as it is settled law in Germany (and in the UK, although not a

Contracting Member State, follows German law in this respect) it is expected that if the equivalent device would lack novelty or was obvious, then the claim scope must be confined to its normal construction.

1.20 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

The principal other grounds of invalidity are: (a) insufficiency (lack of enablement); (b) lack of industrial applicability; (c) extension of the subject matter in the specification during prosecution or opposition proceedings over and above that contained in the application as filed; and (d) extension of the scope of protection of the patent by a post-grant amendment to the claims that should not have been permitted.

1.21 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

The Court has a broad discretion to stay proceedings where the proper administration of justice so requires, but two of the specific examples set out in the RoP are: (a) where the Court is seized of an action relating to a patent which is also the subject of opposition proceedings or limitation proceedings (including subsequent appeal proceedings) before the EPO or a national authority where a decision in such proceedings may be expected to be given rapidly; and (b) where it is seized of an action relating to an SPC which is also the subject of proceedings before a national court or authority.

1.22 What other grounds of defence can be raised in addition to non-infringement or invalidity?

Article 27 of the UPCA sets out several limitations of the effects of a patent of which the Court must take into account, including acts done privately and for non-commercial purposes, acts done for experimental purposes relating to the subject-matter of the patented invention and clinical trials directed to secure a generic marketing authorisation for a medicinal product. Most of these correspond to equivalent provisions under national laws of EU Member States, but their precise scope may in some cases differ – for example, some are not restricted to trials directed to securing a marketing authorisation for a generic medicinal product, but extend to trials directed to securing a marketing authorisation for any type of medicinal product. One such limitation that is not found in such national laws relates to the acts and use of the obtained information as allowed under Articles 5 and 6 of Directive 2009/24/EC on the legal protection of computer programs, in particular, by its provisions on decompilation and interoperability.

Other possible defences include exhaustion, licence and the right based on prior use of the invention, although this latter defence is restricted to the Contracting Member State in which the defendant would have had such a right in respect of a national patent if one had been granted in respect of the same invention.

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) Is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

Preliminary injunctions (provisional measures) are available. The Court may require the applicant to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that the applicant is entitled to commence proceedings, that the patent in question is valid and that it is being infringed, or that such infringement is imminent. The Court shall in the exercise of its discretion, weigh up the interests of the parties and, in particular, take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction, and shall have regard to any unreasonable delay in seeking provisional measures. The Court may order the applicant to provide adequate security for appropriate compensation for any injury likely to be caused to the defendant which the applicant may be liable to bear in the event that the Court subsequently revokes the order for provisional measures.

Preliminary injunctions may be granted on an *ex parte* basis, but the applicant must give reasons for not hearing the defendant and provide information about any prior correspondence between the parties concerning the alleged infringement. Protective letters, which provide a degree of protection against the grant of an *ex parte* injunction, may be filed with Court and are effective for six months.

Where a patent has been held to be valid and infringed, the Court may grant a final injunction aimed at prohibiting the continuation of the infringement. It may also grant such injunction against an intermediary whose services are being used by a third party to infringe a patent. The Court will apply Article 3(2) of the Enforcement Directive 2004/48/EC, in determining whether to grant such an injunction. This requires that the Court only refuse to grant a final injunction where it would be "disproportionate" to grant one, the practical consequence of which is likely to be that the Court will almost never refuse to grant one.

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive/flagrancy damages available?

The amount payable by a losing defendant to an action for patent infringement is assessed by the Court in the procedure for the award of damages, although it may also make an interim award of damages as part of the order made at the conclusion of the oral procedure. This assessment may take place after, and separately from, the trial on liability, and it is envisaged that this will generally be the case. The successful claimant must lodge its application for the determination of damages, which may include a request for an order to lay open books, no later than one year from service of the final decision on the merits (including any final decision on appeal) on both infringement and validity. Where the value of the action exceeds €500,000 a value-based fee is payable in addition to the fixed fee of €3,000. A request for an order to lay open books must include a description of the information held by the unsuccessful party to which the applicant requests access, in particular documents relating to turnover and profits generated by the infringing products or regarding the extent of use of the infringing process as well as accounts and bank documents, and any related document concerning the infringement, as well as the reasons why the applicant needs access to this information.

There is, as yet, no case law as to the approach that the Court will adopt to assessing damages or an account of profits (which is also treated as a measure of damage), so the only guidance as to this is provided by Article 68 of the UPCA. This corresponds to Article 13 of of the Enforcement Directive 2004/48/EC, so the Court of Justice of the European Union (CJEU) interpretations of this will bind the Court. Article 68 provides that:

1. The Court shall, at the request of the injured party, order the infringer who knowingly, or with reasonable grounds to know, engaged in a patent infringing activity, to pay the injured party damages appropriate to the harm actually suffered by that party as a result of the infringement.
2. The injured party shall, to the extent possible, be placed in the position it would have been in if no infringement had taken place. The infringer shall not benefit from the infringement. However, damages shall not be punitive.
3. When the Court sets the damages:
   a. it shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the injured party by the infringement; or
   b. as an alternative to point (a), it may, in appropriate cases, set the damages as a lump sum on the basis of elements such as at least the amount of the royalties or fees which would have been due if the infringer had requested authorisation to use the patent in question.
4. Where the infringer did not knowingly, or with reasonable grounds to know, engage in the infringing activity, the Court may order the recovery of profits or the payment of compensation.

1.25 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

Decisions and orders of the Court are directly enforceable from their date of service in each Contracting Member State. Enforcement takes place in accordance with the enforcement procedures and conditions governed by the law of the particular Contracting Member State where enforcement takes place.

Such decisions and orders may provide for periodic penalty payments payable to the Court in the event that a party fails to comply with the terms of the order or an earlier order. If it is alleged that a party has failed to comply with the terms of the order of the Court, the first instance panel of the division in question may decide on penalty payments provided for in the order upon the request of the other party or of its own motion.

1.26 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

In addition to a permanent injunction, damages and legal costs the Court may also order corrective measures to be undertaken at the expense of the infringer, including: (a) a declaration of infringement; (b) recalling the products from the channels of commerce; (c) depriving the product of its infringing property; (d) definitively removing the products from the channels of commerce; or (e) the destruction of the products and/or of the materials and implements concerned.

Article 71b of Regulation (EU) No 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (introduced by Regulation (EU) No 542/2014) confers jurisdiction on the Court, in a dispute relating to an infringement of a European patent giving rise to damage within the EU, and where the defendant is not domiciled in an EU Member State, in relation to damage arising outside the EU from such an infringement, where property belonging to the defendant is located in any Contracting Member State and the dispute has a sufficient connection with any such Member State.

Application may also be made under Article 71b to the Court for provisional, including protective, measures even if the courts of a third State have jurisdiction over it.

1.27 How common is settlement of infringement proceedings prior to trial?

The Court is too recently established as yet to allow an answer to this question.

1.28 After what period is a claim for patent infringement time-barred?

By Article 72 of the UPCA, actions relating to all forms of financial compensation may not be brought more than five years after the date on which the applicant became aware, or had reasonable grounds to become aware, of the last fact justifying the action.

1.29 Is there a right of appeal from a first instance judgment, and if so, is it a right to contest all aspects of the judgment?

An appeal by a party adversely affected may be brought as of right against final decisions of the Court of First Instance or decisions terminating proceedings as regards one of the parties. Such appeals must be filed within two months of service of the decision appealed against, with the grounds of appeal filed within a further two months. Most other appeals require the leave of the Court of First Instance or in the event of its refusal the Court of Appeal. The fee payable is the same as that for proceedings instituted in the Court of First Instance and thus includes a value-based fee.

1.30 What effect does an appeal have on the award of: (i) an injunction; (ii) an enquiry as to damages or an account of profits; or (iii) an order that a patent be revoked?

An appeal does not have automatic suspensive effect unless against a decision on an action or a counterclaim for revocation or on a review of an administrative decision of the EPO relating to the European patent with unitary effect.

An application for suspensive effect must be made to the Court of Appeal, setting out the reasons why lodging the appeal should have such effect and the facts, evidence and arguments relied on.

1.31 Is an appeal by way of a review or a rehearing? Can new evidence be adduced on appeal?

The requests, facts, evidence and arguments submitted by the parties before the Court of First Instance constitute the subject-matter of the proceedings before the Court of Appeal.

Requests, facts and evidence which have not been submitted by a party during proceedings before the Court of First Instance may be disregarded by the Court of Appeal. When exercising its discretion to take account of such new material, the Court of Appeal shall in particular take into account: (a) whether a party seeking to lodge new submissions is able to justify that the new submissions could not reasonably have been made during proceedings before the Court of First Instance; (b) the relevance of the new submissions for the decision on the appeal; and (c) the position of the other party regarding the lodging of the new submissions.

1.32 How long does it usually take for an appeal to be heard?

There is, as yet, no experience as to the time taken for an appeal to be heard by the Court; however, the RoP envisage the stages of the appeal procedure being completed no more than 11 months after service of the decision appealed against, absent extensions.

1.33 How many levels of appeal are there? Is there a right to a second level of appeal? How often in practice is there a second level of appeal in patent cases?

There is one level of appeal from the Court of First Instance to the Court of Appeal, although the Court can refer questions of interpretation of European Union law to the CJEU, whose decisions are binding on the Court.

1.34 What are the typical costs of proceedings to a first instance judgment on: (i) infringement; and (ii) validity? How much of such costs are recoverable from the losing party? What are the typical costs of an appeal and are they recoverable?

There is, as yet, no experience of the level of costs incurred when litigating in the Court. However, because the general rule applicable to the Court is that the unsuccessful party bears the successful party's costs, guidance has been provided by way of a ceiling on recoverable costs. This is on a sliding scale running from up to €38,000 where the claim is valued at up to and including €250,000 to up to €2 million where the claim is valued at more than €50 million.

1.35 For jurisdictions within the European Union: What is the status in your jurisdiction on ratifying the Unified Patent Court Agreement and preparing for the unitary patent package? For jurisdictions outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

By virtue of Regulation (EU) No 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters as amended by Regulation (EU) No 542/2014, the Court is treated in the same way as the national courts of EU Member States and so its judgments may be enforced as of right throughout the EU. Although no corresponding amendments have been made to the Lugano Convention, it is likely that the Court would be similarly treated under this with the result that its judgments may be enforced as of right elsewhere in the rest of the European Economic Area (namely Iceland, Liechtenstein and Norway) and Switzerland.

2 Patent Amendment

2.1 Can a patent be amended ex parte after grant, and if so, how?

Yes, in *inter partes* revocation proceedings in the Court, as discussed in the answer to question 2.2 below. A European patent with unitary effect may also be amended after grant in the same way as any other European patent in the context of opposition proceedings in the EPO.

2.2 Can a patent be amended in *inter partes* revocation/invalidity proceedings?

Yes. The patentee may when filing its defence to the claim or counterclaim for revocation include an application to amend the patent which shall contain: (a) the proposed amendments of the claims of the patent concerned and/or specification, including where applicable and appropriate one or more alternative sets of claims (auxiliary requests); (b) an explanation as to why the amendments satisfy the requirements of Articles 84 and 123(2), (3) of the EPC and why the proposed amended claims are valid and, if applicable, why they are infringed; and (c) an indication whether the proposals are conditional or unconditional; the proposed amendments, if conditional, must be reasonable in number in the circumstances of the case. Any subsequent request to amend the patent may only be admitted into the proceedings with the permission of the Court.

2.3 Are there any constraints upon the amendments that may be made?

The constraints that apply to amendment in proceedings before the Court are the same as those that apply under the EPC; namely, that an amendment will not be permitted if it would: (a) extend the subject matter over and above that contained in the application for the patent; (b) extend the scope of protection; or (c) if it would not cure the ground of invalidity (if the amendment is made to cure potential invalidity). The amended claim must also be supported by the specification in the same way as during prosecution.

3 Licensing

3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

Yes. EU competition law prohibits agreements which may affect trade between EU Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, unless they contribute, *inter alia*, to promoting technical or economic progress, whilst allowing consumers a fair share of the resulting benefit. Thus, terms such as price fixing, limitations on output, allocation of customers, and restrictions upon the use of the licensee's own technology are potential violations of competition law. However, recognising the generally beneficial nature of most patent licences, Commission Regulation (EU) No 316/2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements provides a safe harbour for patent licences falling within its terms.

Although a European patent with unitary effect may only be transferred in respect of all the Contracting Member States, it may be licensed in respect of the whole or part of the territories of the Contracting Member States.

3.2 Can a patent be the subject of a compulsory licence, and if so, how are the terms settled and how common is this type of licence?

National laws in EU Member States provide for patents to be the subject of compulsory licences in certain limited circumstances, but these are rarely sought and even more rarely granted. The Court has no jurisdiction to settle the terms of such licences, but any such a licence would provide a defence to an infringement action in the Court as to the Contracting Member State in which it has effect.

There is, as yet, no compulsory licensing mechanism on an EU-wide basis, although the European Commission has proposed legislation which would establish one.

4 Patent Term Extension

4.1 Can the term of a patent be extended, and if so, (i) on what grounds, and (ii) for how long?

No, but a form of "extension" is available in EU Member States in respect of patents that cover an authorised medicinal or plant protection product, called an SPC. The intent of the EU SPC Regulations is to reward investment in securing the authorisation of a medicinal or plant protection product, and SPCs are obtained in each EU Member State by filing an application with the relevant Patent Office within six months of the grant of the first marketing authorisation for the product in that country or the grant of a "basic" patent where this takes place after the grant of the first marketing authorisation. The scope of protection of an SPC is limited to the product that has been authorised, and it takes effect upon expiry of the "basic" patent covering the product for a maximum term of five years or 15 years from the authorisation for the product, whichever is earlier.

The Court has jurisdiction over SPCs, and as SPCs are a creation of EU law, the Court is bound by the substantial body of existing EU law on SPCs and can make its own references to the CJEU for interpretation of the SPC legislation.

There is, as yet, no unitary SPC corresponding to the European patent with unitary effect, although the European Commission has proposed legislation which would establish a unitary SPC.

5 Patent Prosecution and Opposition

5.1 Are all types of subject matter patentable, and if not, what types are excluded?

Although the Court is not concerned with the prosecution of European patents, it has jurisdiction over the validity of European patents which have not been opted out of the UPC system and European patents having unitary effect, as to which its main source of law is the EPC, which defines patentable subject matter and exclusions. The EPC, consistent with the WTO TRIPS Agreement, allows patents for all forms of technology. However, methods of performing a mental act, playing a game or doing business, and computer programs, all "as such", are excluded, as are inventions of which the commercial exploitation would be contrary to public policy or morality.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

This is not applicable as the Court is not concerned with the prosecution of European patents other than in the limited area of reviewing administrative decisions of the EPO relating to the European patent with unitary effect.

5.3 May the grant of a patent by the Patent Office be opposed by a third party, and if so, when can this be done?

The grant of a European patent, including a European patent with unitary effect, may be opposed at the EPO within nine months of grant.

5.4 Is there a right of appeal from a decision of the Patent Office, and if so, to whom?

In respect of appeals from the EPO, the Court only has jurisdiction over the limited area of reviewing administrative decisions relating to the European patent with unitary effect.

5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

The Court has no competence as to entitlement to priority and ownership of the invention for European patents as these are issues of national law.

As to the national law that applies to the European patent with unitary effect, this as an object of property is treated as a national patent of the Contracting Member State in which the patent has unitary effect and in which, according to the European Patent Register maintained by the EPO: (a) the applicant had its residence or principal place of business on the date of filing of the application for the European patent; or (b) where point (a) does not apply, the applicant had a place of business on such date of filing. Where two or more persons have been entered in the European Patent Register as joint applicants, these rules are applied in the order in which the applicants are listed. Where no applicant has its residence, principal place of business or place of business in a Contracting Member State in which that patent has unitary effect, the European patent with unitary effect as an object of property is treated as a German national patent, because the EPO has its headquarters in Germany.

5.6 Is there a "grace period" in your jurisdiction, and if so, how long is it?

Yes, to a limited extent. Under the EPC a disclosure of the invention shall not be treated as forming part of the state of the art if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of: (a) an evident abuse in relation to the applicant or its legal predecessor; or (b) the fact that the applicant or its legal predecessor has displayed the invention at a designated "international exhibition". In the latter case, the applicant must, to benefit from the "grace period", file a statement and evidence relating to the disclosure at the international exhibition.

5.7 What is the term of a patent?

The term of a European patent, including a European patent with unitary effect, is 20 years from filing.

5.8 Is double patenting allowed?

Article 139(3) of the EPC allows the EPC Contracting States to prescribe whether and on what terms an invention disclosed in both a European patent and a national patent having the same date of filing or priority may be protected simultaneously by both applications or patents. The approach adopted by EPC Contracting States varies. Most make no express distinction in this respect between European patents with unitary effect and other European patents, although it has been suggested that the definition of a European patent in certain national laws may be such that such a distinction exists. France and Germany make express distinctions between those traditional European patents that are the subject of an opt-out and those that are not. The Enlarged Board of Appeal in Decision G 0004/19 (Double patenting) of 22 June 2021 held that the ban on double patenting also applied as between European patents and applications, despite the EPC being silent as to this, and there would not appear to be any basis for distinguishing between European patents with unitary effect and traditional "bundle" European patents in this respect.

5.9 For jurisdictions within the European Union: Once the Unified Patent Court Agreement enters into force, will a Unitary Patent, on grant, take effect in your jurisdiction?

This is not applicable to the UPC.

6 Border Control Measures

6.1 Is there any mechanism for seizing or preventing the importation of infringing products, and if so, how quickly are such measures resolved?

Yes. Regulation (EU) No 608/2013 provides a mechanism for seizing or preventing the import into the EU of products which infringe, *inter alia*, patents. An application can be filed with the competent customs department on the appropriate form before the expected date of importation, with sufficient identification of the goods and the intellectual property right in issue and with an undertaking to pay all the liabilities and costs of the seizure. The alternative envisaged by the Regulation, where the customs authorities have seized the goods on their own initiative and notify the rights owner before it has filed the application, is unlikely where the intellectual property right in issue is a patent. Upon seizure, a notice is provided to the rights owner who must, within 10 working days, unless the owner of the goods has consented to their destruction, initiate infringement proceedings in the appropriate court, which in the case of patent infringement within its exclusive jurisdiction will be the Court, absent which the seized goods are to be released.

7 Antitrust Law and Inequitable Conduct

7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

In theory yes, although competition law defences to patent infringement proceedings have, to date, only secured any traction in national European patent infringement proceedings in the context of disputes over standard essential patents, as reviewed in the CJEU judgment of 16 July 2015 in Case C-170/13 *Huawei Technologies Co. Ltd v ZTE Corp. and ZTE Deutschland GmbH*.

7.2 What limitations are put on patent licensing due to antitrust law?

See the answer to question 3.1 above.

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts set FRAND terms (or would they do so in principle)? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

The RoP do not directly address this question but envisage the procedure for the award of damages to follow the procedures which deal with validity and infringement and to involve a separate hearing. Thus, FRAND damages, as to infringement in respect of the Contracting Member States, would be assessed separately in such procedure for the award of damages. The so-called "FRAND injunction" is a creation of English law and has not yet been adopted by any other national European jurisdiction, so it remains an open question as to the approach that the Court would take to a request to grant one.

8 Current Developments

8.1 What have been the significant developments in relation to patents in the last year?

The opening of the Court on 1 June 2023.

8.2 Are there any significant developments expected in the next year?

Although we are unlikely to see decisions from the Court on matters of substantive law before the middle of 2024, the coming year will start to see decisions of the Court on procedural matters putting flesh on the bones of the RoP. We are also likely to see Milan established as a further seat of the central division of the Court, and a referendum in Ireland on ratification of the UPCA.

8.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

It is still too early to answer this question.

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1 Patent Enforcement

1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

There are three jurisdictions within the UK, namely England and Wales, Northern Ireland, and Scotland. There are no specialist patents courts in Northern Ireland or Scotland, although there are judges, advocates and lawyers with expertise in patents in these jurisdictions. The answers in this chapter therefore address claims in England and Wales only. Patent infringement proceedings in England and Wales may be brought in the Patents Court (part of the Business and Property Courts of the High Court of Justice) or the Intellectual Property Enterprise Court (IPEC), both of which are situated in London. The IPEC is intended primarily for smaller or simpler cases – its procedural rules are intended to make it a more accessible forum for small to medium-sized enterprises than the Patents Court. In the IPEC, the total legal costs recoverable by a successful party are capped at £60,000 for the final determination of liability, and at £30,000 for enquiries as to damages or accounts of profits, and there is a limit of £500,000 on the financial remedies available. Proceedings in both the Patents Court and the IPEC are conducted before specialist patents judges. Alternatively, infringement claims may be brought in the UK Intellectual Property Office (UKIPO), but since injunctions are not available, the jurisdiction is little used.

1.2 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

Mediation or other forms of Alternative Dispute Resolution (ADR) are not compulsory but are encouraged by the courts as part of their increased involvement in case and costs management. Unreasonable refusal to mediate or engage in ADR may incur costs sanctions, but only if there is considered to be a realistic prospect of success. ADR is becoming more common either as an alternative or adjunct to court proceedings.

1.3 Who is permitted to represent parties to a patent dispute in court?

Most substantial patent litigation in the UK is conducted by a team of solicitors and barristers. Although barristers, qualified solicitor-advocates and patent attorneys certified as IP Patent Litigators may undertake advocacy in the Patents Court, in substantial cases, the oral advocacy at trial is normally conducted by barristers. In the IPEC, in addition to the rules on who can represent litigants before the Patents Court, solicitors and patent attorneys have rights of audience and can conduct the oral advocacy.

1.4 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

Proceedings are commenced in the Patents Court by filing with the court a Claim Form with brief Particulars of the Claim and, in infringement cases, Particulars of Infringement. In contrast, in the IPEC, the Particulars of Claim and Particulars of Infringement must be fuller, setting out all the facts and arguments relied upon in a concise manner. Electronic filing is mandatory; it is not possible to issue claims, applications or file documents on paper.

For infringement actions claiming damages above £10,000, or unspecified damages, the court fee is based on 5% of the value of the claim, subject to a maximum of £10,000. Therefore, if the claim is for more than £200,000, the court fee is £10,000.

Where the claim is for a non-monetary remedy, such as a revocation action or a claim for injunctive relief with no claim for damages, there is a fixed fee of £569. However, where a claim for injunctive relief includes a claim for unlimited damages, the fee is £10,000.

The aim of the Patents Court and the IPEC is to bring cases to trial within 12 months of commencement; however, few cases in the Patents Court are currently meeting this target.

1.5 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

Yes. A mandatory Disclosure Scheme in the Business and Property Courts (B&PCs), which includes the Patents Court, has been introduced (initially from 1 January 2019 as a pilot, then fully from 1 October 2022).

Initial Disclosure of key/limited documents that are relied on by the disclosing party and are necessary for other parties to understand the case they have to meet must be given with the statements of case. A search should not be required for Initial Disclosure, although one may be undertaken.

After close of statements of case, and before the Case Management Conference, the parties are required to jointly

complete a Disclosure Review Document setting out any issues for disclosure and the scope of searching to be done in relation to each issue (referred to as "Extended Disclosure" Models A to E). The Models range from an order for no disclosure in relation to a particular issue, through to the widest form of disclosure, requiring the production of documents that may lead to a train of enquiry. The court will be proactive in determining the appropriate Model and need not accept the Model proposed by the parties. The court will only order search-based disclosure (Models C, D or E) where it is appropriate to do so to fairly resolve one or more of the issues.

In *Merck Sharp & Dohme v Wyeth* [2019], the judge accepted that a wide-ranging search would be both costly and disproportionate, but in the circumstances, it was proportionate to order the patentee to search for and disclose laboratory notebooks, internal reports, e-mails, meeting minutes and presentations created, modified or received by the named inventors that provided information relating to a document pleaded in the Grounds of Invalidity.

Unless the court orders otherwise, no disclosure of the following classes of documents will be ordered: (i) documents that relate to infringement where (*in lieu*) a product or process description is provided; (ii) documents that relate to validity that came into existence more than two years before or after the earliest claimed priority date of the patent; or (iii) documents that relate to commercial success.

The Disclosure Scheme does not operate in relation to IPEC proceedings, nor to proceedings within the Shorter and Flexible Trial Schemes.

In the IPEC, a party does not have an automatic right to any disclosure. Instead, disclosure is dealt with at the Case Management Conference on an issue-by-issue basis in accordance with the IPEC's costs-benefit analysis, balancing the likely probative value of the documents against the cost or difficulty of the search.

Confidential documents that are not legally privileged must be listed and produced for inspection but may be protected by restrictions on disclosure and use by order of the court or agreement of the parties.

Pre-action disclosure is possible. For example, in one case, it was ordered in respect of a patentee's licence agreements, so as to allow a potential defendant to quantify the value of a patent infringement claim and decide whether to litigate or settle. The patentee had repeatedly relied on the fact that others had taken licences in its efforts to persuade the alleged infringer to take a licence under the patent (*Big Bus v Ticketogo* [2015]).

1.6 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

The pre-trial procedural stages in the Patents Court consist of: (i) service of the Claim Form on the defendant with Particulars of Claim and Particulars of Infringement showing which of the claims of the patent are alleged to be infringed, with at least one example of each type of alleged infringement; (ii) service of a Defence (and Counterclaim with Grounds of Invalidity, if applicable); (iii) hearing of the Case Management Conference before a judge, at which directions for the further conduct of the action are given, including deadlines for procedural steps and number of experts permitted; (iv) fixing of the trial date by the court listing office; (v) service of Notices to Admit and replies, to identify points that are not in dispute; (vi) exchange of document lists and disclosure relevant to the issues between the parties – a defendant may, *in lieu* of giving disclosure in relation to the alleged infringing product (or process), serve a product (or process) description; (vii) carrying out experiments permitted by the court to establish infringement (or invalidity); (viii) preparation and exchange of written factual and expert evidence; and (ix) provision to the court of skeleton arguments.

The pre-trial procedure in the IPEC follows the same steps, with the following differences: (i) the defendant(s) is given more time (70 days instead of 42 days) to serve a Defence if the claimant has not sent a letter identifying their claim before commencing the action; (ii) all statements of case must set out concisely all the facts and arguments that are relied upon; (iii) save in exceptional circumstances (see the answer to question 1.7), the judge will not allow the parties to supplement their statements of case; (iv) there is no disclosure of documents, unless ordered by the judge at the Case Management Conference; and (v) the extent (if any) that experiments, witness statements, experts' reports, cross-examination at trial and skeleton arguments are permitted is determined by the judge at the Case Management Conference.

Before the trial, the court is provided with: (i) the statements of case (pleadings) including the Claim Form, Particulars of Claim, Particulars of Infringement, Defence (and Counterclaim, if applicable, with Grounds of Invalidity); (ii) the patent(s); (iii) the prior art where invalidity is raised; (iv) admissions; (v) disclosure documents which the parties wish to rely upon and any product (or process) description; (vi) factual witness statements; (vii) experts' reports, which may address any experiments that have been conducted; (viii) a technical primer (if any); (ix) a guide for the judge's pre-trial reading, with a time estimate for that reading; and (x) each party's skeleton argument. The parties are responsible for the preparation of bundles of these documents for the trial judge, which are generally provided about two weeks before the trial. As noted, (v) to (x) may not apply in a case in the IPEC.

1.7 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

Before the trial in the Patents Court, the judge will usually have read the documents indicated in the reading guide; namely, the documents identified at (i), (ii) and (ix) in the answer to question 1.6, as well as designated parts of (iii), (v), (vi) and (vii). The advocate for the claimant (usually a barrister, but sometimes a solicitor-advocate) opens the trial with an address that follows and supplements the skeleton argument. The judge will ask questions for clarification throughout the trial. Increasingly, the defendant's advocate may also give an opening speech. The claimant's advocate then calls the claimant's experts and witnesses to confirm that their written evidence is, indeed, theirs, after which they are submitted to cross-examination by the defendant's advocate. Experts and witnesses may be cross-examined upon any document or issue in the case. At the conclusion of each cross-examination, the claimant's advocate may put questions to the expert or witness by way of re-examination (without leading the expert or witness to the answer). After the closing of the claimant's evidence, the same process is followed for the defendant's evidence. The defendant's advocate then addresses the judge, following and supplementing their skeleton argument as necessary in the light of the evidence given to the court. Following this, the claimant's advocate closes the trial with an address that supplements his/her skeleton argument in the light of the evidence. In the IPEC, the court may determine the claim without a trial if all parties consent. If there is a trial, the Enterprise Judge will determine the amount of time allocated to each party (and for cross-examination of any of the witnesses and experts) and set the timetable, in order that the trial not last more than two days.

An amendment of a party's case requires the consent of the adversary or, failing that, the permission of the court exercising its discretion to allow or disallow the amendment. Whichever route applies, an amendment is likely to be subject to conditions addressing matters such as (i) the costs of consequential amendments to the adversary's statement of case, (ii) the parties' costs of the case up until the time of the amendment, (iii) consequential directions for the conduct of the action, including the timing of the trial, and (iv) the costs of adjourning any hearing or the trial. In general, in the Patents Court, amendments will be permitted subject to a costs order that reflects the wasted effort caused by the late introduction of a new allegation or position. The position in the IPEC is slightly less permissive because there is a costs cap, meaning that the costs caused by the amendment will have greater significance than in the Patents Court and, similarly, the costs-benefit analysis of permitting amendments is more thorough. This means that litigants must be more circumspect about being able to amend their case in the IPEC.

1.8 How long does the trial generally last and how long is it before a judgment is made available?

On average, in the Patents Court, the trial will take three to five days, but the duration may be shorter in a very straightforward case, or longer in a complex case, where there is a need to hear evidence from several technical experts on each side. Trials in the IPEC are limited to two days. As indicated in the answer to question 1.7, in the IPEC there may be no trial at all (i.e. the case is decided upon the papers filed alone). Judgments are almost always reserved. Although it depends upon the judge and their workload, the average length of time between trial conclusion and handing down of judgment is 75 days (Source: Solomonic).

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

A case may be allocated to the Shorter Trials Scheme (STS) in which case it will be managed by docketed judges to provide greater continuity, efficiency and judicial understanding of and control over the management of the case. The trial should be fixed for a date not more than eight months after the Case Management Conference, and the maximum length of trial is four days including reading time. The trial, which will be before the same docketed judge, should therefore take place within about 10 months of the issue of proceedings, and a judgment will be handed down within six weeks thereafter. The main advantage of the STS is its speed compared to normal High Court proceedings. It is similar to the IPEC in its limitation to specific disclosure only. Costs budgets do not apply to cases in the STS, unless the parties agree otherwise, with costs instead being summarily assessed. Patent judges are keen to promote the scheme and are willing to refuse applications to transfer out where cases are deemed suitable. However, complex patent cases, likely to take longer than four days or require extensive disclosure, may be transferred out.

The parties may also agree to the case being allocated to the Flexible Trials Scheme (FTS), which allows them to adapt the trial procedure to suit their particular case. Trial procedure encompasses pre-trial procedure, witness and expert evidence, and submissions at trial. The FTS is designed to encourage parties to limit disclosure and confine oral evidence at trial to the minimum necessary, and reduce costs and time for trial, enabling earlier trial dates. A default FTS procedure is provided that applies where parties adopt the procedure, unless the parties agree or the court orders otherwise. The key aim is flexibility for the parties to agree a procedure appropriate to their case, although the court retains ultimate control over the procedure adopted.

A further alternative option is available in the Patents Court in that either party may apply for an order that the action proceed by way of a "streamlined procedure". The most appropriate time to make such an application is at the Case Management Conference.

If an action proceeds by way of the streamlined procedure, then, except as otherwise ordered:

- all factual and expert evidence is in writing;
- there is no requirement to give disclosure of documents;
- there are no experiments;
- cross-examination is only permitted on those topics where it is necessary;
- the total duration of the trial is fixed and will not normally be for more than one day; and
- the trial date is normally fixed for about six months after the Case Management Conference.

The streamlined procedure is designed to cater for technically simple cases for which the court's evidence-gathering procedures are not necessary for a satisfactory determination.

1.10 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?

Copies of reserved judgments in writing are generally supplied in confidence to the parties a few days before handing down. The judgment becomes public and may be freely disclosed when it is handed down by the court, subject to any order to preserve the confidentiality of any material contained in the judgment. Judgments with parts redacted may be issued in such circumstances. Third parties can attend hearings when judgments are handed down and/or request copies of judgments from the judges' clerks.

The Royal Courts of Justice currently provide copies of significant judgments to the British and Irish Legal Information Institute (BAILII), for publication on the http://www.bailii.org website and, since 2022, to the National Archives: Find Case Law (http://nationalarchives.gov.uk).

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

In the common law jurisdiction of England and Wales, previous decisions of higher courts are binding on lower courts unless there are reasonable grounds for distinguishing the case on its facts. Only the *ratio decidendi* or essential element of the judgment creates binding precedent, as opposed to *obiter dicta,* which do not have binding authority.

Decisions of the courts of major European and Commonwealth patent jurisdictions and of the European Patent Office (EPO), particularly the Enlarged Board of Appeal, are not binding but are of persuasive authority.

1.12 Are there specialist judges or hearing officers, and if so, do they have a technical background?

Yes to both. In the Patents Court, there are designated judges and deputy judges who have scientific backgrounds, and are

normally allocated to cases with a higher technical difficulty rating. Similarly, the judge in the IPEC has a technical background. There are also specialist patent judges in the Court of Appeal and in the Supreme Court.

1.13 What interest must a party have to bring (i) infringement, (ii) revocation, and (iii) declaratory proceedings?

(i) The claimant must be the owner or co-owner of the patent or an exclusive licensee, and, if a co-owner or exclusive licensee, the other co-owner(s) or the owner must be joined to the proceedings.
(ii) The claimant need not have any commercial or other interest.
(iii) Declaratory proceedings fall into two categories: statutory proceedings (as set out in the Patents Act 1977); and proceedings under the court's inherent jurisdiction. Under the former, any person doing or proposing to do any act may seek a declaration of non-infringement from the court. Under the latter (the court's inherent jurisdiction), there must, in general, be a real and present dispute between the parties as to the existence or extent of a legal right. Although the claimant does not need to have a present cause of action, both parties must be affected by the court's determination.

1.14 If declarations are available, can they (i) address non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?

(i) Yes, as indicated above in the answer to question 1.13. If the statutory grounds are used, the person must first provide the patent owner with full particulars of the act in question, seeking an acknowledgment that it would not infringe the patent; or if an acknowledgment is not provided, the person may bring proceedings for a declaration of non-infringement. If relying on the court's inherent discretion, an application for a declaration of non-infringement must be sufficiently well defined and serve a useful purpose.
(ii) The court has wide discretion to grant any form of declaratory relief (whether affirmative or negative) under its inherent jurisdiction. Thus, the Patents Court has been willing to grant negative declarations in favour of mobile telephone handset manufacturers that certain telecommunications patents had declared as "essential" to the implementation of certain standards are not, in fact, "essential", as purported by the patent owner (so-called declarations of non-essentiality).

The Court of Appeal in *Mexichem v Honeywell* [2020] confirmed the availability of "Arrow declarations" (named after the case of *Arrow Generics v Merck* [2007] where they were first granted in 2007). Arrow declarations are a discretionary remedy that may be used to clear the way in cases where, because the patents potentially blocking a new product or process are not yet granted, a declaration of non-infringement would not be available. Such declarations provide that the intended product or process was known or obvious at the priority date of the patent in suit. As and when the patent is granted, the Arrow declaration will operate as a defence to any future infringement action: if the product or process is known or obvious, then so also is the patent it is alleged to infringe.

1.15 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of, but not all of, the infringing product or process?

Yes. A person infringes a patent where they supply or offer to supply a person in the UK, other than a licensee, with any essential element of the claimed invention when they know, or it would be obvious to a reasonable person in the circumstances, that this was suitable for putting, and intended to put, the claimed invention into effect in the UK. Knowledge of the patent, actual or constructive, is not a pre-requisite for infringement; rather, knowledge of the intended product or process is required. Knowledge of the intention of the ultimate user is also not required, it being sufficient that it would be obvious that some ultimate users would use the essential element so as to infringe.

It is also possible to join parties that have assisted in the infringement as joint tortfeasors by pleading procurement or common design.

1.16 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?

Yes. It is an infringement of a process claim to import any product obtained directly by means of the process claimed. The meaning of "obtained directly by means of the process" has been considered by the courts on a number of occasions, and has been interpreted to mean: "the immediate product of the process"; or, where the patented process is an intermediate stage in the manufacture of some ultimate product, that product, but only if the product of the intermediate process still retains its identity.

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

Yes, in relation to infringement. Courts in the UK apply Article 69 of the European Patent Convention and the Protocol on its Interpretation by giving patent claims a normal or "purposive" interpretation. If infringement is not established on that basis then, following the Supreme Court decision in *Actavis v Eli Lilly* [2017], consideration is given to whether the product infringes because it varies from the invention in a way or ways that is or are immaterial. That question is answered by asking three further questions, namely: (i) does the variant achieve substantially the same result in substantially the same way; (ii) would the functional equivalence be obvious to the skilled person at the priority date (knowing that the answer to question 1 is "yes"); and (iii) did the patentee intend there to be strict compliance with the literal meaning of the claim?

Actavis also raised the question of whether there can be anticipation by equivalence. Although it was rejected in *Generics v Yeda Research and Development* [2017], in *Optis v Apple* [2021], Meade J allowed anticipation by equivalence to be pleaded, while noting the question will need to be considered by the Court of Appeal.

1.18 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

Invalidity can be raised as a defence and is normally also accompanied by a counterclaim for revocation, supported by grounds of invalidity.

A claim or counterclaim for revocation may be raised regardless of whether there is pending opposition. See the answer to question 1.21 for the factors weighed by the court when deciding whether or not to stay an infringement action, including any counterclaim for revocation, pending an opposition.

In the UK, validity and infringement are dealt with in the same proceedings and are not bifurcated.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the "*Formstein* defence")?

This issue has only arisen in the UK following the Supreme Court's decision in *Actavis v Eli Lilly* (see answer to question 1.17). There have, so far, been three decisions at first instance, most recently *Facebook v Voxer* [2021], where the courts have recognised *Formstein* as a possible way forward, but to date no court has actually had to confront the issue. In the Facebook case, the judge, Lord Justice Birss (a judge of the Court of Appeal) commented that, if he had had to decide the matter, he would have held that the *Formstein* approach was the right approach, so that the conclusion if the equivalent device lacked novelty or was obvious, was that the claim scope had to be confined to its normal construction.

1.20 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

The principal grounds are: (i) insufficiency (lack of enablement); (ii) lack of industrial applicability; (iii) extension of the subject matter in the specification during prosecution or opposition proceedings over and above the matter contained in the application as filed; (iv) extension of the scope of protection of the patent by a pre- or post-grant amendment to the claims that should not have been permitted; and (v) the patent was granted to someone who was not entitled to it.

1.21 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

The question of whether a stay of infringement proceedings (with or without a counterclaim for revocation) should be granted pending resolution of validity of the patent in the EPO is a matter of discretion for the court to exercise, addressing whether, on balance, a stay is in the interests of justice. Guidelines were provided by the Court of Appeal in *IPCom v HTC* [2013], which included the following points: (i) if there are no other factors, a stay of the national proceedings is the default option; (ii) the onus is on the party resisting the grant of the stay to adduce evidence as to why it should not be granted; (iii) while the typically shorter length of time that it will take for the proceedings in the national court, as compared with the EPO, to reach a conclusion is an important factor affecting the discretion, this must be considered in conjunction with the prejudice that any party will suffer from the delay; (iv) the judge is entitled to refuse a stay where the evidence is that some commercial certainty would be achieved at a considerably earlier date in the case of the UK proceedings than in the EPO; and (v) in weighing the balance, the risk of wasted costs is material, but will normally be outweighed by commercial factors concerned with early resolution.

The issue of a stay does not arise in practice as between the court and the UKIPO, since any ongoing revocation proceedings before the UKIPO will normally be transferred to the court following the commencement of an infringement action. Further, a decision in relation to a corresponding patent in another country is not binding on the UK court and so an action in relation to such a patent is not a ground for a stay.

1.22 What other grounds of defence can be raised in addition to non-infringement or invalidity?

The right to continue to do something already carried out (or where effective and serious preparations to do such act were carried out) before the priority date of the patent can be raised as a defence. Such prior use must be in public, done in good faith, in the UK, and is personal as it does not extend to granting a licence to another person to carry out the act. The main other substantive defence is that the defendant has the benefit of, or is entitled to, a licence. This may be raised in various ways, depending on the factual and legal background. Statutory grounds for a licence may be available, *inter alia*, because: (i) the patent owner has registered the availability of licences as of right; (ii) compulsory licences are available three years from grant of the patent where (a) broadly speaking, the invention or another invention "which makes a substantial contribution to the art" is not being commercially worked in the UK, or (b) the UKIPO has made a register entry against the patent that licences are available as of right as a result of a Competition Commission report to Parliament; and (iii) compulsory licences are available for service to the Crown: in each case subject to the payment of royalties that are determined by the court in default of agreement by the parties which, in turn, means that these provisions are hardly used. (In one rare case, *IPCom v Vodafone* [2021], the Court of Appeal overturned the decision at first instance, holding that the Crown use defence did not apply.)

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) Is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

(a) Preliminary (interim) injunctions are available and are granted if (i) there is a serious issue to be tried; that is to say there is an arguable case, (ii) the "balance of convenience" favours an injunction or, all things considered, is even (this involves consideration of factors such as: the irreparability of the harm to the claimant and to the defendant, respectively, if an injunction were refused or granted; the adequacy of damages and ability to estimate damages payable to the claimant and defendant, respectively, if an injunction were refused or granted; and the proximity of the trial), and (iii) the claimant gives a cross-undertaking to compensate the defendant in damages if the injunction is wrongly granted. Only in very exceptional cases is an injunction granted on an *ex parte* basis, and then only where the claimant can show that the matter is so urgent that the defendant may not be notified or where there is a real concern that the defendant may dispose of evidence. Interim injunctions are unusual in patent cases and are, in practice, restricted to pharmaceutical cases where a

defendant proposes to introduce a first generic product and where the claimant can show that there will be irreparable damage as a result of irreversible price erosion. If generic manufacturers lose the "first mover" advantage as a result of an injunction wrongly granted, a liberal assessment of damages will be made under the cross-undertaking. Three recent cases have departed from this practice and interim injunctions were refused, therefore permitting the launch of a generic (*Neurim v Mylan* [2020], *Novartis AG v Teva UK* [2022] and *Neurim v Teva* [2022]). In 2022, the Court of Appeal in *Neurim v Mylan* upheld the High Court's decision but stated that, whilst they agreed with the judge's reasoning, they "had not decided any principle of general application". In *Novartis*, Roth J also accepted that whether there will be an irreparable price spiral (supporting an injunction) is very fact specific. Similarly, in *Neurim v Teva*, Mellor J refused Neurim's injunction, noting there had been significant delay in bringing the application and that the *status quo* at the time of filing was that generic products had already been on the market for several months.

Protective letters are not available in the UK.

(b) Final injunctions are almost always granted if the claimant is successful at trial but are a matter for the court's discretion, meaning that flexibility is possible to deal with unusual situations (see (c) below). Article 3(2) of the Enforcement Directive 2004/48/EC, which requires the court to refuse to grant an injunction where it would be "disproportionate" to grant one, is also relevant. Case law confirms that where an injunction is the primary way of enforcing that right, the burden on a party seeking to show that the grant of an injunction would be disproportionate is a heavy one.

(c) The public interest, such as the impact on third parties, is a relevant consideration that might justify refusal of, or a carve-out from, an injunction, and an award of damages *in lieu*. In *Evalve v Edwards Lifesciences* [2020], the court noted that Parliament (rather than the courts) should examine conflicting public issues and draw the appropriate balance, and held that the court's jurisdiction to refuse or qualify a patent injunction on public interest grounds should be used sparingly and in limited circumstances. In the context of a potentially life-saving medical device, what was required for the public interest was sufficient objective evidence that there were patients who ought not to be treated using the patented product, but who could, in the reasonable opinion of doctors, be treated using the defendant's product. In other words, there must be objective evidence that lives would be lost or at risk if an injunction were granted. In the result, the public interest defence was rejected and the injunction granted with a limited exception to deal with a narrow set of facts.

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive/flagrancy damages available?

The quantum payable by a losing defendant is always assessed after, and separately from, the trial on liability for patent infringement in a procedure known as an "inquiry as to damages" or an "account of profits". The claimant is given disclosure by the defendant at the start of this procedure to enable it to elect whether to pursue damages or an account of profits (a claimant cannot seek both). An account of profits is very rarely chosen in a patent action, given the uncertainty of technical and commercial factors that contribute to a defendant's profits. Damages are estimated by the court at a hearing (effectively a trial) on the basis of the disclosure and expert evidence provided to it. The principles applied by the court, in simple terms, are: (i) damages are only compensatory (not punitive); (ii) the burden of proof lies on the claimant, but damages are to be assessed liberally; (iii) where the patent has been licensed, the damages are the lost royalty; (iv) it is irrelevant that the defendant could have competed lawfully; and (v) where the patent owner has exploited the patent by manufacture and sale, they can claim (a) lost profits on sales by the defendant which they would otherwise have made, (b) lost profits on their own sales, to the extent that they were forced to reduce their own price, and (c) a reasonable royalty on sales by the defendant which they would not otherwise have made.

1.25 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

Damages awards or other financial orders of the court may be enforced in two ways: through bailiffs as officers of the court seizing the assets of the non-compliant party and auctioning them off to meet the order; or by the filing of a statutory demand against a company resulting in the winding up of the company. Orders to freeze bank accounts and for sequestration of a judgment debtor's assets are also possible in appropriate cases.

Failure to comply with an order made by a court to do or refrain from doing something may result in proceedings being brought for contempt of court. The penalties for being found to be in contempt of court include a custodial sentence of up to two years and/or an unlimited fine or seizure of assets. In the case of contempt of court by a company, the court can order, in certain circumstances, the committal into custody of a director or other company officer. Given the serious nature of the penalties, contempt is assessed using the criminal standard of proof, i.e. beyond reasonable doubt, as opposed to on the balance of probabilities for civil matters.

1.26 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

The court may order (i) the delivery up or destruction of infringing goods, (ii) appropriate measures for the dissemination and publication of the judgment, at the expense of the infringer, and/or (iii) an award of costs.

In a case where validity was not in issue, the English court granted declarations of non-infringement in respect of the foreign counterparts of a UK European patent under its inherent jurisdiction. The decision was upheld by the Court of Appeal (*Actavis v Lilly* [2013]). In most cases, however, where validity is raised as a counterclaim, there can be no cross-border relief in relation to a European patent because the other countries designated have exclusive jurisdiction over patent validity.

The Supreme Court held in *Unwired Planet v Huawei* [2020] that the court can settle the terms of a Fair, Reasonable and Non-Discriminatory (FRAND) licence on a global basis where a UK patent was found to have been infringed. The determination of such a licence is part of the defence to the claim for an injunction to the UK patent, and therefore the UK court is considered to be the proper forum.

1.27 How common is settlement of infringement proceedings prior to trial?

Many patent actions settle before trial, although this is less likely to happen, for example, in the case of major pharmaceutical patent litigation, where the stakes for both parties are very high. See the answer to question 1.2 regarding mediation or other

forms of ADR aimed at settling the dispute before trial which are actively encouraged by the courts as part of their increased involvement in case and costs management.

1.28 After what period is a claim for patent infringement time-barred?

The time period is six years from when the cause of action accrued. Where there is concealment of the infringement, the six-year limitation period does not start to run until the claimant discovers the concealment or could with reasonable diligence have discovered it.

1.29 Is there a right of appeal from a first instance judgment, and if so, is it a right to contest all aspects of the judgment?

A judgment may be appealed if the trial judge or the Court of Appeal (if the trial judge refuses permission to appeal) considers that the appeal has "a real prospect of success". The prospect of success must be realistic and credible.

1.30 What effect does an appeal have on the award of: (i) an injunction; (ii) an enquiry as to damages or an account of profits; or (iii) an order that a patent be revoked?

(i) A stay of an injunction pending appeal, so as to permit the Court of Appeal to do justice whatever the outcome of the appeal, may be granted on the "balance of convenience" principle and, if an injunction is granted or maintained pending appeal, the claimant may be required to give an undertaking to compensate the defendant if the injunction is lifted by the Court of Appeal.

(ii) An appeal would not normally lead to a stay of the enquiry as to damages or account of profits, unless agreed by the parties.

(iii) An appeal on validity by an unsuccessful patentee will lead to a stay of the order for revocation pending the outcome of the appeal.

1.31 Is an appeal by way of a review or a rehearing? Can new evidence be adduced on appeal?

An appeal is by way of a review, not a rehearing. As such, the Court of Appeal is always reluctant to interfere with findings of fact by the trial judge or with value judgments such as obviousness. New evidence or material is not permitted on appeal unless it could not, with due diligence, have been found for use at the trial, and even then it is only permitted when it is likely to have a material effect on the appeal.

1.32 How long does it usually take for an appeal to be heard?

It takes between 12 and 18 months for the appeal to be heard.

1.33 How many levels of appeal are there? Is there a right to a second level of appeal? How often in practice is there a second level of appeal in patent cases?

There are two levels of appeal from the first instance decision: first to the Court of Appeal (see the answer to question 1.29); and then to the Supreme Court. There is no right to appeal to the Supreme Court; permission must be obtained from either the Court of Appeal or the Supreme Court itself. In practice, permission to appeal patent cases to the Supreme Court is rarely given.

1.34 What are the typical costs of proceedings to a first instance judgment on: (i) infringement; and (ii) validity? How much of such costs are recoverable from the losing party? What are the typical costs of an appeal and are they recoverable?

Infringement and validity are dealt with together at the same trial. The typical cost of such an action is in the region of £750,000 to £1,500,000 for the Patents Court (much lower for the IPEC) depending on such matters as the number of patents/claims in dispute, the number and nature of the invalidity attacks, and whether more than one expert is required to give evidence at the trial. In more complicated actions involving extensive disclosure of documents or experiments, the cost will be higher and, in some cases, substantially higher. The judges are increasingly proactive in the exercise of their case management powers to reduce costs. In the Patents Court, parties must prepare and exchange costs budgets (except where the value of the claim is certified to be £10 million or more). Costs budgets are designed to give the parties and the court visibility of the likely costs to be incurred by both sides and the opportunity for the court to manage them to ensure proportionality. Although the general rule is that costs follow the event, and therefore that the overall winner can expect to be awarded their costs of the action, the Patent Court adopts an issue-based approach which means that, in practice, a discount will be made for the costs of those issues on which the winner lost. A party in whose favour a costs order is made would normally expect to recover approximately 65–75% of their actual legal costs that are the subject of that order. Where costs budgets have been employed, the winning party is likely to recover at least 80–90% of those costs.

As a result of the nature of the appeal process, the costs of an appeal are normally considerably less than those at first instance. Cost recovery is dealt with in a similar way to that in the Patents Court. If a decision is successfully appealed, it will open up the decision on the costs awarded at first instance.

1.35 For jurisdictions within the European Union: What is the status in your jurisdiction on ratifying the Unified Patent Court Agreement and preparing for the unitary patent package? For jurisdictions outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

The UK ratified the Unified Patent Court Agreement (UPCA) but then withdrew its ratification in 2021 as a consequence of Brexit.

Following Brexit, as of 31 January 2020, the UK is no longer a party to the Brussels or Lugano Conventions. By virtue of the UK–EU Withdrawal Agreement, the UK continued to apply the Brussels and Lugano regimes to court proceedings instituted prior to 31 December 2020 (which was the end of the transition period). Therefore, judgments from EU Member States in these proceedings may still be enforced in the UK under the Recast Brussels Regulation (Council Regulation (EU) 1215/2012).

The UK applied to re-join the Lugano Convention in its own right in April 2020; however, this requires consent of all EU Member States and the EU itself, which has not so far been granted. As a result, there is no established mutual recognition

or enforcement system in place for proceedings commenced after 31 December 2020, although the Hague Convention may apply where there is an exclusive jurisdiction clause in favour of the English courts. Outside of any established regime, English courts may consider judgments of foreign courts persuasive in patent cases, but do not have any obligation to recognise or follow those decisions.

2 Patent Amendment

2.1 Can a patent be amended *ex parte* after grant, and if so, how?

Yes, by applying for an amendment to the UKIPO. The application is advertised by the UKIPO on its website and in its journal, and third parties may oppose the amendment (therefore, *ex parte* examination of the application is not, in fact, assured). Central amendment of the UK designation of a European patent, in accordance with the European Patent Convention, is also possible via proceedings at the EPO.

2.2 Can a patent be amended in *inter partes* revocation/invalidity proceedings?

Yes. Amendment is at the discretion of the court, and the validity of the patent as proposed to be amended will be addressed by the court before permitting it. If the patent owner fails to seek amendment before the patent is revoked at first instance, they will generally be refused permission to amend on appeal, as this is regarded as an impermissible attempt to re-litigate issues that should have been addressed at first instance.

2.3 Are there any constraints upon the amendments that may be made?

The constraints are the same as those that apply under the European Patent Convention; namely, that an amendment will not be permitted if it would extend (i) the subject matter over and above the disclosure contained in the application for the patent, (ii) the extent of protection, or (iii) if it would not cure the ground of invalidity (if the amendment is made to cure potential invalidity). The amended claim must also be supported by the specification in the same way as during prosecution.

3 Licensing

3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

Yes, UK competition law prohibits terms in a licence that are restrictive of competition in the relevant market, in the sense that the terms go beyond what the monopoly conferred by the patent accords to the owner or exclusive licensee. Thus, terms such as price fixing, limitations on output, allocation of customers, and restrictions upon the use of the licensee's own technology are potential violations of competition law. The penalties include unenforceability of the offending terms and/or fines.

Distribution and supply agreements are governed by the Competition Act 1998 Vertical Agreements Block Exemption Order 2022 (SI 2022/516), which replaces the EU block exemptions that were preserved after Brexit by the Competition (Amendment, etc.) (EU Exit) Regulations 2019 (SI 2019/93). The 2022 Order has been drafted with digital business in mind and has clarified the criteria for assessing online intermediation services.

3.2 Can a patent be the subject of a compulsory licence, and if so, how are the terms settled and how common is this type of licence?

Yes, see the answers to questions 1.22 and 1.23(c) above.

4 Patent Term Extension

4.1 Can the term of a patent be extended, and if so, (i) on what grounds, and (ii) for how long?

No, although a form of "extension" is available in EU Member States in respect of patents that cover an authorised medicinal or plant protection product called a Supplementary Protection Certificate (SPC). The intent of the EU SPC Regulation is to reward investment in approval of a medicinal or plant protection product, and SPCs are obtained in each Member State by filing an application with the relevant Patent Office within six months of the grant of the first marketing authorisation of the product in that country. The scope of protection of an SPC is limited to the product as authorised, and it takes effect upon expiry of the "basic" patent covering the product for a maximum term of five years or 15 years from the authorisation of the product, whichever is the earlier.

Following the UK's exit from the EU on 31 December 2020, UK SPCs granted before that date remain valid, and there is no change as to their term. Under the UK–EU Withdrawal Agreement, all pending SPC applications filed in the UK before 31 December 2020 were examined in the same way regardless of Brexit, and provided the same rights once granted.

From 1 January 2021, the UK's SPC regime remains largely unchanged. By virtue of the Patents (Amendment) (EU Exit) Regulations 2019, all EU SPC law was transposed into UK national law, but to make this retained EU legislation work in practice, some processes have had to change. Further amendments made by the Intellectual Property (Amendment etc) (EU Exit) Regulation 2020 also accommodated changes in procedure and territorial scope. From 1 January 2021, new SPC applications are filed by submitting an application to the UKIPO. Applicants for new SPC applications require (as before) a UK patent granted by the EPO or the UKIPO, and a marketing authorisation valid in the UK. Therefore, the application can be based on either: (i) existing European Medicines Agency (EMA) authorisations, if the product has already been authorised by the EMA before 2021 and that EMA marketing authorisation has become a UK marketing authorisation by virtue of the grandfathering introduced to ensure that authorised products remained on the UK market; or (ii) marketing authorisations granted by the UK's Medicines and Healthcare Products Regulatory Agency.

The procedural changes have been made more complex because of the Northern Ireland Protocol which provides that Northern Ireland continues to be aligned, post-Brexit, with the EU in relation to medicinal products. The previous SPC system was not designed to accommodate marketing authorisations that cover only part of the UK. As a result, new legislation has had to be introduced (Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020) to replicate, as far as possible, a regime as familiar as feasible to the previous regime whilst adjusting to the new system of marketing authorisations with a different territory scope.

The amendments made by the Patents (Amendment) (EU Exit) Regulations 2019 are written to have the same meaning as the original EU legislation, so that the existing case law of the Court of Justice of the European Union (CJEU) still applies. However, it is no longer possible for courts in the UK to make references to the CJEU for interpretation of the SPC legislation. It therefore remains to be seen whether and to what extent the courts in the UK will continue to apply new CJEU decisions regarding the interpretation of the EU SPC Regulation to the equivalent UK legislation.

SPC protection is subject to the so-called "SPC manufacturing waiver" which allows UK-based companies to manufacture a generic or biosimilar version of an SPC-protected medicine during the term in which the SPC remains in force (i) for the purpose of exporting to a market outside the UK, Isle of Man and EU, or (ii) for stockpiling during the final six months of an SPC ahead of entry into the UK market (to perform a first day entry after lapse of SPC protection).

5 Patent Prosecution and Opposition

5.1 Are all types of subject matter patentable, and if not, what types are excluded?

Yes, in accordance with its obligations under the European Patent Convention and the WTO TRIPS Agreement, the UK Patents Act allows patents for all forms of technology. However, methods of performing a mental act, playing a game or doing business, and computer programs are excluded, as are inventions of which the commercial exploitation would be contrary to public policy or morality.

The UK's exit from the EU does not affect the ability to obtain UK patent protection via the European Patent Convention and the EPO.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

No, there is no such requirement either at the UKIPO or the EPO. The EPO requires an applicant for a patent to provide the results of any official search carried out on any priority application (other than one made in Japan, the UK or the US or one for which the EPO drew up the search report), but there are no immediate legal consequences for failure to do so, save, perhaps, that an applicant in a dominant position is now under a duty to disclose such prior art, given the decision by the CJEU in Case C-457/10P (*AstraZeneca*).

5.3 May the grant of a patent by the Patent Office be opposed by a third party, and if so, when can this be done?

The only way of doing this post-grant in the UK is to seek revocation. However, the grant of a European patent that designates the UK may be opposed at the EPO within nine months of grant.

5.4 Is there a right of appeal from a decision of the Patent Office, and if so, to whom?

Yes, an appeal lies with the Patents Court.

5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

An application for a determination as to entitlement may be made before, or up to two years from, grant of a patent to the UKIPO. The UKIPO may refer the application to the Patents Court if the issues can be more properly determined there (where the rules on disclosure and evidence permit better examination of factually contested cases). Issues as to entitlement to priority are normally dealt with *ex parte* during the prosecution of the patent application, or *inter partes* in revocation proceedings.

5.6 Is there a "grace period" in your jurisdiction, and if so, how long is it?

Yes, under the European Patent Convention, and correspondingly in the UK under section 2(4) of the Patents Act 1977, there are certain limited exceptions that remove from the "state of the art" material which would otherwise form part of it. In the UK, the following, disclosed during the six months prior to filing, is so excluded: (i) matter which is disclosed due to, or disclosed in consequence of, it having been obtained unlawfully or in breach of confidence by any person, which is directly or indirectly derived from the inventor; and (ii) matter which is disclosed due to, or disclosed as a consequence of, the inventor displaying the invention at a designated "international exhibition". In the latter case, the applicant must, to benefit from the "grace period", file a statement and evidence relating to the disclosure at the international exhibition.

5.7 What is the term of a patent?

The term is 20 years from filing.

5.8 Is double patenting allowed?

No, section 18(5) of the Patents Act 1977 provides that where two or more UK national patent applications are for the same invention, and have the same priority date and the same applicant, a patent may be refused for one or more of those applications. In addition, section 73(2) of the Patents Act 1977 provides that the UKIPO may revoke a UK national patent if both a UK national patent and a European patent (designating the UK) have been granted for the same invention.

5.9 For jurisdictions within the European Union: Once the Unified Patent Court Agreement enters into force, will a Unitary Patent, on grant, take effect in your jurisdiction?

No. The UK has withdrawn its ratification of the UPCA – see question 1.35 above.

6 Border Control Measures

6.1 Is there any mechanism for seizing or preventing the importation of infringing products, and if so, how quickly are such measures resolved?

Yes. Following the UK's exit from the EU, the Customs (Enforcement of Intellectual Property Rights) (Amendment)

(EU Exit) Regulations 2019 now dictate customs measures against goods suspected of infringing IP rights, including goods that infringe a patent or an SPC. These Regulations largely mirror the EU process which governed customs seizures under Regulation (EU) No 608/2013. From 1 January 2021:

- pre-existing EU applications for action (AFAs) filed via the UK's HM Revenue & Customs will remain valid and enforceable in the UK but will cease to have effect in the 27 EU Member States;
- pre-existing EU AFAs filed in the 27 EU Member States will cease to have effect in the UK; and
- to obtain protection in the UK, the national system must be followed and an AFA must be filed online with HM Revenue & Customs.

An application to HM Revenue & Customs should be made at least 30 working days before the expected date of importation, with sufficient identification of the goods and the patented subject matter and with an undertaking to pay all the liabilities and costs of the seizure. Upon seizure, a notice is provided to the patent owner, who must apply to the court within 10 working days for an order for the further detention (or destruction) of the goods.

7 Antitrust Law and Inequitable Conduct

7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

Yes, although a competition law defence has never succeeded in a patent action.

7.2 What limitations are put on patent licensing due to antitrust law?

See the answer to question 3.1 above.

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts set FRAND terms (or would they do so in principle)? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

In the UK, technical trials dealing with validity and infringement are heard separately from proceedings relating to FRAND licensing issues. The judges have indicated in an increasing body of case law that they will look to resolve the dispute as speedily as possible.

In *Unwired Planet v Huawei* [2020], the Supreme Court held that courts in the UK can settle the terms of a FRAND licence on a global basis, where a UK or GB patent was found infringed. Since the underlying claim was for infringement of a UK patent, the court was the proper forum even if the UK constituted only a minority of the defendants' global sales. The Supreme Court agreed with Unwired Planet's arguments that companies in the mobile telephony industry did not negotiate licences on a country-by-country basis, and therefore it was commercially unrealistic to determine a licence for only a single country in determining FRAND terms. The European Telecommunications Standards Institute policy, from which the obligation for FRAND licensing derived, empowered a national court to determine the terms that were FRAND and this therefore included determination of terms on a global basis.

Further, the courts grant an injunction to restrain infringement in the UK where a defendant who had been found to infringe a standard essential patent (SEP) refuses to enter into a licence on the terms found by the court to be FRAND (a so-called FRAND injunction). This practice is being challenged in the Supreme Court by Apple following the decision of the Court of Appeal *Optis v Apple* [2022] which is expected to be heard in February 2024 (see also question 8.1 below).

8 Current Developments

8.1 What have been the significant developments in relation to patents in the last year?

How patent systems should deal with inventions devised by AI has continued to be in the spotlight over the last year. The final UK appeal in the series of cases brought by Dr Thaler in relation to the AI entity, known as DABUS (standing for a Device for the Autonomous Bootstrapping of Unified Sentience) was heard by the Supreme Court on 2 March 2023 (*Thaler v Comptroller-General of Patents, Designs and Trademarks*). The appeal to the Supreme Court was a last attempt by the claimant to argue that an AI could be the inventor of a patent after the Court of Appeal held that the Patents Act 1977 requires the inventor to be a natural person. The Court of Appeal also concluded there was no rule of law that new intangible property produced by tangible property is owned by the owner of that tangible property. Consequently, Dr Thaler would not have been entitled to apply for the patent on the basis of his ownership of DABUS. Appeals on both these issues were heard by the Supreme Court and a judgment is eagerly anticipated in the second half of 2023.

In the telecommunications area, the English courts have continued to refine the approach to SEPs and determining FRAND licence terms. In *Apple v Optis* [2022] the Court of Appeal upheld the decision of Meade J at first instance, finding that Optis as the owner of several valid SEPs, was entitled to a so-called FRAND injunction (i.e. an injunction until the implementer agrees to take a licence on FRAND terms) against Apple, unless Apple undertook to enter into a licence on such terms as the court determined to be FRAND in a subsequent trial. The court rejected Apple's argument that the implementer should be able to wait to see the terms of the court-determined FRAND licence before electing whether to take it or withdraw from the market. Similarly, the court also rejected Optis's argument that, having refused to undertake the FRAND licence, Apple had permanently lost the right to a licence on FRAND terms. In this case and also in *Interdigital v Lenovo* [2023], lengthy FRAND rate-setting trials took place in 2022. Judgments were finally delivered in both in the first half of 2023, which were initially heavily redacted. They consolidate the jurisdiction of the English courts over such determinations, leaving them as the only courts in the world prepared to do so currently. However, the rates awarded were disappointing to the patentees.

In other developments, the Court of Appeal in *Sandoz & Teva v Bristol-Myers Squibb* [2023] (*Sandoz v BMS*) has provided some guidance on plausibility and the applicability of the EPO Enlarged Board of Appeal's decision in G2/21 to English law. The case was an appeal from the High Court's decision which found that BMS's patent did not make it plausible that the claimed compound (apixaban) would have any useful activity as a factor Xa inhibitor. Upholding that decision, the Court of Appeal considered that *Warner-Lambert v Generics (UK)* [2018] provides a single plausibility standard which applies to all claims, whether to a single compound (as was the case here), a class of compounds or second medical uses. The fundamental principle

is that the claim scope must be justified by the technical contribution to the art. The court also noted that the approach of the majority in Supreme Court in *Warner-Lambert* is one of so-called '*ab initio* plausibility' – i.e. the technical contribution must be plausible based on the disclosure of the application as filled in combination with the common general knowledge, which aligns with the approach endorsed in G2/21.

8.2 Are there any significant developments expected in the next year?

Several notable cases are due to be considered by the Supreme Court in the coming year. Continuing the focus on plausibility and sufficiency, in October 2022 the Supreme Court granted leave to appeal the decision in *FibroGen Inc v Akebia Therapeutics* [2021]. The hearing date is expected to be in late 2023 or early 2024. The Court of Appeal in this case considered the validity of claims to broad families of compounds which include a mixture of structure and functional limitations. The 'reasonable prediction' approach of the Court of Appeal appears to be a deviation from the normal requirement that a patent must be enabled across the entire scope of the claim, in a reversal of the first instance decision of one of its most experienced patents judges. The Supreme Court's consideration of these issues will be closely watched.

The Supreme Court also granted leave to appeal in April 2023 from the Court of Appeal's decision in *Apple v Optis* [2022] discussed above. The hearing is expected to be in February 2024. If the Supreme Court upholds the Court of Appeal's approach, this will likely cement a more commercially certain, but patentee-friendly approach to FRAND disputes into English law. In contrast, if the Supreme Court rejects the Court of Appeal's approach, this will be welcomed by implementers, but may exacerbate the current issues with resolving FRAND disputes in an efficient and commercially practicable way.

Outside of litigation, over the past year the UKIPO has been very busy addressing the implications of the Retained EU Law (Revocation and Reform) Bill (REUL Bill). The aim of the Bill was to make it easier to amend, repeal or replace EU law retained on the UK statute book and for UK courts to depart from retained EU case law. Many government departments and agencies, including the UKIPO, have been substantially occupied with the huge task of identifying all retained EU law and assessing the impact of its potential repeal. In May 2023, the Bill was amended so that, *in lieu* of automatically revoking all retained EU law in the sunset clause, a list of retained EU law that would be revoked at the end of 2023 was added instead. The amount of legislation affected was significantly reduced and only included seven pieces of IP legislation. The REUL Bill was finally passed by Parliament and received Royal Assent on 29 June 2023. The seven pieces of IP legislation to be repealed effectively amounts to a tidying-up exercise, so the Act is unlikely to have any immediate effect on IP. Now that this process is complete, it is hoped that the UKIPO will have more resources available to progress other projects such as the next steps following the AI and IP consultation and the ongoing consultation and review of the SEP framework.

8.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The Patents Court remains extremely busy, with time to trial still regularly exceeding the Court's target of 12 months. There have also been delays in handing down judgments, with some cases waiting for over six months. This may partly be the reason for an increase in the number of interim injunctions being sought. Previously applications for interim injunctions in patent cases were relatively rare; however, the two recent, albeit unsuccessful applications for interim injunctions to prevent the sale of generic drugs in *Neurim v Teva* [2022] and *Novartis v Teva* [2022] may suggest this is a tactic which is becoming more popular.

Although the Patents Court has generally taken a broad and flexible approach to *Arrow*-type declarations (see e.g. *Philip Morris v Nicoventures* [2022], *Mexichem v Honeywell* [2020]; see also question 1.14 above), recently there have been indications of the limits of the Court's willingness to contemplate this type of declaration. In *Teva UK v Novartis AG* [2022], first the Patents Court and then the Court of Appeal refused to make an *Arrow* declaration where the patentee had de-designated the UK and the sole purpose of the declaration would be to assist foreign litigation. Whether this signals a move towards a stricter approach by the Court generally to *Arrow* declarations is yet to be seen, as is the effect of this decision on the attractiveness of de-designating the UK in order to avoid scrutiny by the English courts.

There continue to be issues relating to the embargo on disseminating information from draft judgments prior to handing down. It is common practice for the courts to provide the parties with a draft judgment for the correction of errors, subject to strict prohibitions on disclosure or taking action based on its contents. A number of decisions, e.g. *InterDigital v Lenovo (CA)* [2023] (patents) and *Match v Muzmatch* (IPEC) [2022] (trade marks and passing off) continue to emphasise the seriousness with which the court views confidentiality around draft judgments.

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1 Patent Enforcement

1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

The Federal Court of Australia (**Federal Court**) and the state and territory Supreme Courts have jurisdiction to hear patent infringement matters.

Patent infringement proceedings are typically brought in the Federal Court. This is because the Federal Court has numerous judges with extensive patent (and intellectual property) expertise who are allocated to hear these matters.

1.2 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

Parties are not required to mediate before commencing proceedings. However, the *Civil Dispute Resolution Act 2011* (Cth) requires the legal representative for the party issuing the proceeding to sign and file a genuine steps statement that sets out the steps that have been taken to try and resolve the matter before issuing proceedings.

In the course of the proceeding, the Federal Court will consider options for alternative dispute resolution, including mediation, as early as reasonably practicable and it may order the parties to mediate. Mediation is more common than arbitration, unless the dispute is governed by a contract mandating that arbitration be undertaken before or *in lieu* of Court proceedings.

1.3 Who is permitted to represent parties to a patent dispute in court?

In the Federal Court, parties in patent proceedings are represented by barristers and solicitors.

In Australia, patent attorneys are a separate profession and have a right of audience in the Australian Patent Office, but they cannot appear in Court.

Litigants can self-represent; however, a corporation must be represented by a legal practitioner unless leave of the Court is given.

1.4 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

To commence patent-related proceedings in the Federal Court, a party must file an originating application. An originating application will be accompanied by a statement of claim and a genuine steps statement in accordance with the *Federal Court Rules 2011* (Cth) (**FCRs**).

The fees to file an originating application are prescribed in Schedule 1 of the *Federal Court and Federal Circuit Court Regulation 2012*. As of 1 July 2022, the fee for filing an originating application for a corporation is AUD 4,450.

The period of time that elapses between the filing of the originating application and the final trial depends on the complexity of the proceedings – for example: whether the applicant seeks to amend the patent(s) in suit; the number of patents asserted; whether experiments need to be carried out; and how long evidence preparation takes.

Generally, parties should allow anywhere between 12 and 18 months from filing of an originating application before the final trial on infringement.

1.5 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

The FCRs provide several mechanisms for disclosure of documents both before and after the commencement of proceedings.

Before commencement

A party that reasonably believes it may have the right to obtain relief against a party but does not have sufficient information to decide whether to start a proceeding, can seek an order for "preliminary discovery" of documents that would assist it in making that decision from the other party.

After commencement

The FCRs also provide mechanisms to obtain "standard" and "non-standard" discovery of documents after the commencement of a proceeding.

Orders for discovery after commencement are not made as a matter of course and a party must only seek discovery (whether "standard" or "non-standard") if it will facilitate the just resolution of the proceeding as quickly, inexpensively and efficiently as possible.

Other mechanisms

A party to a proceeding can use a Notice to Produce, which requires the other party to the proceeding to produce any document or item within the party's control at the trial.

1.6 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

There are numerous steps a party must take in the lead-up to trial.

The Federal Court Practice Note, "Intellectual Property Practice Note (**IP-1**)", provides some examples of special steps that may be ordered to be undertaken in patent matters. For example, the Court may order that the parties file an agreed technical primer to assist in explaining the technical background of the invention claimed in the patent in suit.

The first step in any proceeding is the pleading of each party's case (a statement of claim, a defence and any cross-claim, defence to cross-claim and replies).

After the close of pleadings, evidence will be led by both parties.

Evidence relied on for both infringement and revocation will invariably include expert technical evidence.

In the immediate lead-up to the trial, a case management conference will occur before the judge. At the case management conference, the judge will set a timetable for the filing of submissions, objections to evidence, Court book preparation and other requirements the judge may have in preparing the matter for trial. This may include orders regarding a timetable for competing experts to confer prior to the trial and for expert evidence to be given concurrently at trial.

1.7 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

At the trial, the parties' arguments are made by both written and oral submissions.

As to the parties' evidence, the affidavit evidence upon which a party intends to rely will be formally "read" by the party relying on the evidence and admitted into evidence. A person that has given evidence in an affidavit form may be required for cross-examination by the other party.

In terms of seeking amendments to a pleaded case, the Court is generally receptive to applications for amendment (but it may award costs or vacate orders because of the amendment). The FCRs provide that:

- a party must seek leave from the Court to amend its originating application both before and at trial;
- a party may amend a pleading once without leave of the Court at any time before pleadings close; and
- after pleadings close (as well as during the trial), any amendment is only by leave of the Court or with the consent of the opposing party.

1.8 How long does the trial generally last and how long is it before a judgment is made available?

The length of a trial will depend on the complexity of the issues before the Court.

On average, trials concerning one patent can run from anywhere between five and 15 days.

Judgment can be anticipated six to 12 months after the end of the trial.

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

Parties can seek an expedited or truncated hearing process and a tailored or concise pleading process in any proceeding. Whether a proceeding will be expedited will depend on whether the Court is of the view that there are circumstances that make the matter appropriate to be determined expeditiously.

A party should make known its request for an expedited procedure and hearing at the time of filing an originating application. A party should otherwise make its request for an informal or abbreviated pleading process known at the first case management hearing.

The impact on overall timing will depend on the complexity of the proceeding. It is unlikely that a patent proceeding would be finalised in under three months if expedition is ordered.

1.10 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?

In Australia, judgments are available online to the public, typically within 24 hours of being handed down by the judge.

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

The doctrine of precedent is central to the Australian judicial system. Australian Courts are bound to follow the *ratio decidendi* (reasons for the decision) of superior Australian Courts and will not depart from decisions of the same Court without good reason.

Older decisions from the United Kingdom may be persuasive (Australian patent law has departed from UK patent law), but they are not binding. Decisions of European and US Courts are of interest but are less persuasive. See: *Calidad Pty Ltd v Seiko Epson Corporation* [2020] HCA 41 for an example of this consideration.

1.12 Are there specialist judges or hearing officers, and if so, do they have a technical background?

There are currently 16 judges in the Federal Court's Intellectual Property National Practice Area – Patents & Associated Statutes who can be assigned to patent cases.

There is no requirement for these judges to have a technical background, although some of them do.

1.13 What interest must a party have to bring (i) infringement, (ii) revocation, and (iii) declaratory proceedings?

- **Infringement**

  Only the patentee and the exclusive licensee can bring infringement proceedings.

  The exclusive licensee is defined in the *Patents Act 1990* (Cth) (**Patents Act**) as the licensee that has the right to exploit the patented invention throughout the patent area to the exclusion of the patentee and all other persons.

- **Revocation**
  Any person has standing to bring an application to either the Federal Court or state and territory Courts for an order revoking the patent.
  A defendant in any infringement proceedings may also cross-claim for revocation.
- **Declaratory proceedings**
  A person can apply to the Federal Court for a declaration that an act does not or would not infringe a patent, regardless of whether the patentee has made an assertion that the performance of the act would infringe a claim.
  The person cannot apply to the Federal Court for a declaration unless the patentee has refused or failed to make a written admission of non-infringement.
  The person must have given the patentee full written particulars of the act and asked the patentee in writing for a written admission that the performance of the act does not or would not infringe the patent. The person must also undertake to pay the patentee's reasonable costs of obtaining advice as to whether the act has or would infringe the claim. The patentee must be joined as a respondent in the proceeding.

1.14 If declarations are available, can they (i) address non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?

Yes. Non-infringement declarations can be sought in relation to technical standards and hypothetical activity.

1.15 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of, but not all of, the infringing product or process?

In Australia, a party can be liable for "indirect" or "contributory" infringement of a patent.

The Patents Act (section 117) provides that if the use of the product by a person would infringe a patent, then the supply of that product by one person to another is an infringement of the patent by the supplier, unless the supplier is the patentee or licensee.

1.16 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?

Yes. See: *Warner-Lambert Company LLC v Apotex Pty Limited (No 2)* [2018] FCAFC 26.

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

Australia does not have a doctrine of non-literal equivalents. It can be argued that integers are inessential and need not be present for an infringement finding, but this argument is rarely successful.

1.18 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

A respondent can assert in infringement proceedings, in response to an allegation of patent infringement, that it has not infringed the patent because the patent is invalid and should be revoked. This claim does not arise in relation to a patent application that is under opposition.

In any proceedings for infringement, the alleged infringer can counter-claim for revocation of the patent, including on the basis that the patent is not a patentable invention.

Issues of validity and infringement are usually heard in the same proceeding. However, the Court may consider issues of infringement before issues relating to validity in appropriate circumstances, or the Court may consider it appropriate to hear issues of validity and infringement concurrently.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the "*Formstein* defence")?

No, there is no such defence under the Australian regime, as there is no doctrine of equivalence.

1.20 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

In proceedings in the Federal Court, other than lack of novelty and inventive step, the validity of a patent may be challenged on the grounds that:

- the invention has been secretly used in the patent area;
- the patentee is not entitled to the patent;
- it is not a manner of manufacture;
- it is not useful;
- the patent was obtained by fraud, false suggestion or misrepresentation; and
- the specification does not comply with section 40(2) and (3) of the Patents Act, being support, "best method" and sufficiency requirements.

1.21 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

Court proceedings are the superior proceedings, so no procedure can take place in the Australian Patent Office if there are pending Court proceedings.

If two separate proceedings concerning the patent are ongoing, a party may seek to have the matters listed together; however, there is no rule that a revocation claim must be determined before parallel infringement proceedings.

1.22 What other grounds of defence can be raised in addition to non-infringement or invalidity?

Australian patent law includes these specific exemptions to infringement:

- immediately before the priority date of the claim, the person was already exploiting, or had taken definitive steps (contractually or otherwise) to exploit the product, method or process in Australia;
- use of a patented invention occurred on board or in a foreign vessel, and the vessel came into Australian territory only temporarily or accidentally;
- use of a patented invention occurred in the construction or working of a foreign aircraft or land vehicle if the aircraft or land vehicle came into Australian territory only temporarily or accidentally;

- exploitation was connected with obtaining regulatory approval in Australia; and
- an act was performed for experimental purposes relating to the subject matter of the invention.

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) Is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

Preliminary injunctions

Preliminary injunctions are available on an *ex parte* and *inter partes* basis.

In deciding whether to grant a preliminary injunction against an alleged infringer, the Court will make two enquiries:

- whether the patentee has a *prima facie* case (there is a probability that the patentee will succeed at final hearing); and
- whether the balance of convenience favours the granting of the injunction (this involves an assessment of the harm to the applicant and prejudice to the respondent in ordering the injunction, and whether damages are likely to be an adequate remedy if the applicant is successful at the final hearing).

There is no requirement for a bond. Rather, the patentee will have to give the "usual undertaking as to damages", where it undertakes to the Court to submit to any order the Court may consider to be just for the payment of compensation to any person affected by the operation of the injunction.

If the person in whose favour the preliminary injunction is granted is resident overseas and has no assets in Australia, or is otherwise unlikely to be able to satisfy a call on the undertaking as to damages, the Court may require that person to provide security for the undertaking as to damages.

Protective letters cannot be filed with the Court to protect against *ex parte* injunctions.

Final injunctions

Relief that a Court may grant for infringement of a patent includes an injunction, subject to such terms that the Court thinks fit.

Public interest defence

Australian Courts have not dealt with this issue. The final form of the injunction is a matter within the Federal Court's discretion, and it is likely that public interest can be a factor for consideration. There is *obiter dicta* in recent Federal Court cases that if infringement had been found in respect of a method of treatment patent, then an injunction against all supply of that product that would encompass non-infringing uses would not be an appropriate remedy (e.g., *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 4)* [2015] FCA 634).

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive/flagrancy damages available?

In Australia, it is typical for an order to be made that the issue of liability for infringement/validity be heard prior to and separately from the determination of any damages/account of profits.

Damages are compensatory in nature and so the assessment is by reference to the actual loss suffered by the patentee. The analysis will require the Court to determine what proportion of the infringer's sales would have been sales of the patentee or the exclusive licensee, and then determine the profit that would have been made by reason of the sales.

Additional (punitive) damages can also be awarded; however, this provision is rarely applied. The most recent example where an award was made is *Australian Mud Company Pty Ltd v Globaltech Corporation Pty Ltd* (No 3) [2022] FCA 1189.

An award of additional damages may be appropriate, having regard to:

- the flagrancy of the infringement;
- the need to deter similar infringements;
- the conduct of the infringing party, including after it was informed that it had allegedly infringed;
- any benefit accrued to the infringer because of the infringement; and
- any other relevant matters.

Profits are assessed by calculation of the profit earned by the infringer by reason of the conduct. This is a forensic accounting exercise.

1.25 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

Enforcement of a judgment or orders in the Federal Court are ordinarily an ex parte procedure that commences with the filing of a Request for Enforcement and supporting documentation. A Registrar will consider the Request for Enforcement, and if satisfied, issue the enforcement process, which is then handled by the Sheriff's office.

The methods of enforcement include:

- warrants for the seizure and sale of property;
- order for possession or delivery of goods; and
- an enforcement hearing.

An application may also be made for contempt. This is a broad power of the Court and includes the power to fine and imprison.

1.26 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

Other relief that a Court may grant for infringement of a patent includes declarations of infringement. Cross-border relief will not be ordered.

1.27 How common is settlement of infringement proceedings prior to trial?

Settlement prior to trial is common – it is estimated to occur in 50% of cases.

1.28 After what period is a claim for patent infringement time-barred?

Patent infringement proceedings cannot be brought unless started within:

(a) three years from the day on which the relevant patent is granted; or

(b) six years from the day on which the infringing act was carried out.

The deadline is whichever period ends later.

1.29 Is there a right of appeal from a first instance judgment, and if so, is it a right to contest all aspects of the judgment?

A party can appeal the judgment of a single judge of the Federal Court to the Full Federal Court of Australia. An appeal is as of right in respect of any aspects of the judgment but will only succeed if the Full Federal Court finds that the judge at first instance made an error of law.

1.30 What effect does an appeal have on the award of: (i) an injunction; (ii) an enquiry as to damages or an account of profits; or (iii) an order that a patent be revoked?

The filing of an appeal has no automatic effect on the award of: (i) an injunction; (ii) an enquiry as to damages or account of profits; or (iii) an order that a patent be revoked.

A party would have to seek a stay of any such order, pending the outcome of the appeal. Stay orders are made at the Court's discretion, and only in circumstances where the Court is satisfied that the appeal has some merit, having regard to potential prejudice that might be suffered by the parties as the result of the granting or refusal of the stay.

1.31 Is an appeal by way of a review or a rehearing? Can new evidence be adduced on appeal?

An appeal is not a rehearing. It is limited to the issues raised on appeal and is confined to written and oral submissions. The Court will not consider new evidence or any argument that was not made before the Court below except in exceptional circumstances.

1.32 How long does it usually take for an appeal to be heard?

Between four and six months.

1.33 How many levels of appeal are there? Is there a right to a second level of appeal? How often in practice is there a second level of appeal in patent cases?

An appeal from a single judge of the Federal Court is to a Full Court of the Federal Court (either three or five judges). From a decision of the Full Court, a party can seek leave to appeal to the High Court of Australia. A case will only be granted special leave if it raises a new point of law, or a matter of public importance. Less than 10% of all cases that seek leave are granted special leave to appeal to the High Court of Australia. The most recent patent case to be granted special leave to appeal to the High Court of Australia is *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents [2022] HCA 29* in relation to computer-implemented inventions.

1.34 What are the typical costs of proceedings to a first instance judgment on: (i) infringement; and (ii) validity? How much of such costs are recoverable from the losing party? What are the typical costs of an appeal and are they recoverable?

The range of expected costs in running/defending an infringement case or running/defending a combined infringement and revocation case is between AUD 800,000 and AUD 2.5 million. The successful party would anticipate recovering between 55% and 75% of its costs from the unsuccessful party.

On appeal, typical costs range from AUD 150,000 to 300,000 depending on the number of issues raised on appeal. The successful party would anticipate recovering between 60% and 75% of its costs.

1.35 For jurisdictions within the European Union: What is the status in your jurisdiction on ratifying the Unified Patent Court Agreement and preparing for the unitary patent package? For jurisdictions outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

There is no formal or informal recognition of foreign judgments specifically relating to patents in Australia. Australia is party to enforcement of foreign judgment treaties, and judgment debts of foreign Courts can be recovered in Australian Courts in prescribed circumstances.

2 Patent Amendment

2.1 Can a patent be amended *ex parte* after grant, and if so, how?

A patentee may seek the leave of the Commissioner of Patents to amend a patent after grant (section 104 of the Patents Act) or during infringement proceedings with leave of the Court – see question 2.2.

2.2 Can a patent be amended in *inter partes* revocation/invalidity proceedings?

Yes, a patentee may make an application to a Court during any relevant proceedings for an order that the patent be amended (section 105 of the Patents Act).

2.3 Are there any constraints upon the amendments that may be made?

An amendment must meet the requirements in section 102 of the Patents Act – it is not permissible if the amended specification claims or discloses matter extending beyond the complete specification as filed.

If the application to amend is made to the Court during proceedings, then the Court must also be satisfied that there is no matter that should dissuade the Court from exercising its discretion to allow the amendment (e.g., delay by the patentee in seeking amendment after knowing that it should so amend; covetous claiming).

3 Licensing

3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

A term of a patent licence may be void in certain circumstances (section 144 of the Patents Act), including where the effect of a term is to:

- prohibit or restrict the use of a product or process (whether patented or not) supplied or owned by a person other than the lessor or licensor; or
- require the acquisition of a product not protected by the patent, lessor or licensor.

3.2 Can a patent be the subject of a compulsory licence, and if so, how are the terms settled and how common is this type of licence?

After a period of three years from when the grant has elapsed, a person may apply to the Federal Court for an order requiring the patentee to grant the applicant a licence to work the patented invention (section 133 of the Patents Act). If the fee is not agreed, the Court sets the fee.

Very few compulsory licences have been ordered.

4 Patent Term Extension

4.1 Can the term of a patent be extended, and if so, (i) on what grounds, and (ii) for how long?

The term of a patent relating to a pharmaceutical substance *per se* can be extended if certain criteria are met, including if regulatory approval was not obtained until at least five years after the date of the patent.

The extension period is a maximum of five years – with the length of the extension equal to the difference between the date of the patent and the earliest first regulatory approval date, reduced by five years.

There are a series of recent important decisions regarding the extension terms provisions including: *Commissioner of Patents v Ono Pharmaceutical Co. Ltd* [2022] FCAFC 39 and *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40.

5 Patent Prosecution and Opposition

5.1 Are all types of subject matter patentable, and if not, what types are excluded?

Not all subject matter is patentable, for example:

- Human beings and processes for their biological generation are not patentable (section 18(3) of the Patents Act).
- Pure business processes are not patentable subject matter, even if they are computer-implemented: *Commissioner of Patents v RPL Central Pty Ltd* [2015] FCAFC 177; *Encompass Corporation Pty Ltd v InfoTrack Pty Ltd* [2019] FCAFC 161; *Commissioner of Patents v Rokt Pte Ltd* [2020] FCAFC 86; and *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents* [2022] HCA 29.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

There is no such duty.

5.3 May the grant of a patent by the Patent Office be opposed by a third party, and if so, when can this be done?

Yes – a third party has three months after the patent application has been advertised as accepted by the Patent Office to oppose the grant of the patent by filing a notice of opposition and a statement of grounds.

5.4 Is there a right of appeal from a decision of the Patent Office, and if so, to whom?

There is a right of appeal under the Patents Act from a decision of the Patent Office to the Federal Court from:

- a refusal to grant a patent (section 100A);
- an opposition decision (section 60);
- a decision to revoke after re-examination (section 101); and
- a refusal or grant of, or direction to make, an amendment (sections 104 and 109).

5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

Disputes over ownership can be resolved in the Patent Office (section 32 of the Patents Act), or by the grant of the patent after an opposition in the Patent Office (section 33 of the Patents Act) or by application to the Court.

5.6 Is there a "grace period" in your jurisdiction, and if so, how long is it?

Yes – there is a grace period of 12 months.

5.7 What is the term of a patent?

A standard patent has a maximum term of 20 years (or up to 25 years for pharmaceutical substances per se that have an extension of term). An innovation patent has a term of up to eight years (innovation patents are in the process of being phased out, and ceased being available for new filings after 25 August 2021).

5.8 Is double patenting allowed?

No, it is not (section 64(2) of the Patents Act for standard patents and section 101B(2)(h) for innovation patents).

5.9 For jurisdictions within the European Union: Once the Unified Patent Court Agreement enters into force, will a Unitary Patent, on grant, take effect in your jurisdiction?

This is not applicable to Australia.

6 Border Control Measures

6.1 Is there any mechanism for seizing or preventing the importation of infringing products, and if so, how quickly are such measures resolved?

There is no mechanism available.

7 Antitrust Law and Inequitable Conduct

7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

Yes – the *Competition & Consumer Act 2010* (Cth) (CCA) can be deployed against a patentee. This was argued in *Apple v Samsung*; however, whilst the case proceeded to a concluded trial, the case settled before judgment.

7.2 What limitations are put on patent licensing due to antitrust law?

The licensing, assignment and other contractual arrangements in relation to IP rights are the subject of the same competition laws as other commercial transactions.

The following are examples of the type of conduct prohibited under the CCA that may arise in relation to patent licensing:

(a) cartel conduct;
(b) the making or giving effect to agreements, arrangements or understandings that have the purpose, effect or likely effect of substantially lessening competition in a market; and
(c) engaging in the practice of exclusive dealing.

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts set FRAND terms (or would they do so in principle)? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

There is potential for patent validity and infringement matters to be heard separately in all proceedings relating to FRAND licences. However, the case of *Apple v Samsung*, which ran over a large number of Court hearing days, did not separate the issues.

There are no injunction decisions or any delivered judgments on Standard Essential Patents (**SEPs**) in Australia or FRAND terms; however, in principle, there is no reason why the Australian Courts would not grant a FRAND injunction or set FRAND terms. It is expected that the *Unwired Planet* decision will be influential on Australian Courts.

In the long-running case of *Motorola Solutions Inc v Hytera Communications Corporation Ltd & Anor*, Hytera argued that compliance with the European Telecommunications Standards Institute meant inevitable infringement; the Judge rejected that argument and no infringement was found. There remains no jurisprudence on FRAND terms in Australia.

8 Current Developments

8.1 What have been the significant developments in relation to patents in the last year?

- The Full Court of Australia has provided much needed clarification regarding the Australian Patent Term Extension Regime, finding that the first product registered on the Australian Register of Therapeutic Goods (even if it is a third-party product) is the relevant product for the purposes of the regime: *Commissioner of Patents v Ono Pharmaceutical Co. Ltd* [2022] FCAFC 39 and *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40.
- Artificial Intelligence cannot be an "inventor" for the purposes of the Australian Patent Regime: *Commissioner of Patents v Thaler* [2022] FCAFC 62. The High Court of Australia has refused an application for special leave to appeal to the High Court of Australia (Australia's highest Court).
- In Australia, in addition to direct infringement, if the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement by the supplier in particular circumstances – including use of the product in accordance with instructions for use or other inducement to use the product. In *Hood v Down Under Enterprises Pty Ltd* [2022] FCAFC 69, the Full Court of Australia confirmed that at least insofar as use in accordance with instructions, that only supplies in Australia are captured.
- The High Court of Australia handed down a split decision (3:3 judges) pertaining to the patentability of computer-implemented inventions – in this case, directed at a system and method for a feature game on an electronic gaming machine. The decision sees the uncertainty around the requirements for computer-implemented inventions in Australia continue: *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents* [2022] HCA 29.
- A single judge of the Federal Court of Australia has considered a claim by a patentee for an account of profits for patent infringement, and the extent to which profits should be apportioned where the invention was a component of the infringing product – in this case, the trigger feature of an electronic gaming machine. The Court considered an apportionment was appropriate in the circumstances of the case: *Aristocrat Technologies Australia Pty Limited v Konami Australia Pty Limited (No 3)* [2022] FCA 1373.
- While we have seen cases where multiple expert witnesses give evidence on the same issues in patent infringement matters, the Full Court of Australia has upheld a decision disallowing multiple witnesses giving duplicative evidence as a matter of modern case management: *Novartis AG v Pharmacor Pty Ltd* [2022] FCAFC 58.

8.2 Are there any significant developments expected in the next year?

- A single judge of the Federal Court of Australia has made a rare award of additional damages in a patent infringement proceeding, and also a finding of joint tortfeasorship. This is on appeal to the Full Federal Court, where we expect significant commentary on the circumstances warranting an award of additional damages and joint tortfeasors as between entities that sit within a global group of companies. The decision at first instance is *Australian Mud Company Pty Ltd v Globaltech Corporation Pty Ltd (No 3)* [2022] FCA 1189.
- A single judge of the Federal Court of Australia has been asked to determine whether the patentee can make a split election – i.e. an election of damages in relation to certain infringing acts, and an account of profits, in respect of others. This case will determine if the principles in *Aristocrat Technologies Australia Pty Limited v Konami Australia Pty Limited (No 3)* can be generally applied. We anticipate a decision by December 2023.

8.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There is a lower appetite to seeking and obtaining preliminary injunctions in pharmaceutical patent cases as the Courts have refused injunctions in circumstances where a patentee would have previously expected to achieve an injunction – this is an ongoing artefact of the difficulty in establishing the entitlement and quantum of compensation payable under the usual undertaking as to damages (see *Sigma v Wyeth* [2018] FCR 1556). See e.g. *Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591.

There are also signs that blanket final injunctions for patent infringement where contributory infringement in respect of method patents is found, but where there are many other non-infringing uses, may no longer be ordered *c.f. Generic Health Pty Ltd v Otsuka Pharmaceutical Co., Ltd* [2013] FCAFC 17.

The Australian Competition & Consumer Commission has taken an active interest in settlement in pharmaceutical patent disputes – after parties to such a settlement sought authorisation and the ACCC issued a Draft Determination (March 2022) refusing authorisation (Application for Authorisation AA 1000592). In the draft determination, the ACCC expressed its view that the early entry settlement was akin to a "pay for delay" case and anti-competitive, public benefit insufficient to warrant authorisation. The application was withdrawn after the draft determination.

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