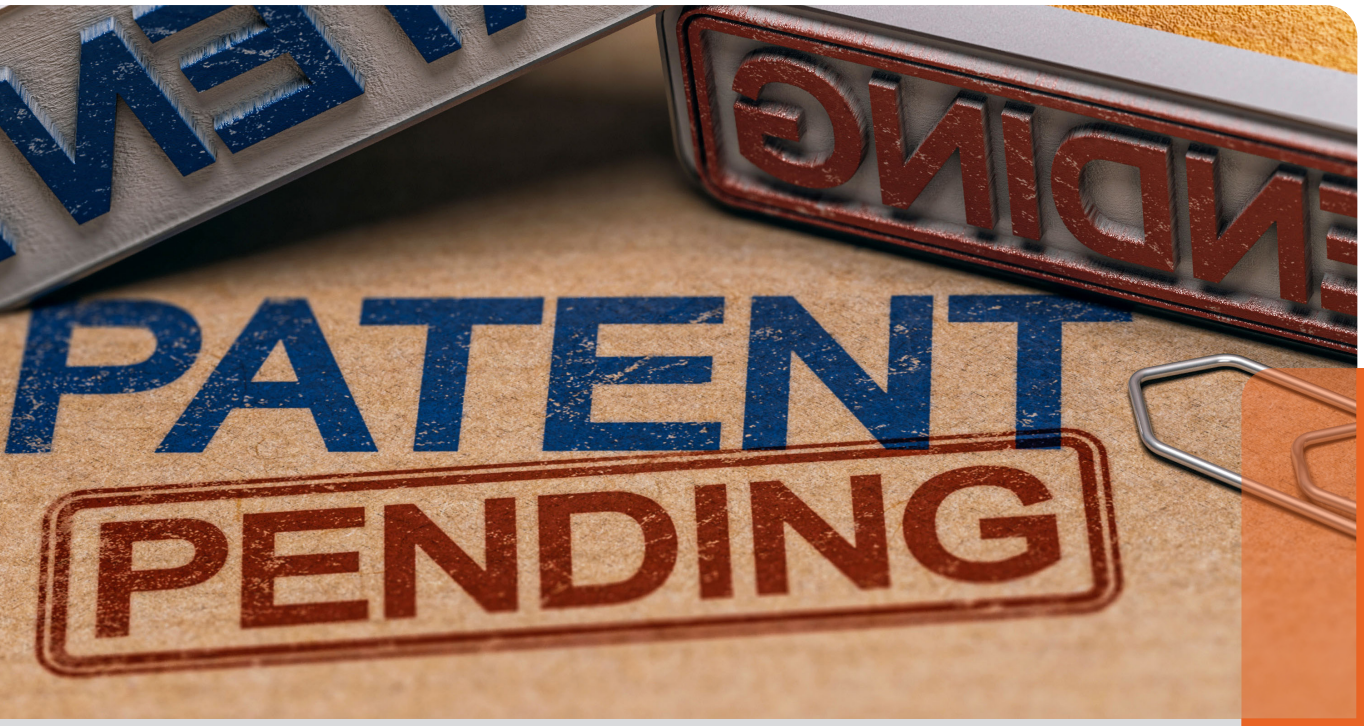
International
Comparative
Legal Guides



Patents

2024

14th Edition

Contributing Editor:
Katharine Stephens
Bird & Bird LLP

glg Global Legal Group

Expert Analysis Chapters

1 **Recent Developments in SEP Litigation and FRAND Determination**
Katharine Stephens & Juliet Hibbert, Bird & Bird LLP

8 **Unified Patent Court**
Trevor Cook, Bird & Bird LLP

17 **Product Prior Art and IPR Estoppel**
Kenneth R. Adamo & Eugene Goryunov, Law Office of KRAdamo & Haynes and Boone

20 **Watching Out For Lurking Hazards When Drafting Patent Applications; Using Generative Artificial Intelligence as a Tool**
Dunstan H. Barnes, Wil Rao & Andrew W. Mills, McAndrews, Held & Malloy

Q&A Chapters

26 **Australia**
Bird & Bird LLP: Jane Owen & Rebecca Currey

35 **Austria**
GRAF ISOLA Rechtsanwälte GmbH: Claudia Csáky
REDL Life Science Patent Attorneys: Gerda Redl

43 **Belgium**
Stibbe: Philippe Campolini, Louis Bidaine & Clémence Jonckheere

50 **Canada**
CPST Intellectual Property Inc.: Anthony Prenol, Antonio (Tony) Turco, Brett Slaney & Junyi Chen

59 **Chile**
COOPER & CIA: Rodrigo Cooper

65 **Germany**
Gleiss Lutz: Dr. Matthias Sonntag & Dr. Herwig Lux

73 **Ghana**
Minkah-Premo and Co: Renee Panarkuor Kusah Owusu Ansah, Eunas Kofi Eshun, Eric Vidzah & Edufuah Larbi

81 **India**
LexOrbis: Manisha Singh & Rajeev Kumar

91 **Ireland**
A&L Goodbody LLP: John Whelan, Sinéad Mitchell King & Sarah Douglas

100 **Israel**
Gilat, Bareket & Co., Reinhold Cohn Group: Adv. Eran Bareket & Adv. Jackob (Koby) Kasulin

110 **Japan**
Nagashima Ohno & Tsunematsu: Kenji Tosaki

118 **Korea**
Lee International IP & Law: Yoon Suk Shin, Dong-Hwan Kim, Gon-Uk Huh & Kyu-Bok Lim

129 **Kosovo**
IPLegals: Kujtesa Nezaj-Shehu

136 **Mexico**
OLIVARES: Sergio L. Olivares, Daniel Sánchez & Rommy Morales

146 **Norway**
ACAPO AS: Stein Roar Gjoen & Helen Christie

152 **Philippines**
SyCip Salazar Hernandez & Gatmaitan: Vida M. Panganiban-Alindogan

160 **Poland**
JWP Patent & Trademarks Attorneys: Dorota Rzążewska, Małgorzata Furmańska, Tomasz Grucelski & Tomasz Gawliczek

168 **Spain**
Elzaburu: Colm Ahern

175 **Taiwan**
TIPLO Attorneys-at-Law: J. K. Lin & H. G. Chen

185 **Turkey/Türkiye**
BRANDIT: Yasemin Aktaş

194 **Ukraine**
ADVANCE PARTNERS: Oleg Zhukhevych & Elena Biloshuk

203 **United Arab Emirates**
Primecase Hamad Alrahma Advocates & Legal Consultants: Mohammad AlShraideh, Dr. Mohammed Zaidan & Salem Rawabdeh

211 **United Kingdom**
Bird & Bird LLP: Katharine Stephens & Patrick Brown

223 **USA**
Mintz: Michael T. Renaud & Matthew A. Karambelas

231 **Zambia**
Dentons Eric Silwamba, Jalasi and Linyama Legal Practitioners: Joseph A. Jalasi, Jonathan Chileshe & Ntasi Silwamba

Ireland


John Whelan


Sinéad Mitchell King


Sarah Douglas

A&L Goodbody LLP

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?

In Ireland, patents are governed by the Patents Act 1992, as amended (the Irish Patents Act). The Patents Rules 1992, as amended, prescribe related procedural rules. Ireland has no specialist patent court, but patent proceedings are generally heard in the Intellectual Property and Technology List, which is a subdivision of the Commercial List, that came into operation in late 2021. This List is dedicated to intellectual property disputes or cases that are technologically complex. Cases heard in the Commercial List are subject to a case management system which ensures that they progress in an as efficient and cost-effective manner as possible.

Short-term patents, which last for a maximum period of 10 years, may be enforced in the Circuit Court, Ireland's second highest court of first instance. In 2021, the Circuit Court Rules were amended to extend jurisdiction to a range of intellectual property disputes, including patents, to facilitate rightsholders in bringing intellectual property claims within the monetary jurisdiction of €75,000.

An application for revocation may be brought before the Controller of Patents, Designs and Trade Marks (the Controller) or before the court. If there are any related proceedings pending before the court, a revocation action may only be brought before the Controller with leave of the court.

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 is a process that is used voluntarily by the parties to a dispute. However, the Mediation Act 2017 (the Mediation Act) (effective as of 1 January 2018) places an obligation on parties to consider mediation and to confirm to the court that they have considered mediation. The Meditation Act imposes cost sanctions for unreasonably failing to engage in mediation.

Yes, mediation and arbitration are an increasingly common alternative to court proceedings. The Mediation Act is expected to lead to a further increase in the use of mediation as an effective dispute resolution mechanism in this jurisdiction.

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

Parties may be represented by qualified solicitors and barristers, with solicitors preparing the case and barristers arguing it before the court at trial. While, in principle, solicitors have a right of audience in all Irish Courts, it is usual to instruct a barrister.

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?

Infringement proceedings may be commenced by a Plenary Summons. Revocation proceedings in the court are commenced by a Petition grounded upon Particulars of Objection setting out the grounds for revocation. At any time before the close of pleadings either party can apply to have the proceedings transferred into the Commercial List. There is a fee of €5,000 to have the case entered into the Commercial List. There are no other significant court fees related to commencing proceedings. Nominal stamp duty is payable when issuing proceedings and filing affidavits.

The Commercial Court will actively case manage the proceedings and issue directions for exchange of pleadings, discovery, witness statements, legal submissions and any motions required along the way. It is common practice for the parties to agree directions for the exchange of pleadings in advance.

The procedural stages from filing proceedings to trial are as follows:

- Issue of Plenary Summons (infringement) or Petition (revocation).
- Entry of Appearance.
- Delivery of Statement of Claim together with Particulars of Infringement (or Particulars of Objections).
- Delivery of Defence and Counterclaim (if any).
- Reply and Defence to Counterclaim (if any).
- Discovery.
- Exchange of Witness Statements and Legal Submissions.
- Trial.

During the course of the exchange of these pleadings, the parties have the opportunity to raise interim particulars (i.e. targeted questions) to elicit information from the other party to assist with the preparation of their case. A Notice for Particulars will usually be raised following delivery of the Statement of Claim and the Particulars of Infringement or Particulars of Objection.

There is no set time limit within which a case must reach trial before the court. The time taken will depend on the complexity of the case and whether there are pre-trial disputes in relation to discovery. Patent actions in the Commercial List generally reach trial within 12 to 18 months from commencement. Parties have an automatic right of appeal and currently parties can expect to wait 12 to 18 months for an appeal hearing before the Court of Appeal. This timeframe can be shortened where the appeal is considered urgent or if it involves a very net point of law.

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. Discovery generally arises once the exchange of pleadings between the parties has closed. Discovery may be carried out voluntarily by agreement between the parties or, if the parties fail to agree (which is more typical), by Order of the court following an application by one or both parties. Depending on the volume of discovery sought and ordered to be made, this process can typically take two to four months to complete.

Each party issues a written request for voluntary discovery from the other party of specific categories of documents now or previously in its possession, power or procurement, relevant to the dispute. This request must comply with the following requirements:

- Parties must stipulate the exact categories of documents that they require.
- Requests must be confined to documents that are material to the issues in dispute, and that are relevant and necessary for the fair disposal of the proceedings or for saving costs.
- A reasonable amount of time must be provided for discovery to be made.

In addition, experiments can be ordered by the court, on application by either party.

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

Each party must set out its case in the exchange of pleadings referred to in question 1.4 above, witness statements (including experts) and written legal submissions.

In an infringement action, the Statement of Claim sets out the particulars of the wrong alleged against the defendant and is delivered with the Particulars of Infringement. These particulars outline which of the patent claims are alleged to be infringed. If the defendant is disputing the validity of the patent in suit, it delivers its Defence together with the Particulars of Objection. The Particulars of Objection state every ground on which the validity of the patent is disputed.

All technical evidence and related expert witness statements are produced by the parties in advance of the trial, usually at an agreed time. Opposing experts are often directed by the court to meet in advance of the trial in order to narrow down the issues in dispute as much as possible.

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

Expert witnesses prepare and deliver expert reports in advance of any trial. In patent cases, it is frequently agreed that the witness statements shall be taken as evidence in chief (i.e. they are taken as read into the record). The experts can then provide oral testimony at the trial and are cross-examined as to their evidence in chief.

Written legal submissions are exchanged in advance of trial, and oral legal submissions are made by both parties at the opening and closing of the trial.

An amendment of pleadings may require the permission of the court, which will generally be allowed provided irreparable prejudice is not suffered by the other party.

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

Patent trials involving infringement and/or validity can take anywhere from three to six weeks, depending on the technical complexity of the case and the number of witnesses involved. Judgment is usually reserved following the end of the trial and can be expected approximately one to three months later.

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?

The Commercial Court procedure is a faster, more streamlined and closely managed procedure. Please see question 1.4 above for further details regarding Commercial Court procedure.

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

Yes, judgments are published and available on the Courts Service website (https://www.courts.ie) and in the Irish Reports.

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?

As a common law jurisdiction, the doctrine of precedent applies in Ireland. There are two concepts under Irish law which are relevant to assessing the weight which an Irish Court will give to related decisions from other jurisdictions. The Irish High Court has previously distinguished between (i) a case in a foreign jurisdiction where the same legal principles arose, where the foreign judgment would have the status of persuasive authority, and (ii) a case where foreign litigation touches upon the same actual matters, rather than the same legal principles. As regards the latter concept, the principle of the comity of courts requires that the courts in Ireland should not lightly depart from a decision on the same issue made by a court of competent jurisdiction in another country which had to deal with that issue as part of litigation.

In the absence of any precedent on a particular issue, Irish Courts will often look to the case law of other, particularly common law, jurisdictions for guidance. Historically, Irish Courts have often demonstrated a preference to follow the decisions of the English Courts and such decisions are of persuasive authority in Ireland.

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

There are no specialist patent judges in Ireland, but the Commercial Court judges usually have some patent trial experience. With the introduction of the IP and Technology List, an Intellectual Property and Technology List Judge will be appointed to hear and manage the proceedings. The Irish Patents Act also provides that the court may request the assistance of a specially qualified assessor where necessary. The court must request such assistance if the parties request it to.

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

(i) A patent proprietor or exclusive licensee may initiate an infringement action. Where an exclusive licensee brings the action, the proprietor must be named as a defendant to the proceedings or else joined as a co-plaintiff so that they have sufficient notice of the action. Similarly, where there is more than one proprietor of a patent, each proprietor has standing to bring an action and any remaining co-proprietor should be named as co-defendants to the proceedings.

(ii) Any person may initiate revocation proceedings before the court or the Controller.

(iii) Any person may apply for a declaration that he has not acted in a manner that infringes a patent, provided that he has first written to the proprietor (or licensee) for written acknowledgment that he is not infringing and has been refused such acknowledgment. For declaratory relief in groundless threats proceedings, the plaintiff must be a person aggrieved by such threats.

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

Such declarations can address non-infringement and may, if the court deems appropriate, address claim coverage in respect of a technical standard and/or 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?

Yes. A patent proprietor has the right to prevent indirect use of an invention (Section 41 of the Irish Patents Act). Indirect use of an invention occurs where one party supplies another with means for putting a patent proprietor invention into effect without the patentee's consent. The supplying party must know (or should know) that those means are suitable and intended for putting the invention into effect.

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. Section 40(c) of the Irish Patents Act confers on the patent proprietor the right to prevent third parties from importing a product obtained directly by a process which is the subject matter of a patent in Ireland.

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 scope of protection of the patent is determined by the claims. Patents are interpreted purposively in Ireland with the claims of the patent being interpreted by the "skilled addressee" using the description and drawings as an aid if necessary.

The Protocol on the Interpretation of Article 69 of the European Patent Convention applies to the interpretation of claims in Ireland. The Protocol requires that, in determining the scope of a claim, a balance should be found which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties as to what is covered by the claims.

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?

Yes, invalidity may be raised as a defence to infringement proceedings in the following circumstances: (i) by way of defence to infringement proceedings; (ii) by way of defence to a groundless threats action; and (iii) as a standalone court application for revocation of the patent.

In addition to court proceedings, it is possible to bring standalone proceedings to invalidate a patent before the Controller, as long as no court proceedings are in being and the Controller does not otherwise consider that the matter is more appropriate to be determined by the court.

The issues of infringement and validity are usually dealt with simultaneously at the same trial; any defence to a claim for infringement on the grounds that the patent is invalid would generally be coupled with a counterclaim by the defendant for invalidity of the patent.

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 Irish published judgment on the *Formstein* defence.

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

A patent may be revoked on the grounds that:

- The subject-matter of the patent is not patentable under the Irish Patents Act.
- The specification of the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

- The matter disclosed in the specification of the patent extends beyond that disclosed in the application as filed.
- The protection conferred by the patent has been extended by an amendment which should not have been allowed.
- The registered proprietor of the patent is not entitled to it (by reason of the fact that he is, for example, neither the inventor nor his employer).

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

Irish infringement proceedings are susceptible to being stayed, particularly when opposition proceedings are pending before the European Patent Office (the EPO), but this must be on application to the court arguing the merits of the stay. There is no automatic right to have proceedings stayed by virtue of the existence of a validity challenge to a patent in a foreign court. This is because a finding of invalidity of a corresponding patent by a foreign national court has no legal effect on the validity of an Irish patent under Irish law. However, the Irish Courts may decide to stay the proceedings upon request by the parties if it is practical to do so in the circumstances.

Leave of the High Court is required to take revocation proceedings to the Controller, if court proceedings are pending in relation to the patent. Conversely, infringement proceedings may be stayed by the court where the Controller's decision in respect of a patent's validity is pending.

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

Consent, whether express or implied, is a defence to patent infringement. Section 42 of the Irish Patents Act provides for a defence in circumstances where the effect of the patent relates to:

- Acts done privately for non-commercial purposes.
- Acts done for experimental purposes.
- The preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription.
- The use of the invention on board foreign registered vessels or aircraft.
- Acts done with a view to satisfying marketing authorisation requirements for medicinal or veterinary products.

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 injunctions are available from the Irish Courts.

(i) An interim injunction can be granted *ex parte* but they are rare in a patent infringement case in Ireland.

(ii) Preliminary injunctions are typically granted *inter partes*, i.e. after a hearing with all parties present and, while temporary, will in most cases last until trial.

The grant of a preliminary injunction is an equitable remedy under Irish law and therefore it is ultimately at the court's discretion to grant it or not. The probability of obtaining a preliminary injunction in the context of a pharmaceutical patent is higher where the infringing drug is not yet being marketed to the public or has only just launched.

The Irish Courts will grant a preliminary injunction where the party seeking the injunction establishes that:

- there is a fair issue to be tried; and
- if so, that the balance of justice (i.e. the balance of convenience) favours the grant of an injunction pending the trial and, in this regard, the most important element is, in most cases, the question of adequacy of damages.

For an *ex parte* injunction application, the applicant must also establish that there is an urgent and immediate risk which requires the unilateral application.

In 2019, the test for a preliminary injunction in Ireland was reformulated by the Irish Supreme Court in *Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd* [2019] IESC 65. In summary, the Supreme Court took the view that, when considering whether it is appropriate to grant or refuse to grant an injunction, the Court cannot simply ask whether damages would be an adequate remedy. The question as to adequacy of damages should preferably be considered as part of the balance of convenience assessment, rather than an issue to be tried before that assessment. The test for interlocutory injunctions is therefore recognised as being more flexible.

There is no requirement to provide a bond. Instead, the plaintiff must provide to the court an undertaking as to damages, to compensate the defendant in the event that the preliminary injunction is later held to have been wrongly granted.

It is not possible to file protective letters with the court to protect against *ex parte* injunctions.

(b) Final injunctions are available from Irish Courts.
The Irish Courts will grant a final injunction in circumstances where the plaintiff is successful at the trial of action, where there is an act to be restrained on an ongoing basis and where damages alone are not an adequate remedy.

(c) There is no established Irish standard for a "public interest" defence. The "public interest" evidence before the court will be just one of a number of the factors it considers when assessing the balance of convenience.

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?

(a) The issues of liability and quantum can be heard either together or separately. In practice, the parties usually request that the liability module of the trial is held first and if infringement is found, quantum of damages is heard at a separate hearing in order to deal with matters as quickly and cost efficiently as possible.

(b) A successful plaintiff in Irish patent proceedings may seek damages, or as an alternative, an account of the defendant's profits (but not both). An account of profits is based on the principle of restitution (or unjust enrichment). The focus is therefore on the gain made by the infringing party. In assessing the appropriate damages to be awarded, an Irish Court will seek to place the patent owner in the same financial position as he would have been in had the infringement (direct or indirect) not taken place.

(c) Punitive/flagrancy damages are typically not awarded in IP infringement cases in Ireland.

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

A party must comply with any judgment or order, under which it is directed to pay money, to refrain from doing something or to deliver any personal or real property to another. Where a party does not comply with such an order, a court may make orders for sequestration, attachment and committal. Where an order against a company has been wilfully disobeyed, attachment against the directors/officers of the company and/or sequestration against the property of the directors/officers may be considered.

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

In addition to injunctions or damages (or an account of profits) the following reliefs may be sought:

- An order requiring the defendant to deliver up or destroy any infringing product.
- An order requiring that information regarding the origin and distribution networks of infringing goods be disclosed.
- An order requiring the dissemination and publication of the judgment at the defendant's expense.
- Costs.

There are no guiding Irish decisions from the Irish Courts in relation to cross-border relief.

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

Settlement of infringement proceedings prior to trial is reasonably common.

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

A claim for patent infringement is time-barred six years from the date of the first infringing act.

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?

There is an automatic right to appeal in Ireland. A decision of the High Court may be appealed to the Court of Appeal with a further right to appeal to the Supreme Court. As an appeal is a review of the judgment from the court of first instance, no new evidence may be adduced save for in exceptional circumstances. It is open to the parties to seek a stay or enforcement of any High Court order pending an appeal to the Court of Appeal depending on the justice to the parties of granting a stay or not.

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?

Filing an appeal does not operate as a stay on the execution of a decision. The grant of a stay pending an appeal is at the discretion of the court.

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

An appeal is a review of the judgment from the court of first instance. The Court of Appeal may give any judgment and make any order which ought to have been given or made and may make any further or other order as the case requires. If on the hearing of an appeal, it appears to the Court of Appeal that a new trial ought to be had, it may set aside the original decision or order and direct a new trial which may be confined to a particular question or issue, without interfering with the original finding on any other question or issue.

It is generally accepted that no new evidence may be adduced on appeal save for in exceptional circumstances. The appellant will require special leave of the court to introduce new evidence. Once leave to introduce new evidence has been granted, the court must consider the new evidence.

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

Currently parties can expect to wait 12 to 18 months for an appeal before the Court of Appeal.

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?

In Ireland, the High Court hears appeals from the Circuit Court. The Court of Appeal hears appeals from the High Court divided into two categories, ordinary appeals and expedited appeals. Finally, there is the Supreme Court which is the Irish Court of final appeal. There is no general right of appeal to the Supreme Court (unlike the automatic right of appeal to the Court of Appeal) and appeals to the Supreme Court are allowed by leave of the Supreme Court only where the decision (i) involves a matter of general public importance, or (ii) is necessary in the interests of justice. A leapfrog appeal from the High Court to the Supreme Court is possible where the Supreme Court is satisfied that there are exceptional circumstances warranting a direct appeal to it, although this does not happen often in practice.

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 cost of proceedings will depend on the complexity of the matter, the length of the trial and the amount of pre-trial applications involved. Proceedings for infringement and invalidity are usually dealt with concurrently by the Irish Courts. The general principle is that costs are awarded to the successful party with approximately one-half to two-thirds of costs incurred being recoverable. The same principle applies to the costs of an appeal.

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?

In Ireland, ratification of the UPC Agreement will require a referendum to amend the Irish Constitution. In May 2023, the Irish Government reaffirmed its commitment to hold a referendum and suggested the referendum would take place in late Autumn or in Spring 2024 to coincide with the local and European elections. Ireland has previously committed to the establishment of a local division of the UPC.

2 Patent Amendment

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

Yes. An application to amend a patent after grant can be made to the Controller and will be advertised for the purposes of facilitating any third-party objection within a prescribed time-frame. Such an application cannot be made where proceedings concerning the validity of the patent are before the courts or the Controller (Section 38(1) of the Irish Patents Act).

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

Yes. The court (or the Controller) may permit the amendment of a patent as part of invalidity proceedings subject to such terms as to advertising the proposed amendment and as to costs, expenses or otherwise as the court or the Controller thinks fit. Irish Courts have also held that the application for amendment must be made before the trial of the invalidity action so as to be heard at the same time and therefore cannot be taken post trial with the benefit of hindsight (Section 38(2) of the Irish Patents Act).

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

Yes. Section 23(3) of the Irish Patents Act provides that amendments that extend the subject-matter disclosed in the application as filed or that extend the protection conferred by the patent are invalid.

3 Licensing

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

Patent licences are subject to provisions of competition law (Irish and EU). There are also statutory restrictions on patent licences containing conditions that would directly or indirectly prevent or restrict a party using a third party's product or process and/or that would require a party to acquire from another party a product not subject to the patent, with limited exception (Section 83 of the Irish Patents Act).

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, the Irish Patents Act provides that the Controller may order the grant of a compulsory licence, provided that the patent has been in existence for three years, on the grounds that:

- A demand in the State for the subject-matter of the patent is not being met or is not being met on reasonable terms.
- A demand in the State for a product which is protected by the patent is being met by importation other than from a member of the World Trade Organization (the WTO).
- The establishment or development of commercial or industrial activities in the State is unfairly prejudiced.
- A patent owner is unable to exploit his patent without infringing his rights deriving from a first patent (but only to the extent necessary for such exploitation and provided that the invention involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent).

Such applications are made to the Controller and settled based on the terms of the application or at the Controller's discretion, subject to certain statutory requirements. Compulsory licensing of patents is also available in Ireland where such licences relate to the manufacture of pharmaceutical products for export to countries with public health problems and applications are also made to the Controller in that regard.

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?

It is not possible to extend a standard 20-year patent save in accordance with EU Regulations (Regulations) concerning Supplementary Protection Certificates (SPCs) for medicinal and plant protection products. The criteria for obtaining the relevant extension are set out in those Regulations. The Regulations also govern the calculation of the extended period which is limited in any event to no longer than five years following expiry of the patent or 15 years from the date of authorisation for the product, whichever is the earlier.

5 Patent Prosecution and Opposition

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

The Irish Patents Act expressly provides that the following subject-matter or activities are not patentable 'as such':

- A discovery, a scientific theory or a mathematical method.
- An aesthetic creation.
- A scheme, rule or method for performing a mental act, playing a game or doing business, or a program for computers.
- The presentation of information.

In addition, the following subject-matter or activities are not patentable in any circumstances:

- An invention, the commercial exploitation of which would be contrary to public order or morality (in this regard, the

mere fact that such exploitation is contrary to law does not of itself render it contrary to public order or morality).
- A plant or animal variety or an essentially biological process for the production of plants or animals other than a micro-biological process or the products thereof.
- A method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body.

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 not.

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?

No. Revocation proceedings will be necessary to challenge an Irish patent. A European patent designating Ireland can be opposed at the EPO within the prescribed process and timeframe there.

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

Yes, within a three-month timeframe. Such an appeal is heard before the High Court (with an application possible to the Commercial List of the High Court) and involves a full rehearing. A further appeal can be made from the High Court to the Court of Appeal on a question of law only.

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

Disputes are typically resolved in the High Court. A party may apply, within two years of a patent being granted, for a determination as to entitlement to ownership of the patent. Disputes as to entitlement to priority generally arise in the context of revocation proceedings.

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

Yes, six months.

5.7 What is the term of a patent?

A patent lasts for 20 years from the filing/priority date. Provision is also made in Ireland for a short term (10-year) patent which is subject to less stringent patentability criteria, i.e. it is clearly not lacking an inventive step.

5.8 Is double patenting allowed?

No. The Irish Patent Office will revoke a patent if there are two patents in respect of the invention, i.e. if:

(a) An Irish patent and a European patent designating Ireland have been granted for the same invention.
(b) The applications for both patents have the same date as their date of filing or, where priority was claimed, their date of priority.
(c) The applications for both patents were filed by the same applicant or his successor in title.

The proprietor of the patent will generally be given an opportunity to make observations and amend the specification of the patent before it is revoked.

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?

As of yet, Ireland has not ratified the UPC Agreement and the Unitary Patent will only be covered in Ireland when ratification of the UPC Agreement takes place.

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. Ireland has given full effect to Regulation (EU) No 608/2013 of the European Parliament and Council allowing customs authorities to deny entry and destroy counterfeit and pirated goods in certain circumstances.

7 Antitrust Law and Inequitable Conduct

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

The Irish Courts have not used competition law as a basis to refuse relief for patent infringement. However, Irish patent law is subject to EU and national competition law, so it is possible that this could be used as a basis in future cases.

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

Please refer to questions 3.1 and 7.1 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?

There is currently no guidance from the Irish Courts as to whether patent validity and infringement would be heard separately to proceedings relating to the assessment of FRAND licences or regarding FRAND injunctions in patent proceedings.

8 Current Developments

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

As mentioned above at question 1.23, in 2019, the test for a preliminary injunction in Ireland was reformulated by the Irish Supreme Court in *Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd* [2019] IESC 65. As part of that judgment, granted IP rights were held to have presumptive validity. This year, we have seen a number of judgments reinforcing that position, in particular:

- *Merck Sharp & Dohme LLC v Mylan Ire Healthcare Limited & Ors* [2023] IEHC 24.
- *Biogen MA Inc & Anor v Laboratories Lesvi SL & Anor* [2023] IECA 71.
- *Bristol-Myers Squibb Holdings Ireland v Norton (Waterford) Limited T/A Teva Pharmaceuticals Ireland* [2023] IECA 173.

As such, in the last number of months, there has been a trend towards the Courts placing reasonable emphasis at the preliminary injunction stage on the presumption of validity of granted IP rights.

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

The CJEU decision in *Merck Sharp & Dohme Limited v Clonmel Healthcare Limited* 2022 [IESC] 11 is awaited, expected in 2023.

In March 2022, a referral was sent to the Court of Justice of the European Union (the CJEU) in the above case. The case concerns two SPCs which are in place for the drug ezetimibe. Ezetimibe, marketed as a mono-product under the brand name Ezetrol, is also subject to a second SPC under the scope of SPC regulation Article 3(a) of Regulation No 469/2009 (the SPC Regulation) for a combination of ezetimibe and simvastatin. The plaintiff markets this under the brand name Inegy.

The referral follows unsuccessful attempts by the plaintiff in the Irish High Court and Court of Appeal in seeking an injunction and damages for infringement of the second SPC by Clonmel Healthcare, who counterclaimed for invalidity, arguing that under Article 3(a) patent claims merely mentioning a product does not mean that the basic patent covers the product. The High Court found that its SPC for Inegy was invalid under Articles 3(a) and 3(c) of the SPC Regulation, and the decision remained unchanged by the Court of Appeal. The plaintiff appealed further to the Supreme Court, focusing on the tests which determine the validity of the combination SPC under Article 3(a) and 3(c) of the SPC Regulation.

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

Please refer to question 8.1.

John Whelan is a Partner and leads the IP Group at A&L Goodbody. John advises clients in both the private and public sectors on commercial, regulatory and contentious matters across the full range of IP and privacy laws. He has been involved in many of the leading cases in these areas that have come before the Irish Courts, including multiple referrals to the CJEU, over the past 20 years.

A&L Goodbody LLP
3 Dublin Landings
North Wall Quay
Dublin 1, D01 C4E0
Ireland

Tel: +353 1 649 2234
Email: jwhelan@algoodbody.com
URL: www.algoodbody.com

Sinéad Mitchell King is a Senior Associate in the IP Group at A&L Goodbody, specialising in contentious IP matters. Sinéad's experience includes advising clients on high-profile IP disputes, including acting in a number of multi-jurisdictional patent cases before the Commercial Court and trade mark cases before the High Court.

A&L Goodbody LLP
3 Dublin Landings
North Wall Quay
Dublin 1, D01 C4E0
Ireland

Tel: +353 1 649 2354
Email: smitchellking@algoodbody.com
URL: www.algoodbody.com

Sarah Douglas is a Solicitor and Registered Trade Mark Agent in the IP Group at A&L Goodbody. Sarah has a science background (chemistry) and advises clients across a wide range of IP matters. Her contentious experience includes acting for domestic and international clients in a number of patent cases before the Irish Commercial Court and non-contentious experience includes advising on a broad range of patent, trade mark and copyright matters.

A&L Goodbody LLP
3 Dublin Landings
North Wall Quay
Dublin 1, D01 C4E0
Ireland

Tel: +353 1 649 2475
Email: sdouglas@algoodbody.com
URL: www.algoodbody.com

A&L Goodbody is internationally recognised as one of Ireland's leading law firms advising on the most innovative, challenging and complex client mandates. The IP Group at A&L Goodbody is a team of dedicated IP specialists with a depth of expertise across all industry sectors. The group have a proven track record in acting for prominent international clients across multiple sectors in relation to both contentious and non-contentious IP matters in the Irish market. The combined contentious and non-contentious offering within one team gives us a unique selling point and facilitates our development of an unparalleled repository of knowledge and experience when compared to peers in the market. The success of this approach is reflected in our ability to win mandates on many of the most significant IP cases that come before the Irish Courts.

www.algoodbody.com

International Comparative Legal Guides

The **International Comparative Legal Guide** (ICLG) series brings key cross-border insights to legal practitioners worldwide, covering 58 practice areas.

Patents 2024 features four expert analysis chapters and 25 Q&A jurisdiction chapters covering key issues, including:

- Patent Enforcement
- Patent Amendment
- Licensing
- Patent Term Extension
- Patent Prosecution and Opposition
- Border Control Measures
- Antitrust Law and Inequitable Conduct
- Current Developments

The International Comparative Legal Guides are published by: glg Global Legal Group