

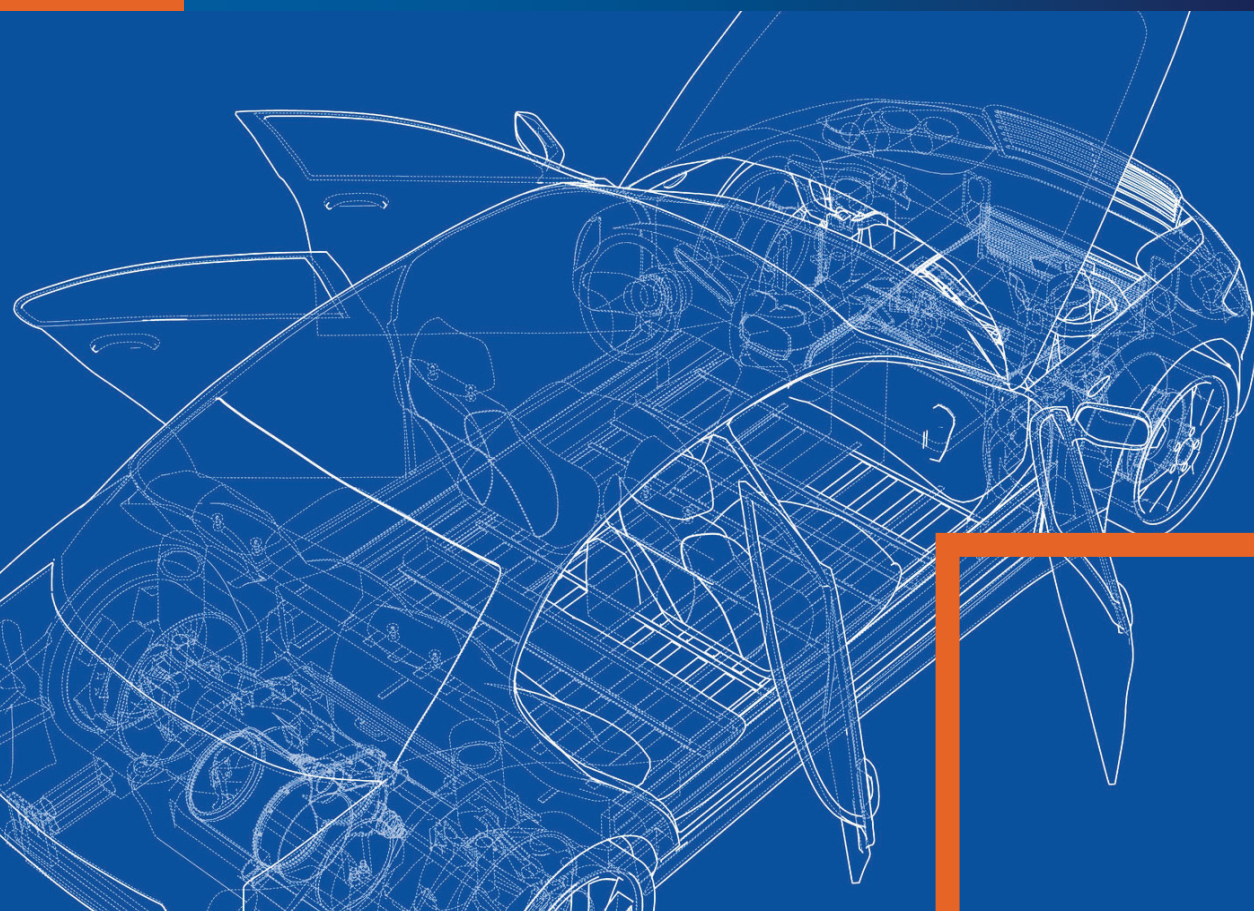
International Comparative Legal Guides

Patents 2027

A practical cross-border resource to inform legal minds

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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 High Court has exclusive jurisdiction over patent infringement actions, save for actions in respect of short-term patents and actions for infringement of a published application. Most patent disputes are heard in the Intellectual Property ("IP") and Technology sub-division of the Commercial List in the High Court (introduced by amendments to Order 63A of the Rules of the Superior Courts ("RSC") in 2021).

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

Mediation is a voluntary process which is used by the parties to a dispute in order to bring disputes to a close before a trial begins. While voluntary, the Mediation Act 2014 has introduced measures that make it mandatory for solicitors to advise their clients about mediation before commencing proceedings, and to provide a statutory declaration to the effect that such advice was given. There may be costs penalties imposed for failure to meet this obligation. The Court may also invite parties to mediate during proceedings. In practice, mediation and arbitration are an increasingly common alternative to court proceedings.

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

Parties may be represented by qualified barristers and solicitors, and both have a right of audience in Irish Courts. In practice, however, it is usual to instruct a barrister to advocate for parties in Court.

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 begin with a plenary summons (Order 1 RSC), generally served within 12 months of issue (Order 8 RSC,

as amended). A warning letter beforehand is usual though not compulsory. Parties then typically apply to admit the case to the Commercial List, and in particular its IP and Technology List, where cases are closely managed to ensure they are progressed efficiently and expeditiously. IP cases are given preferential treatment when it comes to entry into the Commercial List – e.g. culpable delay alone is not a ground for refusal, it must be culpable delay that, for example, causes prejudice to the other party. The fee to be paid in respect of an entry application to the Commercial List is EUR 5,000.

The steps to trial then typically include at least an exchange of pleadings, discovery, experiments (if any), the exchange of witness (including expert) reports and the exchange of written legal submissions. Time to trial in the Commercial Court ranges from 12 or 15 months up to 24 months, depending on the complexity of the dispute and the procedural steps involved.

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

Pre-action disclosure is possible in exceptional cases.

The Court may grant an order *ex parte*, known as an *Anton Piller* order, directing the defendant to allow the plaintiff, attended by his solicitor, to enter the defendant's premises to inspect specified documents or evidence specified in the order and to copy or remove the same so that they may be preserved for use as evidence at the hearing of the matter. The order cannot be enforced without the defendant's consent. However, when the defendant does not consent, he will be in contempt of court.

The conditions for obtaining an *Anton Piller* order are as follows:

- (a) The plaintiff must have an extremely strong *prima facie* case on the merits.
- (b) The actual or potential damage to the plaintiff must be very serious.
- (c) There must be clear evidence that the defendant has incriminating documents or articles in his possession.
- (d) There must be a real possibility that these will be destroyed before an application *inter partes* can be made.

Certain specific information could also be obtained via a *Norwich Pharmacal* order. This arises where an action is brought against a third party in order to obtain information necessary to identify a wrongdoer.

When proceedings have been brought, after pleadings close, parties may be compelled to make discovery of documents within that party's possession, power or procurement

that are relevant to an issue in dispute and necessary for fairly disposing of the case or saving costs. Discovery is often agreed between the parties; however, where it is not agreed, a party can bring a motion seeking an order to compel it.

Under Order 94 RSC, where a party delivers a Product or Process Description, it may not have to make discovery of documents relating to the features of the product or process concerned unless the Court for special reasons otherwise orders.

A party may also serve a notice seeking inspection of documents or other evidence under Order 31 RSC and, in the absence of consent, may apply to the Court for an order permitting such inspection. As with discovery, however, these measures are unlikely to be ordered before the close of pleadings and will typically take place alongside discovery.

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

Pre-trial, parties are required to exchange formal pleadings that set out each party's case, make discovery (if agreed or ordered by the Court), respond to any interrogatories (sworn answers to questions) raised by the other side, and exchange witness statements and legal submissions.

Technical evidence is typically central to patent proceedings and witness statements (including expert reports) comprising a *précis* of the evidence to be given by a witness at trial are typically (and necessarily in the Commercial List) exchanged in advance of trial. Expert witnesses are generally called by both parties. The Court may direct opposing experts to meet before trial to narrow the issues in dispute and produce a joint report, often referred to as a "debate among experts".

Since the 2021 amendment to Order 94 RSC, experiments are subject to a formal Notice of Experiments procedure, and the Court may direct experiments at a case-management conference or appoint an independent assessor to assist with complex technical evidence.

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

Trials are oral hearings in open court with witnesses examined in chief and cross-examined, plus legal argument. Written witness statements exchanged before trial may by agreement stand as evidence in chief, with the witness still available for further oral evidence and cross-examination. Documentary evidence generally requires witness verification.

The Court may, at any stage of the proceedings (including during trial), allow either party to alter or amend his indorsement or pleadings in such manner and on such terms as may be just, and all such amendments shall be made as may be necessary for the purpose of determining the real questions in controversy between the parties.

An amendment of pleadings generally requires the leave of the Court during the course of proceedings, save that a plaintiff's statement of claim or a defendant's counterclaim may be amended without leave within a prescribed short period as set out in Order 28 Rules 2 and 3 of the Superior Court Rules.

It is within the Court's discretion to grant leave. In practice, leave is often granted, though amending the case can have cost implications.

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

Hearing length varies with the number of issues and volume of evidence. Complex patent infringement/validity trials may take up to six weeks, with the Court sitting for four days a week. Judgment is often given within about three months of the hearing, though this timeline can vary from case to case.

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?

Commercial Court proceedings are case managed to ensure they are progressed with due efficiency and expedition; however, no shorter or further abridged procedure is available.

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

Judgment is delivered in open court, either immediately or, in complex cases, as a reserved judgment some weeks later. This reflects the constitutional requirement that justice be administered publicly. Judgments are published and available to the public via the Courts Service website (<https://www.courts.ie>) and in the Irish Reports. A party may apply to the Court to have certain confidential information permanently redacted from a published judgment. However, the Court will permit such redactions only in exceptional circumstances, where the party has provided cogent and specific evidence demonstrating the risk of harm that would result from disclosure.

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 considered persuasive?

As a common law jurisdiction, Ireland is bound by domestic precedent interpreting the Patents Act 1992 (the "1992 Act"). Irish Courts will also frequently have regard to persuasive authorities from other common law jurisdictions, particularly from the English Courts. This is especially so where foreign proceedings concern the same underlying facts or issues, rather than merely analogous legal principles. In such circumstances, the principle of comity between courts dictates that Irish Courts should not lightly depart from a decision of a court of competent jurisdiction in another country that has already determined the same issue in the course of related litigation.

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

Ireland does not have specialist patent judges, as such, however, the judges overseeing the IP and Technology List will have some experience with patent litigation. The judges, however, do not have a technical background. The Court may also call in the aid of a suitably qualified independent assessor under section 95(1) of the 1992 Act to try the case with his assistance (though we have not seen this happen in practice).

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

- (i) Infringement proceedings may be brought by the proprietor, or by one co-owner alone if the others are joined as defendants. An exclusive licensee may sue for post-licence infringement, with the proprietor joined as defendant unless already a co-plaintiff; a non-exclusive licensee has no such right.
- (ii) Revocation may be brought by any person before the High Court or Controller.
- (iii) Any person may apply for a declaration of non-infringement, provided that they have first requested from the patent proprietor (or licensee) a written acknowledgment that the relevant acts do not infringe the patent and that such acknowledgment has been refused. In proceedings concerning groundless threats, declaratory relief is available only to a person aggrieved by the threats in question.

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

Declarations are available. Section 54 declarations of non-infringement are available and can be used as a pre-emptive step before contemplated activity. The Irish Courts have not yet considered whether declarations may be granted in relation to claim coverage of a technical standard and/or hypothetical activity. However, it is possible that such relief could be granted under the Courts' inherent jurisdiction. Given the willingness of the English Courts to grant both affirmative and negative declarations in essentiality disputes, as well as in respect of hypothetical activity (at least where it would resolve a real (as opposed to hypothetical) commercial issue between the parties), the Irish Courts may take a similar approach.

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. Under section 41 of the 1992 Act, a party may be liable for indirect infringement, arising from supplying, in the State, means relating to an essential element of the invention to a person not entitled to exploit it, where the supplier knows or ought to know that the means are suitable and intended for putting the invention into effect. This excludes staple commercial products unless the supplier induces direct infringement.

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 1992 Act prohibits offering, marketing, using or importing a product obtained directly by a process that is the subject matter of a patent in Ireland, even where the process was carried out outside of the jurisdiction.

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?

Section 45 of the 1992 Act provides that the scope of protection of a patent is determined by the claims. Where a claim contains non-literal equivalents, this will be subject to an interpretation exercise. In Ireland, a purposive interpretation is applied, meaning that claims will be interpreted from the perspective of the notional "skilled addressee", i.e. a person with practical knowledge and experience of the kind of work in which the invention was intended to be used. Article 69 of the European Patent Convention ("EPC") provides that section 45 should combine a fair protection for the patent proprietor with a reasonable degree of certainty for third parties. The Protocol to the Interpretation of Article 69 EPC provides that due account shall be taken of any element that is equivalent to an element specified in the claims.

In the landmark decision of *Actavis v Eli Lilly* [2017] UKSC 48, the UK Supreme Court established a doctrine of equivalents in that jurisdiction. As of the date of publication, the Irish Courts have not yet considered the *Actavis v Eli Lilly* decision, and the law in Ireland remains in line with the old UK approach, i.e. the purposive approach outlined by Lord Hoffman in *Kirin-Amgen*.

There has been no judicial consideration in Ireland of the question whether there could be anticipation by equivalents.

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 defendant may bring validity of a patent into issue in its defence. In practice, a defendant will usually combine such a defence with a counterclaim for revocation, setting out detailed grounds of invalidity.

There are some procedural restrictions: while stand-alone revocation proceedings may be brought before the Controller, this route is generally unavailable where infringement proceedings are already before the Court unless leave of the Court is obtained. Issues of validity and infringement are not generally bifurcated and are usually heard together in the same proceedings. Where there are opposition proceedings ongoing at the European Patent Office ("EPO"), the Court may consider staying the Irish proceedings.

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")?

There has been no published judgment in Ireland that refers to the *Formstein* defence.

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

Other than lack of novelty and inventive step, Irish case law has identified the following as grounds for finding invalidity:

- The subject matter of the patent is not patentable (see question 5.1).

- The proprietor is not entitled to the claimed priority.
- AgrEvo-type obviousness/lack of plausible technical contribution.
- For short-term patents, the claim is unsupported by the description.

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

There is no automatic right to stay on Irish infringement proceedings pending the resolution of validity in another forum; however, the Court will have discretion in this regard. In practice, where parallel EPO opposition proceedings are ongoing, a stay of the Irish proceedings is often sought, and the Courts have recognised a general presumption in favour of a stay pending the EPO's determination, particularly where that determination is expected within a reasonable timeframe. The party opposing the stay bears a significant burden in showing why the Irish proceedings should nevertheless continue.

By contrast, validity proceedings in foreign national courts do not directly affect the validity of an Irish patent and do not, of themselves, justify a stay, although the Court may take such proceedings into account when exercising its discretion.

1.22 What other grounds of defence can be raised in addition to non-infringement or invalidity (e.g. 'Bolar' or experimental use exceptions)?

Consent, whether express or implied, is a defence to infringement. Section 42(b) of the 1992 Act provides an exemption for acts done for an experimental purpose, specifically where the purpose of such acts is to find new information. Section 42(g) and (h) contain Bolar-style exemptions which cover studies and trials for marketing authorisation of medicinal/veterinary products, including generics/biosimilars and new medicines.

1.23 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?

Yes. In Ireland, both *ex parte* (interim) and *inter partes* (interlocutory) preliminary injunctions are available, although *ex parte* relief is rare in patent cases and will generally be granted only where there is an urgent and immediate risk of irreparable harm requiring action before the defendant can be heard. Applications for interim relief require full and frank disclosure from the applicant usually grounded upon an affidavit setting out all of the facts necessary to satisfy the Court that an interim injunction is appropriate, and will usually require an undertaking as to damages.

Inter partes interlocutory injunctions are more common and may be granted pending trial where the applicant demonstrates that there is a serious issue to be tried and that the balance of convenience (or balance of justice) favours the grant of relief. Following the Supreme Court's decision in *Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd* [2019] IESC 65, the adequacy of damages is considered as part of the overall balance of convenience assessment rather than as a separate threshold requirement. Subsequent decisions, including *Merck Sharp & Dohme LLC v Mylan Ire Healthcare Ltd* [2023] IEHC 24, *Biogen MA*

Inc v Laboratorios Lesvi SL [2023] IECA 71 and *BMS v Teva* [2023] IEHC 159, have emphasised the significance of the presumption of validity attaching to granted patents and Supplementary Protection Certificates ("SPCs"). Where damages are not clearly adequate for either side, the Courts will consider factors such as the strength of any invalidity challenge, whether the presumption of validity has been materially undermined (for example by consistent adverse decisions in other jurisdictions), and, in appropriate cases, whether the defendant has sought to "clear the way" before launch. No bond is required, but the applicant must provide an undertaking as to damages to compensate the respondent if the injunction is subsequently found to have been wrongly granted.

Protective letters are not recognised under Irish procedure and therefore cannot be filed to guard against *ex parte* injunction applications.

1.24 Are final injunctions available and what is the basis on which they are granted?

Yes. Final injunctions are among the reliefs that the Irish Courts may grant under section 47(1) of the 1992 Act. They generally follow a finding of infringement (though see question 1.25). A final injunction may be stayed after a first-instance decision pending appeal and the test whether to stay the injunction is similar to the test for an injunction pre-trial.

1.25 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?

There is no established public interest defence available in Ireland barring injunctions merely because the patent covers a life-saving product. However, while an injunction would be the default remedy, there may be circumstances where preserving access to life-saving products could be a consideration (while this has been considered in UK case law, we understand that there has not been a case where a permanent injunction has been refused on that basis).

In the context of a pre-trial injunction, in *Biogen v Lesvi*, the Court of Appeal found that the public interest in cheaper generics was not an appropriate remedy in the circumstances of that case (where the patentee's product was available on the market).

1.26 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 issues of liability and quantum can be heard together or separately, with the assessment of quantum constituting a subsequent module to a trial. The default position in Ireland is a unitary trial. However, in patent cases, it is common for the proceedings to be split into a liability and quantum stage. This is done for efficiency, to avoid unnecessary time on assessing damages or account of profits if no infringement is found.

Generally speaking, damages are compensatory, not punitive. Punitive/flagrancy damages are available only exceptionally. Loss may be calculated via lost profits or a notional licence fee. An account of the infringer's profits is an alternative remedy, elected after disclosure of the defendant's financial information. Innocent infringement (no knowledge or reasonable grounds to suppose the patent existed) is a defence to damages/account.

1.27 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 a judgment or order directing payment of money, an act to be refrained from, or delivery of property; non-compliance can result in orders for sequestration, attachment and committal. Where a company wilfully disobeys an order, attachment against its directors or officers, or sequestration of their property, may also be considered.

1.28 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief? Are criminal sanctions available?

Beyond injunctions and damages/account, the Court may order delivery up/destruction of infringing goods, a declaration of validity/infringement, and costs. The Court may also make an order for disclosure of the origin and distribution of suspected infringing goods under Directive 2004/48/EC. Criminal sanctions arise out of the customs regulations (see question 6.1).

Cross-border relief may, in principle, be available based on the Court of Justice of the European Union ("CJEU") jurisprudence in Case C-339/22 (*Electrolux*); however, this has not yet been considered by the Irish Courts.

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

Settlement of infringement proceedings prior to trial is reasonably common.

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

Patent infringement claims are time-barred six years from the date of the first infringing act, as per section 11 of the Statute of Limitations 1957.

1.31 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 generally an unlimited right of appeal from the High Court at first instance to the Court of Appeal. This includes not only decisions on the merits of the substantive action, but also preliminary decisions, such as decisions in respect of preliminary injunctions. Such appeals are limited to points of law and so no new evidence may be adduced on appeal.

1.32 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 automatically stay the effect of a High Court order. The decision whether to stay the effect of such an order is at the discretion of the Court. For example, in *BMS v Teva*, the Court of Appeal granted an injunction pending appeal notwithstanding a first-instance finding that the patent was invalid, holding that the balance of convenience favoured preserving the *status quo* while the appeal was pending.

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

An appeal to the Court of Appeal is by way of review, not rehearing. The Court of Appeal does not ordinarily hear witnesses or retry the case but instead reviews the High Court's decision, relying on a record from the High Court proceedings. New evidence cannot ordinarily be adduced on appeal and will only be admitted in exceptional circumstances with the leave of the Court of Appeal.

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

Appeals to the Court of Appeal can take approximately one year.

1.35 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?

Two further levels of appeal exist above the High Court: the Court of Appeal; and the Supreme Court, which hears further appeals only where satisfied the case involves a matter of general public importance or the interests of justice require it, including via a "leapfrog" appeal directly from the High Court. A second-level appeal in patent cases is possible only in limited circumstances, not as of right.

1.36 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?

Approximate first-instance costs are as follows: EUR 140,000–175,000 for preliminary injunctions; EUR 250,000–350,000 for infringement or validity alone; and EUR 350,000–550,000 for combined infringement/invalidity proceedings. Appeal costs to the Court of Appeal are approximately EUR 125,000–175,000 in preliminary injunctions or normal proceedings.

2 Patent Amendment

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

Yes. After grant, the proprietor may apply *ex parte* to the Controller under section 38 of the 1992 Act to amend the patent specification. The proposed amendment must then be advertised in the Journal of the Intellectual Property Office of Ireland (the "Journal"), and any person may oppose it within the prescribed period.

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

Yes. Where *inter partes* revocation/invalidity proceedings are pending, under section 38(2) of the 1992 Act, a proprietor may apply to the Court, or as appropriate, to the Controller, for leave to amend the patent specification, subject to conditions

such as advertisement in the Journal of such proposed amendments, or subject to costs and expenses.

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

An amendment to a specification shall be invalid to the extent that it extends the subject matter disclosed in the application as filed or the protection conferred by the patent (section 38(3)).

3 Licensing

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

Patent licences are subject to provisions of EU/Irish competition law. The technology transfer block exemption (Regulation 772/2004/EC) approves certain provisions while blacklisting others, distinguishing competing from non-competing undertakings. Section 83 of the 1992 Act also imposes restrictions on parties' ability to agree certain terms by invalidating specified restrictive licensing 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 exceptions.

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?

Compulsory licences may be sought from the Controller no earlier than three years after grant, under sections 70–75 of the 1992 Act. The applicant must satisfy at least one of the following grounds:

- (i) that a demand in Ireland for the subject matter of the patent is not being met or is not being met on reasonable terms;
- (ii) that a demand in Ireland for a product that is protected by the patent is being met by importation other than from a member of the World Trade Organization; or
- (iii) that the establishment or development of commercial or industrial activities in Ireland is unfairly prejudiced.

A separate regime permits compulsory licences for pharmaceutical export to countries with public health problems. Compulsory licences are non-exclusive and non-assignable.

3.3 Is there a requirement to register the licence at the Patent Office?

Under section 85(1) of the 1992 Act, a licensee shall apply to the Controller to have their interest recoded on the register.

3.4 What right does a licensee have to enforce a patent?

An exclusive licensee may bring proceedings, according to section 51 of the 1992 Act, for any act of infringement committed after the date of grant of the licence. In any such proceedings, the exclusive licensee must join the proprietor of the patent as a co-defendant. A non-exclusive licensee has no statutory enforcement right.

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?

A patent's 20-year term cannot be extended, but protection for certain authorised medicinal and plant-protection products may be extended by up to five years through an SPC in order to compensate the patentee for the loss of time during which the patentee was required to obtain market authorisation. This does not technically extend the term of the patent itself, but only the protection for the specific product subject to market authorisation.

5 Patent Prosecution and Opposition

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

To meet the criteria for patentability, an invention must be susceptible of industrial application, new and involve an inventive step. The following subject matter is regarded as not being an invention (and hence not patentable as such) according to section 9(2) of the 1992 Act:

- (i) A discovery, scientific theory or mathematical method.
 - (ii) An aesthetic creation.
 - (iii) A scheme, rule or method for performing a mental act, playing a game or doing business, or a program for computers.
 - (iv) The presentation of information.
- Expressly excluded subject matter as per section 10(1) includes:
- (i) An invention, the commercial exploitation of which would be contrary to public order or morality.
 - (ii) 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.
 - (iii) 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.

Regulation 5(1) of the European Communities (Legal Protection of Biotechnological Inventions) Regulations 2000 (S.I. No. 247 of 2000) further purports that the human body at any stage of formation, including a gene sequence, is not patentable.

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 duty to disclose prejudicial prior disclosures or documents.

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?

There is no formal third-party opposition procedure. Under section 30A of the 1992 Act, after a patent application has been published, a third party may make observation to the Controller on the question of whether the invention is a patentable invention, stating reasons for the observations, and the Controller shall consider the observations.

A granted patent may also be challenged by any person, by applying under section 57 of the 1992 Act, through revocation proceedings before the Controller or the High Court.

Proceedings for revocation of a patent may be brought before the High Court or the Controller of Intellectual Property (through the Intellectual Property Office of Ireland, the "IPOI"), although when proceedings are pending before the High Court in respect of a patent, no application may be made to the Controller without the prior leave of the Court. The Controller is not a judge but exercises a judicial function. Evidence before the Controller is normally by way of a written statutory declaration, although the Controller does have the power to examine witnesses and hear oral evidence. An appeal lies to the High Court from the decision of the Controller. Proceedings before the Controller are governed by the Patents Rules 1992 (S.I. No. 179).

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

Yes. A decision by the Controller may be appealed, within a three-month timeframe, to the High Court, as per section 96 of the 1992 Act. This can include decisions on revocation, entitlement or inventorship. High Court decisions can subsequently be appealed to the Court of Appeal strictly on a point of law.

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

Under section 81 of the 1992 Act, any person may refer an entitlement question to the Court, within two years of grant of the patent, or transfer unless the proprietor knew at the time of the grant, or of the transfer or assignment of the patent to him, that he was not entitled to the patent. The Court may make any order to give effect to its decision, as it considers expedient, including an order for apportionment.

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

Yes. There is a six-month grace period during which disclosure of an invention shall not be taken into consideration if it occurred due to, or in consequence of, (a) a breach of confidence, or agreement in relation to, or the unlawful obtaining of the matter constituting the invention, or (b) the fact that the applicant or his legal predecessor has displayed the invention at an international exhibition.

5.7 What is the term of a patent?

A national Irish patent, or a European patent designating Ireland, has a term of 20 years. Short-term patents have a 10-year term, a maximum of five claims, and a lower inventive-step threshold, without pre-grant novelty/inventive-step examination.

5.8 Is double patenting allowed?

Double patenting is not permitted in Ireland and the IPOI will revoke a patent if there are two patents in respect of the invention. This includes circumstances in which an Irish patent and a European patent designating Ireland have been granted for the same invention.

5.9 When do co-ownership rights arise and what right does each co-owner have to exploit the patent application/granted patent?

Under section 80 of the 1992 Act, co-owners hold an equal undivided share absent any agreement to the contrary, and each may exploit the invention without accounting to others. Any co-owner may sue for infringement without the others' concurrence provided they are joined as defendants, and a defendant co-owner bears no costs liability unless it participates. No licence or assignment of a share may be made without all co-owners' consent, and supplying one co-owner does not constitute indirect infringement.

5.10 For Member States within the European Union: Can a Unitary Patent, on grant, take effect in your jurisdiction? If your Member State has not yet signed or ratified the Unified Patent Court Agreement, is it likely to do so and, if so, when?

Ireland has signed the International Agreement on a Unified Patent Court and confirmed its intention to establish a local division of the Unified Patent Court ("UPC"). Ratification of this agreement by Ireland will require a constitutional referendum, with no clear timeframe in place from the Irish Government.

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?

The Revenue Commissioners are Ireland's designated competent customs authority under Regulation (EU) 608/2013 and may act to enforce a patent holder's rights through seizure of suspected infringing goods that enter the country. There is a procedure in place for destruction of such goods, on the advice of the patent holder (in the absence of an objection from the consignee of the goods) or detention of the goods pending the outcome of IP proceedings. The Health Products Regulatory Authority assists in this role in relation to medicinal products.

7 Antitrust Law and Inequitable Conduct

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

Patent enforcement may in exceptional circumstances be contrary to competition law under Articles 101/102 of the Treaty on the Functioning of the European Union and the Competition Act 2002, though the Irish Courts have not used competition law as a basis to refuse relief for patent infringement to date.

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

There is a block exemption governing anticompetitive licence terms relating to technology transfer agreements. The Regulation approves certain contractual provisions that are considered to have certain positive attributes that might otherwise be deemed anticompetitive. The Regulation also sets out a

“blacklist” of clauses that are considered anticompetitive. The blacklisted clauses are divided into those that apply when the parties to the agreement are competing undertakings and those that apply when they are not competing undertakings.

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?

To date, the Irish Courts have provided no guidance on whether issues of patent validity and infringement would be heard separately from proceedings concerning the assessment of FRAND licence terms or the grant of FRAND-related injunctions.

8 Current Developments

8.1 What have been the significant developments, including any leading cases, in patent law and practice in your jurisdiction in the last year?

The most significant developments concerning patent law and practice in Ireland over the last year or so concern international jurisdiction and have taken place not in the Irish Courts but rather in the Courts of other EU Member States and in the UPC. In particular, issues concerning long-arm jurisdiction over patent infringement outside of the jurisdiction, based on domicile of one of the parties, as recently confirmed by the CJEU in *Electrolux*, has been considered by practitioners and companies.

In Ireland, judgment on the merits was handed down on 25 June 2025 in *Sandoz AG and Rowex Ltd v Bayer Intellectual Property GmbH* [2025] IEHC 357, where Bayer’s dosing regimen patent for X was revoked for lack of inventive step.

8.2 Are you looking forward to any particular developments in patent law or practice in the coming year or two and what effect might they have in your jurisdiction?

We look forward to resolution or at least substantial clarification of the question of jurisdiction of the UPC, including with

a CJEU decision on the referral from the UPC on that issue. We also look forward to seeing how proposals to significantly amend and reduce the scope of discovery in Ireland play out.

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

We have noticed increased activity relating to non-practising entities established in Ireland over the last year or so. We have also seen parties increasingly considering Ireland among other jurisdictions as part of their global enforcement strategies when considering venues to bring multi-jurisdictional claims in accordance with *Electrolux*.

8.4 Are there any key issues in relation to patent law or practice that you feel are not addressed by the questions above which are worth mentioning here?

Discovery can often be a significant part of Irish litigation, including patent litigation. Therefore, upcoming changes to the discovery regime would be of interest and are worth mentioning here.

The Civil Reform Bill 2025, published in January 2026, proposes a significant overhaul of Ireland’s discovery regime. The Bill would replace the current discovery process with a new framework requiring substantially greater upfront document production. The reform is intended to reduce delays and address the disproportionate costs often associated with discovery in Irish litigation. Under the proposed new regime, parties would be required to produce:

- all documents they intended to rely on at trial;
- documents relevant and material to the outcome that other parties would reasonably rely on; and
- documents necessary for the administration of justice.

A claimant would be required to produce such documents within 28 days of serving the claim form, while a respondent would have 42 days from the date of service of its defence to do likewise.

The proposed reforms remain under consideration, and it is therefore unclear what the final legislation will ultimately provide for or how the new regime, if enacted, will affect the conduct of litigation in practice.



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