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Ireland

Patent Litigation Q&A June 2024

Ireland – Patent Litigation

Where can patent infringement actions be started? Is there a choice of venue?

The High Court of Ireland has jurisdiction to hear infringement actions commenced under the Patents Act 1992 (as amended). Patent infringement proceedings are generally dealt with by the commercial division of the High Court, known as the Commercial Court.

The Intellectual Property Office of Ireland ("**IPOI**") has no jurisdiction to hear patent infringement actions. Applications for revocation of a patent can be brought to the High Court or the Controller of Intellectual Property (Controller).

Under Order 63A of the Rules of the Superior Courts (as amended) "**RSC**", intellectual property (IP) proceedings which include proceedings instituted under the Patents Act 1992 may be assigned to the Intellectual Property & Technology List, a specialist sub-division of the Commercial Court. Generally, in matters before the Commercial Court the value of the claim should exceed €1,000,000; however, there is no such threshold for IP proceedings.

It is preferable that patent infringement actions are entered into the IP & Technology List in the Commercial Court which benefits from efficient case management procedures, specialised judiciary, and a faster track to trial. In the alternative, the High Court can result in stagnated proceedings and much higher costs overall.

Actions for infringement of a short-term patent (which last for a maximum of 10 years) may be brought in the High Court or Circuit Court which normally has a monetary jurisdiction of up to €75,000 regardless of the value of the claim.

The Irish Government announced its intention to set up a local division of the Unified Patent Court ("**UPC**"). However, although Ireland signed the UPC agreement in 2013, it must hold a referendum to amend the Irish constitution and ratify the UPC. A referendum was due to take place on 7 June 2024, but this has been deferred and no alternative date has been confirmed by the Irish Government.

Are the judges' specialists? Do they have technical backgrounds?

Irish judges are generally assigned to lists which align with their experience and background. Judges assigned to the IP and Technology List have experience in the area. Notably judges can also call a specialist assessor to assist them when necessary.

How long does it take from starting proceedings to trial?

In the IP and Technology List, the expected time from starting proceedings to trial is 12 to 18 months. However, in urgent cases, such as when an injunction application has been refused on the basis that the proceedings are concluded expeditiously, the trial may take place in less than one year. It can take longer for proceedings to reach trial if extensive discovery is required or there are other interlocutory disputes.

Can a party be compelled to disclose documents before or during the proceedings?

Yes. A party can be compelled to disclose documents before and during the proceedings.

1. Duty to preserve.

In the first instance, where litigation is contemplated or ongoing, each party has an obligation to identify and preserve documents that may be relevant to the issues in the litigation.

2. Norwich Pharmacal Order

It is well settled in Ireland that the Courts have jurisdiction to make an Order for Discovery in an action that has been instituted solely for the purpose of establishing the identity of the wrongdoer on the basis that it may be of considerable value towards the attainment of justice. The person seeking the Order must have a genuine intention of commencing proceedings and must establish clear proof of a wrongdoing. An Order of this nature may only be sought for the purpose of establishing the identities of the wrongdoers, rather than obtaining

factual information concerning the commission of the wrong. This was confirmed by the Irish Supreme Court in *Megaleasing UK Limited v Barrett (No.2)* [1993] ILRM 497.

Prior to 2023 there was uncertainty as to the Irish position with respect to such orders. It remains the case in Ireland that this relief is exceptional. The Court of Appeal recently confirmed in *Blythe v. The Commissioner of An Garda Síochána [2023] IECA 255* that the threshold to establish "very clear proof of the existence of a wrongdoing" was too high of a barrier. However, the Court of Appeal did not accept that the position in Ireland was the same as that in England and Wales (i.e. that the plaintiff must simply demonstrate a "good arguable case" against the alleged wrongdoer) and instead confirmed that the appropriate test in Ireland is whether the applicant can demonstrate that it has a "strong case" against the alleged wrongdoer i.e. has the applicant shown that it is likely to succeed at trial. The Court confirmed that the Norwich Pharmacal jurisdiction should be "strictly limited" to disclosure sought for the purpose of bringing a claim, as opposed to material required to prove that claim. In rare cases, such as fraud, a Norwich Pharmacal Order may be granted to gather additional information needed to plead the claim against prospective defendants.

3. Anton Piller Order

The Court may also grant Anton Piller Orders (preservation orders where documents and items may be seized by the moving party) where there is a serious risk that articles or documents vital to a party's case may be imminently destroyed or otherwise disposed of.

4. Voluntary Discovery during the course of Proceedings

Discovery is a key component of the litigation process in Ireland. Either party to litigation is entitled to seek discovery of documents (the definition of which is broad and includes electronic information). The documents must be:

- In the possession, power or procurement of the other party;
- Relevant to the issues in the case; and
- Necessary for the fair disposal of the case or for the saving of costs.

Where discovery is to be sought, parties must write to each other first and seek to agree on the categories of documents to be discovered (this is referred to as voluntary discovery). If the categories cannot be agreed, the parties can apply to the court for an order requiring the other party to make discovery of the categories of documents sought. Discovery motions can be hard fought in IP cases.

Discovery must be made on affidavit and there is an ongoing obligation to discover documents falling within the scope of the discovery order (or the agreed discovery) that are in the power, possession or procurement of a party. All documents within the power, possession or procurement of a party must be listed and scheduled in the affidavit of discovery, including privileged documents. However, privileged documents need not be handed over to the other side.

As part of the discovery process, it is possible to request samples and/or to request an order for inspection. Where the interests of justice require, the inspection may be limited to solicitors, counsel, patent agents and/or independent experts. Interrogatories can also be useful to obtain admissions in respect of a defendant's product or process. Leave is not required from the Court to serve interrogatories in the course of proceedings before the Commercial Court.

Discovery process for matters in the IP and Technology List

(i) **Provision of Product or Process Description**

Order 94 Rule 14 RSC provides that where a party to proceedings in the IP and Technology List notifies another party of its intention to deliver full particulars of the features of the product or process alleged to infringe or breach another party's rights and any necessary drawings or other illustrations, it will not be necessary for the notifying party to make discovery of documents relating to the features of the product or process which is the subject matter of the notification, unless the judge, for special reasons to be set out in the Court's order, otherwise orders.

(ii) Alleged Commercial Success

Where a patentee intends to rely upon the commercial success of a patent in proceedings concerned with its validity, unless the Court, for special reasons to be set out in the Court's order, otherwise orders, under the revised Rules it is unnecessary for the patentee to make discovery of categories of documents relating to the

issue of commercial success, provided that the patentee has offered to deliver within a reasonable time a schedule containing specific information relating to the commercial success of the product in question.

How are arguments and evidence presented at the trial?

In Ireland, legal argument is centred on oral evidence and is adversarial in nature. The Court will also direct the parties to provide written legal submissions.

A variety of evidence may be submitted to the Court including:

1. Documentary Evidence

Documentary evidence is a commonly used form of evidence. A party who wishes to rely on a document may be required to "prove" the document by oral evidence. However, generally parties consent to the documents being admitted into evidence without the need for formal proof.

2. Witness Evidence

Witness evidence is normally provided as oral evidence and is subject to cross-examination. Deponents of affidavits in interlocutory and summary applications can be cross-examined with leave of the court.

- *Affidavit Evidence*: in certain circumstances (e.g. interlocutory motions), evidence is given on affidavit. The opposing party can apply for the deponent of the affidavit to appear before the court for cross-examination.
- *Witness Statement*: when a witness is due to provide oral evidence at trial, they are usually required to provide a witness statement in advance containing a precis of the oral evidence which they will give at trial.
- *Expert Evidence*: independent experts play a crucial role in patent proceedings in Ireland. They provide an expert report or expert witness statement before the hearing. Further, experts are invariably required to give oral evidence and are subject to cross-examination. While experts are instructed by a paying party, they must remain independent and have an overriding duty to the court. The expert must adopt the attributes of the person skilled in the art.

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

Hearings for interlocutory injunctions generally last anywhere between 3 days and 2 weeks. Interlocutory injunctions proceedings are normally heard, and decisions handed down, within six to twelve weeks of being issued. This can be expedited depending upon the circumstances and at the discretion of the Court.

The main action lasts anywhere between 2-6 weeks depending upon the amount of evidence at play. The expected timeline for the main infringement action would be 18 months. This will also depend upon preliminary matters like any motions for discovery, interrogatories etc. which can considerably delay the time to trial.

This timeline can lengthen considerably if the main infringement is appealed to the Court of Appeal. The current timeline for a case being heard by the Court of Appeal is between 9 - 18 months (depending on the complexity of the appeal). Further, it may take an additional 12 months for the Court of Appeal to issue its decision.

Irish Superior Court judgments are publicly available.

Can a defence of patent invalidity be raised? Are infringement and validity issues heard together?

Invalidity may be raised as a defence to infringement proceedings or in stand-alone revocation proceedings. Issues of infringement (if any) and validity are heard during the same proceedings.

A patent may be revoked on the grounds that:

1. the subject-matter of the patent is not patentable under the Patents Act;

- 2. 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;
- 3. the matter disclosed in the specification of the patent extends beyond that disclosed in the application as filed;
- 4. the protection conferred by the patent has been extended by an amendment which should not have been allowed; or
- 5. the registered proprietor of the patent is not entitled to the patent (by reason of the fact that he is, for example, neither the inventor nor his employer) (section 58, Patents Act).

Additionally, a short-term patent can be revoked if the claims of the patent specification are not supported by the description (section 67, Patents Act).

The burden of proof rests with the person bringing the application for revocation. The applicant must prove their case on the balance of probabilities, as decided by a judge sitting alone without a jury in the High Court or by the Controller.

Further, the Controller can revoke a patent on their own initiative (subject to providing the proprietor with an opportunity to make observations and amend the specification) for inventions that already form part of the state of the art (section 60, Patents Act). A patent application with an earlier filing or priority date, although published after the filing or priority date of the patent being considered, can be taken into account in determining novelty (sections 11(3) and 27(1), Patents Act).

The Controller can also revoke a patent in cases of double patenting where both a national patent and a European patent (designating Ireland and therefore dealt with under the Patents Act) have been granted and one must be elected by the proprietor.

Are infringement proceedings stayed pending resolution of validity in the national patent office (or, if relevant, the EPO) or another court?

The High Court found that the default position in Ireland remains that a stay on revocation proceedings in the Irish courts should be granted where there are proceedings concerning the patent in suit pending before the EPO (*Condensed Aminodihydrothiazine Derivative & The Patents Act 1992 [2018] IEHC 467*).

Notably, the Court also found that there may be good reasons why the default position should not be adopted. Conclusively, the High Court found that the balance of justice lay in staying the trial pending the determination of the EPO proceedings but refusing to stay the progress of the Irish proceedings up to the point of readiness for trial. Accordingly, a stay was refused with respect to discovery, the carrying out of experiments or the other interlocutory steps that would be required to be taken to put the proceedings in a state of readiness for trial.

Are preliminary injunctions available? If they are, can they be obtained *ex parte*? Is a bond necessary? Can a potential defendant file protective letters?

Preliminary injunctions ("**PI**") are available from the Irish Court in patent litigation proceedings. Whether a preliminary injunction will be granted by the Irish Court tends to be highly fact sensitive.

In 2019 the Supreme Court decision of *Merck Sharpe & Dohme Corporation v Clonmel Health Care Limited* [2019] *IESC 65 ("Merck Sharpe & Dohme decision")* reformulated the way in which the Irish courts apply the three-stage test set out in *American Cyanamid Company v Ethicon Limited* [1975] 1 *AER 504* and adopted by the Irish courts in *Campus Oil v the Minister for Energy* [1983] *IR 88.* While the Courts will consider the three factors set out in these decisions, they will also evaluate the risk of injustice which may result in granting or refusing an injunction. While the third hurdle (adequacy of damages) remains an important consideration, it is no longer determinative. It will now be a factor the Court will consider when deciding whether or not the balance of convenience lies with granting the injunction.

Following the Merck Sharpe & Dohme decision, the Supreme Court set out eight steps that a court should follow in determining whether to grant an injunction. Distilled down, the key questions a court will consider are:

- 1. Whether there is a serious/fair issue to be tried; and
- 2. The balance of convenience.

With respect to the balance of convenience the decision outlined some of the factors that may be considered and weighed in the balance by a court in considering how matters are to be held most fairly pending a trial, and in recognising the possibility that there may be no trial. While the Supreme Court highlighted that the most important element in the balance of convenience assessment is, in most cases, the question of adequacy of damages it also commented that this should not be dispositive, and that weight should be given to other factors. These factors may include:

- presumptive validity of IP rights,
- a preference for preserving the status quo ante, and
- whether the alleged infringer could have "cleared the way" by way of invalidity proceedings.

The Court emphasised that failing to clear the way would not be decisive and recognised that clearing the way may pose some problems for a generic manufacturer. It was nonetheless a factor to be weighed in the balancing exercise.

Since then, there have been a number of PI decisions in Ireland which have applied the Merck Sharp & Dohme decision and have highlighted the importance of "clearing the path" for generic entrants.

In March 2023, the Court of Appeal ruled in *Biogen MA Inc. & Biogen International GMBH v Laboratorios Lesvi SL & Neuraxpharm Ireland Ltd. [2023] IECA 71* that, when assessing clearing the path arguments in the balance of convenience, "the threshold test is that the case for invalidity must be strong and/or that there have been successive determinations on the merits invalidating the right" and only then "it might weigh against the grant of an injunction".

In a more recent Court of Appeal decision, *Bristol-Myers Squibb Holdings Ireland Unlimited Company v Norton (Waterford) Limited T/A Teva Pharmaceuticals Ireland [2023] IECA 173*, the principle of clearing the path was given further consideration. In this case, Teva had issued a revocation action on the grounds of invalidity and lack of priority. The purpose of the revocation action was to clear the path. When notice was given during the proceedings of intention to launch, BMS sought an interlocutory injunction restraining entry. The High Court granted a PI, which was appealed. In its judgment in June 2023, the Court of Appeal was firmly of the view that if a generic producer seeks to clear the path, it must do so until *"all arguable objections from the patentee have been eliminated"*, including the conclusion of any appeal. Furthermore, in response to the argument that a generic entrant should get credit for the steps that it had taken to attempt to clear the path, the court dismissed this argument, commenting that no cogent argument was advanced as to what weight, if any, should be given to a generic manufacturer that has tried to clear the path but has ultimately not yet done so. Teva sought leave to appeal that decision to the Supreme Court but was refused.

Since then and in the same case, the High Court at first instance again had to consider an application from BMS to continue the injunction already granted against Teva pending an appeal to the Court of Appeal with respect to the substantive decision which held that the patent in issue was invalid (*Bristol-Myers Squibb Holdings Ireland v Norton (Waterford) Limited t/a Teva Pharmaceuticals Ireland* [2024] IEHC 91). According to the High Court the decision as to the invalidity of patent rendered the previous granted injunction expired. Barrett J commented that "for what it is worth, there appears to be no reported case in this jurisdiction in which a generic company succeeded in revocation proceedings but was then injuncted from launching its generic product pending appeal". In response to this and BMS' submissions that the path is not cleared until all appeals have been resolved the Court considered this "a deficient proposition". The Court held that while it is "literally true" no question could ever arise as to an injunction if the path was fully cleared i.e. because if the path is fully cleared, that would mean that the patent in issue had been finally held by some appellate court to be invalid, and in that situation, no one could ever bring an application for an injunction. Accordingly, the Court held that "while clearing the path is a factor, its limitations and its context need to be borne in mind, which is clear from Merck".

The applicant for a preliminary injunction will need to adduce affidavit evidence in support of the application. In Ireland, the granting of preliminary and permanent injunctions is subject to equitable principles and therefore the Court always has discretion whether to order an injunction.

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

Are final injunctions available as of right? Is a bond necessary?

In Ireland, a final or permanent injunction is a discretionary remedy which is decided by the Court at the final determination of the case (section 47(1), Patents Act). It must be demonstrated to the Court that there is some activity to be injuncted on an ongoing basis. Where infringement and a threatened continuation of such infringement to a material extent, has been established, then the proprietor will have a *prima facie* entitlement to a permanent injunction. However, as a general principle of Irish law, the Irish Courts may refuse to grant a final injunction if it is considered that an award of damages alone is a more appropriate remedy. This would be assessed on a case-by-case basis in accordance with the Court's underlying discretion to grant an injunction.

A bond is not necessary.

What other remedies are usually ordered if a patentee is successful?

Other remedies which may be ordered if a patentee is successful include:

- Damages or an Account of Profits the plaintiff may elect for either damages or an account of the defendant's profits (section 47(1), Patents Act). Generally, damages are awarded only to compensate the loss suffered due to the infringement. In assessing the appropriate "quantum" to be awarded, a Court will therefore seek to place the plaintiff in the same financial position as they would have been in had the infringement not taken place. Loss of profits will, naturally, be central to this determination. The Court may also look to the amount which would have been payable by the defendant as a reasonable royalty for the infringing use. Damages are not generally awarded on a punitive basis in infringement actions.
- 2. Orders for Delivery up or Destruction This remedy can only be ordered in respect of patented articles, or of any article in which they are inextricably comprised. The articles must be within the power or possession of the defendant. Infringing goods which have been delivered and sold to third parties will not be within the power or possession of the defendants.

Would the tribunal consider granting cross-border relief?

This tribunal is not applicable in Ireland.

Is there a right of appeal from a first instance judgment? How long between judgment at first instance and hearing the appeal?

Yes, there is a right of appeal to the Court of Appeal on a first instance judgment from the High Court.

An appeal against a first instance decision on a combined infringement/invalidity action usually takes between 9-18 months, depending on the complexity of the appeal and whether an expedited appeal is granted or not. The duration of an appeal hearing before the Court of Appeal would depend on the number of issues involved.

In addition to the above, it may take an additional 12 months for the Court of Appeal to issue its decision depending on a variety of factors including the complexity of the case, judge availability, etc.

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. The standard of review on appeal for infringement and invalidity issues is such that findings of fact made by the trial judge that are supported by credible evidence will not ordinarily be overturned on appeal.

In certain circumstances new evidence can be adduced on appeal. The Supreme Court recently considered, in *Ennis v Allied Irish Bank [2021] IESC 12,* the test for adducing new arguments in (i) appeals from Plenary Judgments and; (ii) appeals from Summary Judgment / Interlocutory Orders.

• **Plenary Judgment**: The Supreme Court confirmed that an appellate Court needs to adopt a "sensible flexibility regarding the possibility of raising new grounds on appeal having regard to the "interests of justice".

• Summary Judgment / Interlocutory Orders: the Court outlined a threefold test to determine the admissibility of new evidence: (1) the evidence to be adduced must have been in existence at the time of the trial and must be such that it could not have been obtained with reasonable diligence for use at the trial; (2) it would probably have had an important influence on the result of the case, thought it need not be decisive; and (3) the new evidence must be presumed to be believed, that is, it must be apparently credible, though it need not be incontrovertible.

What is the cost of a typical infringement action to first instance judgment? If the issues of invalidity and infringement are bifurcated, what is the cost of the invalidity action? Can the winner's costs be recovered from the losing party? How much is the cost of an appeal?

The typical cost of an infringement/invalidity action is in the region of \leq 400,000 – \leq 750,000, plus counsel fees and other outlay.

The level of costs will depend on many factors including the length of proceedings, complexity of the issues, the extent of discovery, interlocutory applications, and so on. Costs are awarded at the conclusion of a case and at the discretion of the judge. The general principle is that costs are awarded to the successful party. In general, about one-half to two-thirds of the total legal costs incurred are recoverable. Where the parties cannot agree on quantum, the assessment of costs can be listed before the Legal Costs Adjudicator, who will settle the figure to be paid.

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

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