

Ireland

Legal basis

Compulsory licences can be granted in accordance with Sections 70 to 75 of the Patents Act 1992 (as amended) (hereinafter PA).

Provision for compulsory licences is also made in Irish secondary legislation as follows:

- S.I. No. 247/2000: European Communities (Legal Protection of Biotechnological Inventions) Regulations 2000 (which implemented the Biotech Directive); and
- S.I. No. 408/2008: European Communities (Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries With Public Health Problems) Regulations 2008 (which was implemented to give further effect to EU Regulation 816/2006).

In respect of SI No. 247/2000, Regulation 11(4) states that the provisions of the PA shall apply, with any necessary modifications, to applications for licences under the Regulations.

In respect of SI No. 408/2008, these Regulations specify the form for which an application for a compulsory licence under EU Regulation 816/2006 should be made to the Controller of Patents, Trade Marks and Designs in Ireland.

Grounds for applying for a licence

The Controller (or the arbitrator – as the case may be) will consider whether the grounds for the granting of a compulsory licence have been met.

The grounds on which an application can be made are as follows:

- 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; or
- that 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 WTO; or
- that the establishment or development of commercial or industrial activities in the State is unfairly prejudiced.



Furthermore, if an invention protected by a patent (“the second patent”) cannot be exploited in the State without infringing rights deriving from another patent (“the first patent”), the proprietor of the second patent may apply to the Controller for a licence under the first patent to the extent necessary for the exploitation of the invention concerned, provided that such invention involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.

General procedure

Applications are made to the Controller of Patents, Trade Marks and Designs. The application is made to the Controller in the first instance. The Controller may decide to refer the proceedings to an arbitrator if the parties agree or if he is of the view that the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot, in his opinion, conveniently be made before him.

The legislation does not specify what sort of arbitrator must be appointed, and as such it is someone who is selected by the Controller or the parties, but it would usually be someone very familiar with the type of patent in question and with sufficient knowledge in the field to be able to make an informed decision. There is no prescribed process for the appointment of the arbitrator in the legislation.

If the proceedings are not referred to an arbitrator, the Controller will make whatever decision he sees fit. If they are referred to an arbitrator, the arbitrator will make whatever decision he sees fit (unless he has only been asked to decide a question of fact, in which case he will report back to the Controller, who will then decide whether a licence should be granted).

A compulsory licence cannot be applied for until after three years from the date of publication of grant of the patent, after which any person may apply for a licence under the patent and/or for an entry to be made on the Register to the effect that licences are available as of right.

An application to the Controller can be made by any person, provided that the applicant first sought to obtain a licence from the proprietor of the patent but was unable to obtain one on reasonable terms and within a reasonable time.

The Controller may, when so requested by the applicant, dispense with the requirement for the above evidence in the event of a national emergency or other circumstances of extreme urgency, or in the case of an application for a licence for public non-commercial use, provided that the proprietor of the relevant patent has been informed as soon as reasonably practicable of the intention of the applicant to apply to the Controller for a licence under the patent.

If the Controller is not satisfied that a prima facie case has been made out for making the order, he shall notify the applicant accordingly and the applicant will then have one month to request a hearing on the matter. If no such hearing is requested, the application will be refused. If the applicant requests a hearing within the time allowed, the Controller, after giving the applicant an opportunity of being heard, will determine whether the application may proceed to advertisement or whether it shall be refused.

The proprietor of the relevant patent (or any other person who wishes to oppose the application) will then be given an opportunity to oppose the application within three months of the application being advertised in the Journal by the Controller.

Where an application is opposed by the proprietor of the patent, the Controller may also order the whole proceedings (or any question or issue of fact arising therein) to be referred to an arbitrator if he is of the view that the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot, in his opinion, conveniently be made before him. All or part of the proceedings can also be referred to an arbitrator if both parties consent.

Where an issue of fact is referred to an arbitrator, the arbitrator shall report his findings to the Controller, who will then make a decision.

The Irish courts have not, to date, granted a compulsory licence by way of preliminary relief.

Where the Controller makes an order for the grant of a compulsory licence, the licence will be granted upon such terms as the Controller thinks fit. Similarly, if the proceedings are referred to an arbitrator, the arbitrator will grant a licence upon such terms as he/she thinks fit, although it is not open to the arbitrator to grant a licence which it would not have been possible for the Controller to grant.

The terms of the licence must be non-exclusive and must be predominantly for the supply of the market in the State. The licence may not be assigned without the prior consent of the Controller and with that part of the enterprise or goodwill which uses the patented invention.

The scope and duration of the licence must also be limited to the purpose for which it is granted.

If the licence granted is in respect of a patent that relates to semiconductor technology, the licence must be for public non-commercial use only.

Furthermore, a licence will be granted only subject to the payment to the proprietor of the patent of adequate remuneration in the circumstances of the case, taking into account the economic value of the licence.

If an invention protected by a patent ("the second patent") cannot be exploited in the State without infringing rights deriving from another patent ("the first patent"), the proprietor of the second patent may apply to the Controller for a licence under the first patent to the extent necessary for the exploitation of the invention concerned; no licence can be granted unless the proprietor of the second patent is able and willing to grant the proprietor of the first patent and the licensee of that proprietor a cross-licence, on reasonable terms, to use the invention claimed in the second patent.

Appeal/review

Where the whole proceedings have been referred to an arbitrator, an appeal to the High Court shall lie from that decision.

A decision of the Controller can also be appealed to the High Court. The decision of the High Court can be further appealed to the Court of Appeal on a point of law. If the

matter is of general public importance or the interests of justice require it, an appeal shall lie to the Supreme Court.

Every appeal to the High Court from an order or decision of the Controller must be made by special summons. The summons shall be served upon the Controller and upon all other persons (if any) interested.

The summons shall state whether the appeal is from the whole or part only, and if so what part, of the order, decision or award, and shall also state concisely the grounds of the appeal. No grounds other than those so stated shall, except with the leave of the Court, be allowed to be taken by the appellant at the hearing.

The summons must be issued within one calendar month from the date of the order or decision of the Controller, or the award of the arbitrator (as the case may be) appealed against, or within such further time as the Controller may have allowed for the purpose.

Every such appeal to the Court shall be by way of rehearing and shall be heard on the materials stated by the Controller to have been used by him in arriving at his decision. Every appeal shall be heard on the same evidence as that used at the hearing before the Controller. No further evidence shall be given, nor further material be brought forward for the consideration of the Court on the hearing of any appeal without special leave of the Court granted on an application made at or before the hearing.

Statistics and jurisprudence

No statistics are available on the number of applications for compulsory licences in Ireland. Applications for compulsory licences are not particularly common.

There are very few Irish cases which consider the circumstances in which compulsory licences should be granted.

In the case of *Hunter v Fox* [1966] 1 IR 520, the Irish Supreme Court held that even though there was a void restrictive clause in an agreement, this did not necessarily mean that demand was not being met on reasonable terms. However, this case was decided under legislation that has now been repealed. Such a restrictive clause would now fall foul of Section 83 of the Patents Act 1992 (as amended).

Decisions of the UK courts are likely to be considered of persuasive effect by the Irish courts and so it may be instructive to consider these, although again it must be

borne in mind that these cases have often been decided under now repealed legislation.

In *Brownie Wireless Co Ltd's Application* (1929) 46 RPC 457, the UK courts held that what is meant by "reasonable terms" involves a review "of all the surrounding circumstances including the nature of the invention, the terms of existing licences, if any, the expenditure and liabilities of the patentee in respect of the patent, the requirements of the purchasing public and so on".

In *Research Corporation's (Carboplatin) Patent* [1990] RPC 663, the plaintiff sought a compulsory licence in the UK for a drug used in the treatment of certain cancers. It already formulated and sold the drug in Australia, where there was no patent protection. Bristol-Myers had an exclusive licence under the patent in the UK for a term of 10 years from the first sales in the U.K.

The UK Comptroller granted the plaintiff a sub-licence from the UK licensee. The Plaintiff appealed this decision. The appeal was dismissed for a number of different reasons. However, the case is instructive for its consideration of what is meant by "failure to meet demand". The Court held that "demand", unless wholly inelastic, must mean demand at a given price. If the price being charged by the patentee or the licensee was reasonable and the demand at that price was being fully met, it was irrelevant to argue that the demand would be greater at a lower price.

In *Penn Engineering and Manufacturing Corpn's Patent* [1973] RPC 233, the decision of the Comptroller to grant a compulsory licence on the basis that demand for the patented article in the United Kingdom was being met solely by importation was upheld on appeal. This case is also interesting because the export of the patented article was also permitted under the terms of the compulsory licence.

In *Monsanto's CCP Patent* [1990] FSR 93 it was held that the onus was on an applicant for a compulsory licence to show that the licence offered by the patentee was not on reasonable terms. The mere allegation was not in itself conclusive evidence that commercial or industrial activity was being unfairly prejudiced. This reasoning may still arguably apply by analogy in the case of unfair prejudice to the establishment or development of commercial or industrial activities in the State under Section 70 of the Patents Act 1990.

