

United Kingdom

Legal basis

Compulsory licences under Section 48 Patents Act

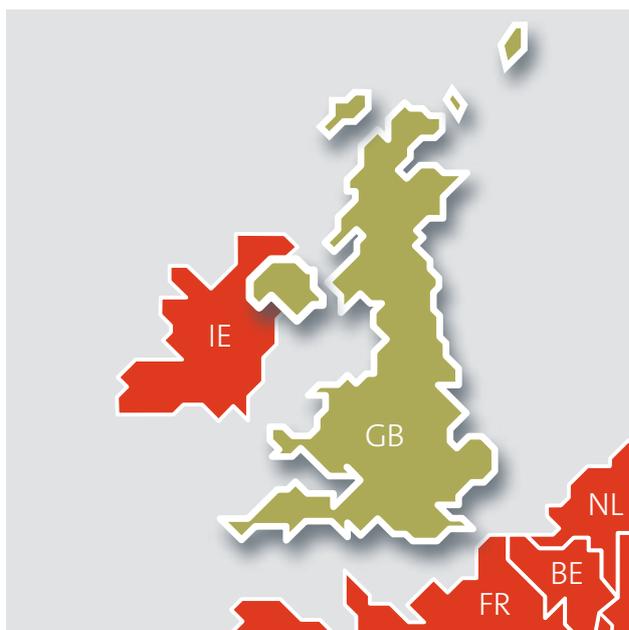
Compulsory licences are available for patents that were granted three or more years ago¹ under Sections 48 to 54 Patents Act 1977 (the “Patents Act”). Some of the provisions contained in these sections, particularly those relevant to WTO proprietors (defined below), derive from the UK’s obligations arising under the TRIPS Agreement.

The basis for obtaining a compulsory licence under the Patents Act depends on whether or not the proprietor is a national of, or is domiciled in, a country which is a member of the WTO, or has a real and effective industrial or commercial establishment in such a country (a “WTO proprietor”). The procedure and grounds for obtaining a compulsory licence under Section 48 Patents Act are discussed below.

Other compulsory licences

Compulsory licences over plant variety rights are also available pursuant to Art. 12 Biotech Directive, enacted into the UK by Statutory Instrument. This provides that, where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.

Finally, EU Regulation 816/2006 (the “Compulsory Licensing Regulation”) has been implemented into UK law through the introduction of Section 128A of the Patents Act. These Regulations arise from the TRIPS Agreement and are intended to be part of wider European and international action to address public health problems faced by least developed countries and other developing countries, and in



particular to improve access to affordable medicines which are safe and effective, including fixed-dose combinations, and whose quality is guaranteed².

Grounds for applying for a licence

The relevant grounds for obtaining a compulsory licence to a WTO proprietor patent or a non-WTO proprietor patent differ, and are discussed below, but in general they are concerned with determining whether a monopoly is being used against public interest.

WTO Proprietors

For WTO proprietor patents, the relevant grounds for obtaining a compulsory licence are³:

(a) where the patented invention is a product, that a demand⁴ in the UK for that product is not being met on reasonable terms⁵;

1 Patents Act, s48(1)

2 Compulsory Licensing Regulation, recital 5

3 Patents Act, Section 48A(1)

4 There must be an actual demand, rather than one which is hoped and expected to be created should a licence be granted (*Cathro's Applications* (1934) 51 RPC 75). Whilst this case was decided under repealed patent statute, it is still considered to be applicable today.

5 The answer to the question of what constitutes “reasonable terms” must in each case depend on a careful consideration of all the surrounding circumstances. The nature of the invention, the terms of the licences (if any) already granted, the expenditure and liabilities of the patentee in respect of the patent, the requirements of the purchasing public, and so on (*Brownie Wireless Co Ltd's Applications* (1929) 46 R.P.C. 457, 473). In order to be “reasonable”, any price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand, although this is not to deny that demand and price are almost always related (*Swansea Imports' Application* BL O/170/04). Further, if the price being charged by the patentee or its licensee is reasonable and the demand at that price is being fully met, it is irrelevant to say (as one almost invariably could) that the demand would be greater at a lower price (*Research Corporations' (Carboplatin) Patent* [1990] RPC 663).

(b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms

(i) the exploitation in the UK of any other patented invention that involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or

(ii) the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced;

(c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the UK, is unfairly prejudiced.

Further, the applicant must have made efforts to obtain a licence from the WTO proprietor on reasonable commercial terms and conditions, and his efforts must have not been successful within a reasonable period⁶. Note that WTO proprietor patents in the field of semiconductor technology are excluded from the compulsory licensing regime⁷.

Non-WTO proprietors

For non-WTO proprietor patents, the relevant grounds for obtaining a compulsory licence are⁸:

(a) where the patented invention is capable of being commercially worked in the UK, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable⁹;

(b) where the patented invention is a product, that a demand for the product in the UK

(i) is not being met on reasonable terms: or

(ii) is being met to a substantial extent by importation from a country which is not a member state;

(c) where the patented invention is capable of being commercially worked in the UK, that it is being prevented or hindered from being so worked

(i) where the invention is a product, by the importation of the product from a country which is not a member state;

(ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;

(d) that by reason of the refusal of the proprietor of the patent to grant a licence of licences on reasonable terms

(i) a market for the export of any patented product made in the UK is not being supplied¹⁰; or

(ii) the working or efficient working in the UK of any other patented invention which makes a substantial contribution to the art is prevented or hindered; or

(iii) the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced;

(e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the UK, is unfairly prejudiced.

Note that unlike WTO proprietor patents, there is no obligation on the applicant to have made efforts to obtain a licence from the proprietor prior to making an application.

Finally, with respect to compulsory licences under the Biotech Directive, it is necessary to try and obtain a licence voluntarily from the right owner before applying for a compulsory licence. Further, in order to obtain a licence under Art. 12 Biotech Directive, the applicant must show¹¹:

⁶ Patents Act, Section 48A(2)

⁷ Patents Act, Section 48A(3)

⁸ Patents Act, Section 48B(1)

⁹ A compulsory licence will not be ordered if the patent invention is being commercially worked in a country which is a member state, and demand in the UK is being met by importation from that country (Patents Act, Section 48B(3)). This provision is particularly important in light of the free movement of goods arising from of Art. 34 of the Treaty on the Functioning of the European Union (TFEU). See *Re Compulsory Patent Licences: EC Commission v United Kingdom* (C-30/90) [1992] 1 E.C.R. 777, which addressed this issue prior to the introduction of this provision. Further, the applicant must show what the demand for the invention might reasonably be expected to be, and how far short, if at all, production under the patent falls, as far as is practicable to supply it (*Kamborian's Patent* [1961] RPC 403).

¹⁰ Note that a licence granted under this ground must contain provisions as appear to the UKIPO to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee (Patents Act, Section 48B(4)).

¹¹ The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002, Regulations 3 and 6.

(a) that they cannot acquire or exploit plant breeders' rights or a Community plant variety right without infringing a prior patent;

(b) that they have applied unsuccessfully to the proprietor of the prior patent for a licence to use that patent to acquire or exploit plant breeders' rights or a Community plant variety right; and

(c) the new plant variety, in which the applicant wishes to acquire or exploit the plant breeders' rights or Community plant variety right, constitutes significant technical progress of considerable economic interest in relation to the invention protected by the patent.

General procedure

The competent authority to grant a compulsory licence is the Comptroller i.e. the UK Intellectual Property Office (the "UKIPO").

Given their greater scope, the below information focuses on the procedure for compulsory licences under the Patents Act, Sections 48 to 54. The procedures for compulsory licences under the Biotech Directive and the Compulsory Licensing Regulation are, however, largely similar.

An application for a compulsory licence may be made by anyone, including an existing licensee¹². The application is made to the UKIPO by filing Patents Form 2 on one of the grounds set out above. This must include a concise statement of the facts on which the applicant relies¹³, as well as the period or terms of the licence which it believes are reasonable¹⁴.

The proprietor of the relevant patent (and anyone else that the UKIPO believes is likely to have an interest in the applicant) is informed by the UKIPO of the application. The application is also advertised in the Official Journal¹⁵.

The proprietor (or any other person) may then oppose the application within four weeks from the advertisement by giving the UKIPO notice of opposition (i.e. by filing a

counterstatement in the proceedings), which must be considered when deciding whether to grant a compulsory licence¹⁶. The applicant is informed of any filed opposition and all parties are informed of the time by which any evidence must be submitted¹⁷.

Once the evidence has been concluded, the application is then decided by the UKIPO, which may involve an oral hearing¹⁸. This involves a two-step process, namely, determining whether a relevant ground has been satisfied, followed by an exercise of discretion, during which the UKIPO must take account of¹⁹:

(a) the nature of the invention, the time which has elapsed since the publication in the journal of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;

(b) the ability of any person to whom a licence would be granted under the order concerned to work the invention to the public advantage²⁰; and

(c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted.

A decision will be made based on the balance of probabilities. If the application for a compulsory licence is successful, the UKIPO may then order that a licence be granted²¹ or if the applicant is already a licensee, the UKIPO may amend the existing licence or order for it to be cancelled and grant a new licence²².

It is possible for a defendant to apply for a compulsory licence before the UKIPO and simultaneously deny infringement in parallel court proceedings. However, pending compulsory licence proceedings before the UKIPO are not usually sufficient reason to justify staying infringement proceedings before the court, and so they will not ordinarily be obtainable by way of preliminary relief. That being said, in the event that a compulsory licence is granted by the UKIPO before the patent infringement action is heard before the court, then the court may refuse to grant an injunction.

12 Patents Act, Section 48(3)

13 Patents Rules 2007, r76(4)(a)

14 Patents Rules 2007, r76(4)(c)

15 Patents Rules 2007, r75

16 Patents Act, Section 52(1)

17 Note that an applicant cannot seek discovery from the proprietor to establish a relevant ground in its evidence (*Richco Plastic Co's Patent* [1989] RPC 722).

18 Patents Rules 2007, r80(4)

19 Patents Act, Section 50(2)

20 An applicant does not need to show contracts or firm agreements for finance or other forms of assistance to work the invention, but the UKIPO will need to establish whether the applicant is likely to have available to them the various resources, including technical expertise and know-how, which would be necessary to put the inventions into practice in a way that would benefit the public (*Enviro-Spray Systems Inc's Patents* [1986] RPC 147).

21 Patents Act, Section 48(2)(a)

22 Patents Act, Section 49(2)

A proprietor (or any other person) may apply for the termination of a compulsory licence to a WTO proprietor patent (which may be opposed) if the circumstances that led to the making of the order have ceased and are unlikely to recur²³. This will be a matter of discretion for the UKIPO. Termination is not, however, available in relation to non-WTO proprietor patents.

Where there is opposition to an application for (or termination of) a compulsory licence and the parties consent, or the proceedings require prolonged examination of documents or scientific or local investigation which cannot in the opinion of the UKIPO conveniently be made before it, then the matter (or any part thereof) may be referred to arbitration²⁴.

If an application for a compulsory licence is successful, the UKIPO may order the grant of a licence to the applicant on such terms as it thinks fit²⁵. The terms of the licence will depend on the facts of each case.

Factors the UKIPO will consider when exercising its discretion as to the terms of a compulsory licence will depend on whether or not the proprietor of the patents is a WTO proprietor. In particular, in respect of WTO proprietor patents, the licence²⁶:

- (a) shall not be exclusive;
- (b) shall not be assigned except to a person to whom there is also assigned the part of the enterprise that enjoys the use of the patented invention, or the part of the goodwill that belongs to that part;
- (c) shall be predominantly for the supply of the market in the UK²⁷;
- (d) shall include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case, taking into account the economic value of the licence; and
- (e) shall be limited in scope and in duration to the purpose for which the licence was granted.

The above provisions do not apply to compulsory licences concerning non-WTO proprietor patents. In these circumstances, however, the UKIPO should have regard to the following general purposes when exercising its discretion as to the terms of the compulsory licence (which, for the avoidance of doubt, are not applicable to WTO proprietor patents)²⁸:

- (a) that inventions which can be worked on a commercial scale²⁹ in the UK shall be worked there without undue delay and to the fullest practicable extent;
- (b) that the inventor or other person entitled shall receive reasonable remuneration having regard to the invention; and
- (c) that the interests of any person working or developing an invention in the UK shall not be unfairly prejudiced³⁰.

Further, as with WTO proprietor patents, compulsory licences to non-WTO proprietor patents must not be exclusive³¹.

The UKIPO applies its discretion and the factors outlined above by considering what would result from negotiations between a willing licensor and a willing licensee, particularly when considering appropriate royalties³².

Guidance may also be found on the approach taken by the UKIPO in the context of "licences as of right" i.e. the approach taken by the UKIPO when settling terms of a licence under a patent that are available as of right. These arise when either a proprietor has volunteered their patent to be open to licensing³³ or by order of the UKIPO³⁴.

Appeal/review

A decision of the UKIPO may be appealed to the Patents Court³⁵.

23 Patents Act, Subsection 52(2) and (3)

24 Patents Act, Section 52(5)

25 Patents Act, Section 48(2)(a)

26 Patents Act, Section 48A(6)

27 The licence may accordingly place restrictions on exportation.

28 Patents Act, Section 50(1)

29 "Commercial scale" was considered in *McKechnie Bros Ltd's Application* (1934) 51 R.P.C. 461, 468. to mean "in contradistinction to research work or work in the laboratory".

30 The fact that the proprietor may be prejudiced by loss of its own market share cannot of itself be said unfairly to prejudice the proprietors (and any licensees). (*Therma-Tru Corporation's Patent* (BL O/92/96))

31 *Allen & Hanburys Ltd v Generics* (UK) Ltd [1986] R.P.C. 203, HL

32 *Montgomery Reid's Application* BL O/145/83

33 Patents Act, Section 46(1)

34 Patents Act, Section 48(2)(b)

35 Patents Act, Section 97

Where a proprietor did not oppose the application, it is unlikely that they will be permitted to appeal the UKIPO's decision, on the basis that in the absence of an opposition the proprietor is considered to have supported the applicant's case³⁶.

If the decision concerning a compulsory licence under the Patents Act was referred to arbitration, any appeal shall lie from the award to the court, unless the parties otherwise agree before the award of the arbitrator is made³⁷.

Statistics and jurisprudence

In practice, compulsory licences are rarely granted in the UK. Applications for compulsory licences are accordingly infrequent. By way of illustration, since 2002 the UKIPO has received four filings for compulsory licences under Section 48 Patents Act, of which two were withdrawn, with the remaining two applications resulting in one decision, namely, Swansea Imports' Application³⁸.

In Swansea Imports' Application, an application for a compulsory licence was made in respect of heater units manufactured by the patentee for use in caravans. The patentee was acquired and the manufacture of the heater units in issue subsequently ceased, causing the products to no longer be installed in new caravans. The applicant therefore wished to continue to repair and replace (using existing stock) the heater units falling under the patent. It therefore sought a compulsory licence by arguing that there was a demand among users of the old heater units for new heaters of similar design, which was not being met.

The patent was a WTO proprietor patent, and so the UKIPO considered whether the conditions set out in Section 48A(1) Patents Act were met (as set out above). The UKIPO cited Cathro's Application³⁹, and in particular the principle that the demand to be established must be an actual one and not merely one which an applicant hopes and expects to create. After considering the evidence, the UKIPO considered that many of the spare parts needed to repair the heaters are generic spare parts (such as bolts), and there was no evidence as to which of these may fall within the scope of the patent.

With respect to replacing complete heater units, whilst the patentee did not deny that some demand existed for these, the UKIPO asked two questions, namely, whether there is a demand, and whether that demand is being met. The UKIPO relied on evidence indicating that some intermediaries (i.e. dealers) retained the particular heater units in stock that were not being sold, and so found that the demand is being met by the existing supply held by dealers.

Therefore, in summary, the UKIPO found that the applicants failed to show that the situation amounted to a failure to meet the demand on reasonable terms, and for this reason, the application for a compulsory licence was refused.

Cases have been provided in the footnotes where relevant. There are earlier cases where a compulsory licence has been granted under Section 48 Patents Act. These include Gebhardt's Patent⁴⁰ and F Hoffmann La Roche & Co AG's Patent⁴¹.

Gebhardt's Patent was an appeal to the Patents Court. The patented invention, namely, an accumulation conveyor for articles such as packages and pallets, was manufactured and sold under licence by a UK company which became insolvent. As a result, exploitation of the patented invention in the UK ceased for five years, after which time a new company was established (formed with personnel from the insolvent company), and the patentee refused to grant the new company a similar licence. The new company therefore applied for a compulsory licence, which was opposed by the patentee.

No evidence was provided by the patentee before the UKIPO on whether the existing demand in the UK was being met in the UK or by importation from another member state of the EU, and the Patents Court refused to admit new evidence on appeal.

Further, the Patents Court found that the market for the patented invention greatly exceeded the proprietor's expected sales and there would be good ground for granting a compulsory licence even if the proprietor was manufacturing in the UK. The ground set out in what was then Section 48(3)(a) Patents Act (and now Section 48B(1)(a), i.e. the patented invention not being worked to fullest practicable extent in UK, was therefore established.

³⁶ Patents Rules 2007, r77(9)

³⁷ Patents Act, Section 52(6)

³⁸ BL O/170/04

³⁹ (1934) 51 RPC 75

⁴⁰ [1992] R.P.C. 1

⁴¹ [1970] F.S.R. 225

F Hoffmann La Roche & Co AG's Patent concerned whether a compulsory licence should be granted over a patent concerning quinazoline, an intermediate used in the manufacture of the drug chlordiazepoxide⁴². The applicants wished to import quinazoline for manufacture of chlordiazepoxide in the UK. The UKIPO, and Patents Court on appeal, found that a licence to import quinazoline should be granted on the basis that the licensed intermediate should be used solely for the manufacture of the drug⁴³.

⁴² A compulsory licence had already been granted in respect of the drug chlordiazepoxide. This was granted under old legislation i.e. Patents Act 1949, Section 41(1). Whether such a licence would have been granted under the current legislation is doubtful.

⁴³ Again, this was decided under the old legislation, although the principle would likely apply under the current legislation.