43

INFRINGING ACTS AND 'LITERAL INFRINGEMENT'

Australia

Infringing Acts

Under Australian law, infringement is the doing of an act, without the authority of the patentee, which the patentee has the exclusive right to do.[1] The exclusive rights of the patentee are set out in s 13(1) of the Patents Act 1990 (Cth): **43.1.01**

> Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.

'Exploit' is defined in Sch 1 to the Act as: **43.1.02**

> (1) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
> (2) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

The exploitation must occur in Australia, the Australian continental shelf, the waters above the continental shelf, or the airspace above Australia and the Australian continental shelf.[2] A person outside Australia may be liable in patent infringement proceedings under the **43.1.03**

[1] *Bristol-Myers Squibb Company v F H Faulding & Co Limited* (2000) 97 FCR 524; *Eli Lilly and Company v Pfizer Overseas Pharmaceuticals* [2005] FCA 67.
[2] Patents Act 1990 (Cth), s 13(3); Sch 1, 'patent area'.

law of contributory infringement or authorization of infringement even if they have not committed an infringing act within the jurisdiction.[3]

43.1.04 'To make' means to do all things required to create the whole invention. Thus, a person who prepares design drawings does not make the invention.[4] However, it is still patent infringement to make the entire invention in the course of making an end product which does not infringe.[5]

43.1.05 Use of a product or process in anything more than an unimportant or trifling way in the course of producing a non-infringing product or process is still an infringing use of the invention.[6] Although it has not been universally adopted, there is case law to suggest that in order to 'use' an invention, a person should derive some commercial advantage from it.[7]

Literal Infringement

43.1.06 The test for literal infringement of a patent claim under Australian law is whether the alleged infringing product, method or process takes each of the essential integers of the claim. Thus, the scope of the claims must first be construed by the court.[8] The essential integers are determined by a common sense assessment of what the words of the claims convey in the context of then-existing common general knowledge.[9]

43.1.07 Thus, if on its true construction, the claim is for a particular combination of integers and the alleged infringer omits one of the essential integers, the infringer escapes liability. A defendant will not escape liability if an inessential integer is omitted or replaced by an equivalent.[10]

References

Bucknell, D., Beattie, K., Rofe, H. M., and Goatcher, P. A., *Australian Patent Law* (Butterworths, 2004), s 120

Dwyer, J. W., Dufty, A., Lahore, J., and Garnsey, J., *Patents, Trade Marks & Related Rights* (LexisNexis, 2005), ss [8025], [8156], [8213], [18,000], [18,075], [18,080], [18,095]

IPAC Report, 33–5, 66–8

Terrell (12th edn), chs 6 and 14

[3] See Chapter 45.

[4] *Cave Holdings Pty Ltd v Taperline Pty Ltd* (1985) 4 IPR 476 at 482; *Pinefair Pty Ltd v Bedford Industries Rehabilitation Association Inc* (1998) 42 IPR 330.

[5] *Pinefair Pty Ltd v Bedford Industries Rehabilitation Association Inc* (1998) 42 IPR 330.

[6] *Saccharin Corp v Anglo-Continental Chemical Works Ltd* (1900) 17 RPC 307; *Beecham Group Ltd v Bristol Laboratories International SA* [1978] RPC 521; *Pinefair Pty Ltd v Bedford Industries Rehabilitation Association Inc* (1998) 42 IPR 330.

[7] *Pinefair Pty Ltd v Bedford Industries Rehabilitation Association Inc* (1998) 42 IPR 330 at 340; see also Chapter 51 for discussion of the 'Experimental Use' defence in Australia.

[8] See Chapter 4.

[9] *Pharmacia Italia SPA v Mayne Pharma Pty Ltd* [2005] FCA 1078; *Populin v H B Nominees Pty Ltd; Populin v Binder* (1982) 41 ALR 471.

[10] *Populin v H B Nominees Pty Ltd* (1982) 41 ALR 471; *Populin v Binder* (1982) 41 ALR 471.

Canada

Infringing Acts

43.2.01 The Canadian Patent Act does not provide a definition of what constitutes infringement. Section 42 of the Act provides that the grant of a patent affords the patentee the exclusive right of 'making, constructing and using the invention', as well as the exclusive right of selling the invention to others to be used. The Canadian courts have used the wording of s 42 to frame the concept of infringement. Consequently, there is infringement where any person (other than the patentee or a licensee) makes, constructs, uses or vends to others, the subject matter claimed by the patent.

43.2.02 The absence of a statutory definition for infringement has meant that the courts have taken a broad approach to this issue. Generally, any act that interferes with the exercise of the patentee's monopoly will constitute infringement.

43.2.03 The concept of 'use' of a patented invention gives rise to inherent ambiguity, especially with respect to the degree of remoteness associated with the defendant's actions relative to the claimed subject matter.

43.2.04 Recent jurisprudence indicates that even indirect use may be sufficient to underpin a finding of infringement. In *Monsanto Canada Inc v Schmeiser*,[11] the Supreme Court of Canada concluded that the collection, saving, and planting of seeds containing Monsanto's patented gene and cell, constituted a 'use' of the gene and cell. By cultivating, harvesting and selling plants incorporating the patented cells or genes, the defendant had deprived Monsanto of the full enjoyment of the patent monopoly, and had secured a commercial benefit in doing so. In making this finding, the court set out the following principles:

(1) 'Use', in its ordinary meaning, denotes a utilization with a view to production or advantage.
(2) The basic principle in determining whether the defendant has 'used' a patented invention is whether the inventor has been deprived, in whole or in part, directly or indirectly, of the full enjoyment of the monopoly conferred by the patent.
(3) If there is a commercial benefit to be derived from the invention, it belongs to the patent holder.
(4) It is no bar to a finding of infringement that the patented object or process is a part of or composes a broader unpatented structure or process, provided the patented invention is significant or important to the defendant's activities that involve the unpatented structure.
(5) Possession of a patented object or an object incorporating a patented feature may constitute 'use' of the object's stand-by or insurance utility and thus constitute infringement.
(6) Possession, at least in commercial circumstances, raises a rebuttable presumption of 'use'.
(7) While intention is generally irrelevant to determining whether there has been 'use' and hence infringement, the absence of intention to employ or gain any advantage from the invention may be relevant to rebutting the presumption of use raised by possession.

[11] 31 CPR (4th) 161.

43.2.05 Infringement is a question of fact to be determined by the court. When determining the issue of infringement, the court must compare the defendant's product with the product as claimed by the plaintiff's patent; and not with the plaintiff's product as sold in the marketplace.[12]

Literal Infringement

43.2.06 In considering the issue of infringement, a Canadian court will first construe the patent. The specification is addressed to a person skilled in the relevant art and must be construed through the eyes of such a person. Expert evidence may be presented to the court, but the construction of the patent is a matter of law reserved for the court. See Chapter 4 for a discussion of the principles to be applied in construing patent claims in Canada.

43.2.07 The concept of 'literal infringement' is no longer applied in Canada. Traditionally, the courts adopted a two-step approach to an infringement analysis. After construing the patent, the text of the claim was compared with the allegedly infringing subject matter to determine if all integers were present. If so, 'literal infringement' would be established. In the event of any differences, the court would then assess whether the defendant had nonetheless adopted the 'pith and substance' of the claimed invention. Essentially, this amounted to an application of the doctrine of equivalents.

43.2.08 However, this 'two stage' infringement analysis has now been explicitly rejected by the Supreme Court of Canada, in favour of the doctrine of purposive construction.

43.2.09 Once the claims are purposively construed and the essential elements of the invention are identified, there will be no infringement if an essential element is different or omitted from the defendant's product or process. For example, if the claims are construed as being directed to a pharmaceutical compound which is be 'highly pure' and 'in substantially amorphous form', there is no infringement unless the defendant's product possesses both of these characteristics.[13]

43.2.10 Similarly, a patent which claimed an extended release composition comprising a drug and an effective amount of a wetting agent (which may be a sugar) was not infringed by a composition containing the drug and a sugar as an excipient, where the preparation was formulated such that the sugar cannot function as a wetting agent.[14]

China

43.3.01 Chinese patent laws do not provide clear guidance on the meaning of direct infringement. However it is generally understood that under Art 11 of the Patent Law any of the following, if not authorized by a patent holder, constitutes direct infringement of a patent:

- making products covered by one or more patents for invention/utility model/design;
- using products covered by one or more patents for invention/utility model;

[12] *DuPont Canada Inc v Glopak Inc*, 81 CPR (3d) 44.
[13] *Glaxo Group Ltd et al v Minister of National Health and Welfare et al,* 11 CPR (4th) 417.
[14] *Biovail Corp v Canada (Minister of Health)*, 32 CPR (4th) 210.

- offering to sell products covered by one or more patents for invention/utility model/design;
- selling products covered by one or more patents for invention/utility model/design;
- importing products covered by one or more patents for invention/utility model/design;
- using a process covered by one or more patents for invention;
- using, offering to sell, selling, or importing products directly obtained by a process covered by one or more patents for invention.

43.3.02 Chinese patent laws also provide no information on literal infringement. However in provisional guidelines [15] of Beijing Higher Court published in 2003, literal infringement is interpreted as full-coverage infringement, which means the accused product or process reproduces all the necessary technical features of the technical solution claimed in a patent, and the accused infringing product or process is in full correspondence and identical with all the necessary technical features in the independent claims of the patent. In other words, if the technical features of the accused product or process contain all the necessary technical features of the claims of a patent, then the accused product or process falls into the scope of protection of the patent.

India

Overview

43.4.01 Infringement is a mixed question of law and fact.[16] Infringement may be in a number of ways, one of which is by using the patent or any colourable imitation thereof in the manufacture of the patented article. The infringement does not need to be of the complete process but only in part. If there is an infringement in parts, it is necessary that the protection which is sought for such part is material or entirely new.[17] To ascertain infringement, it has to be shown that the 'invention' has been taken in some way. The Patents Act, 1970 is silent on what qualifies as 'infringement' of a patent, although, s 48 of the Act gives exclusive rights to the patentee, his agent, or licensee to prevent a third party which does not have the patentee's consent, from the *act of making, using, offering for sale, selling, or importing* the patented invention into India. To ascertain infringement in a particular case, one has to look at the type of rights given to the patentee as the violation of these rights would constitute of an infringement.

Direct and Literal Infringement

43.4.02 Prior to the amendment of 2005, most patent infringement cases did not go further than the interim injunction stage. Since the amendment, patent litigation has greatly increased.

[15] The guidelines were drafted and published to be followed by the District Courts in Beijing only. However, in fact some courts of other provinces and cities also follow patent infringement litigations.

[16] *Farbwerke Hoechst AG Meister Lucius & Bruning Corpn v Unichem Laboratories* AIR 1969 Bom 255; *B J Wadia, J in Lallubhai Chakrubhai v Chimanlal Chunilal & co* AIR 1936 Bom 99 at 100, 37 Bom LR 665.

[17] *Laxmi Dutt Roop Chand v Nankau* AIR 1964 All 27.

43.4.03 The actual infringement of a patent is taken by the courts to imply an intention to continue the infringement, notwithstanding any promise not to do so and, unless it is clear that there is no intention to continue the infringement, an injunction will be granted. A person may infringe a patent by making the article himself or by his agents. In such cases, action may be taken against the servants and agents individually or collectively along with their employer and principal.[18]

43.4.04 Where the invention is a *product*, s 48(a) provides that the patent will be infringed directly by any person who:

(1) makes;
(2) uses;
(3) offers for sale;
(4) sells; or
(5) imports the patented product.

43.4.05 Where the invention is a *process*, s 48(b) provides that the patent will be infringed directly by any person who:

(1) uses the process;
(2) commits the act of using;
(3) offers for sale; or
(4) imports for those purposes the product obtained directly by the process in India.

43.4.06 Under this section, making and selling separate parts of a patented instrument, the parts of which can be put together without any difficulty by an ordinary skilled person, will constitute infringement of the patented product. However, if a non-infringing part of a patent is manufactured or sold, then it would not qualify as an infringement even though it is used in infringing the patent.

43.4.07 Possession with the intention of 'using' will also constitute an infringement.[19] It should be noted that an application to the regulatory authority seeking approval for marketing will not come within the ambit of use.[20]

43.4.08 Where the subject matter imported is covered by a patent for the purpose of distributing and selling, it will amount to infringement.

43.4.09 The act of importing a patented product for uses relating to the development and submission of information required under any law in India or abroad that regulates the import of any product will not amount to infringement.[21] Also, the importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product will also not amount to an infringement of such a product.[22]

[18] *Rohtas Ind Ltd v Indian Hume Pipe Co Ltd* AIR 1954 Pat 492 (DB); *Shoe Machinery Co Ltd v Cutlan* (1895) 3452/357.
[19] See *Hoffman-La Roche & Co AG v Harris Pharmaceuticals Ltd* [1977] FSR 200; *SmithKline Corpn v DDSA Pharmaceuticals Ltd* [1978] FSR 109, 112–13.
[20] See Patents Act, 1970, s 107A.
[21] Ibid, s 107A(a).
[22] Ibid, s 107A(b).

43.4.10 In direct infringement, the patentee can take action against the person making the product or using the process. Literal infringement is analogous to anticipation. An infringement can be called literal when a person makes, uses, sells, or offers for sale or imports an invention described in the claims of someone else's patent. An invention can infringe a patent by equivalents even if it does not meet the literal criteria of the claim. This might appear to be an easy way to test whether an infringement has occurred, but in reality it can be relatively confusing as things which are equivalent for one purpose may not be equivalent for another. The issue is often resolved by the testimony of experts, and the one with a more believable opinion is considered.[23]

43.4.11 In literal infringement, to determine whether an infringement has occurred, the following steps need to be followed:

(1) interpretation of the claim;
(2) comparison with the interpreted claims with features of the accused product or process;
(3) all the elements of claims must read on the infringing product/process.

43.4.12 The context of the words used in the claim may be understood from their usage in the body of the specification, by reading the specification as a whole. Infringement involves a mixed question of fact and law.[24]

Japan

'Direct' Infringing Acts

43.5.01 If a product or process has all the elements of a patent claim, then it is said to fall under the technical scope of the patented invention. This is called 'direct infringement' as opposed to 'indirect infringement' to be discussed separately in Chapter 45.

43.5.02 Section 2 of the Patent Law defines 'working' of an invention for a product and provides that it include acts of production, use, assignment of such product, and offer to assign or import such product.

43.5.03 It is considered that the patented invention for a product is worked and thus constitutes direct infringement of the patent if one produces, uses, assigns, or offers to assign or import such a product falling under the technical scope of the patented invention.

Literal Infringement

43.5.04 The first step in deciding whether a particular product or process infringes a patent is to identify the technical scope of the patent claims. Section 70(1) of the Patent Law provides that the technical scope of a patented invention shall be determined based upon the wording of a claim. Consequently, the technical scope of the patented invention must be determined

[23] *Terrell on the Law of Patents* (15th edn, 2000), 125.
[24] See *Lallubhai Chakubhai Jariwala v Chimanlal Chunilal & Co* AIR 1936 Bom 99, 105.

upon interpretation of the literal meaning of the wording in the claim. See Chapter 4 for a discussion of construction of patent claims under Japanese law.

Product-by-Process Claims

43.5.05 The current prevailing view under Japanese law is that product-by-process claims are *not* limited by the process elements of the claim. Thus, an identical product which is made by a different process would *infringe* such a claim. However, there would be no infringement if the accused product is not identical to the one manufactured by the process elements of the claim.[25]

43.5.06 In relation to patents that claim a process for producing a product, note also that s 2 of the Patent Law provides that not only the use of such process but also production, assignment, or use of the product produced by such process is deemed working of the patented invention. This is a separate issue to indirect infringement, but should be borne in mind.

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United States

43.6.01 The US Constitution provides that 'Congress shall have the power to 'promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their . . . inventions'.[26] This provision is implemented in relation to patents in Title 35 of the United States Code ('35 USC'), which gives a patentee the right to exclude others from, among other things, making, using, selling, offering for sale, or importing an invention claimed in a patent for a specified period of time.[27]

43.6.02 Infringement can be either direct, or indirect, and direct infringement can be either literal (where every recited element of a claim is literally present), or by equivalents (where the equivalent is found of a claim element not literally present). Indirect infringement is treated in Chapter 44 (inducement of infringement under § 271(b)) and Chapter 45 (contributory infringement under § 271(c)).

[25] See eg *F Hoffmann-La Roche Ltd v Otsuka Pharmaceutical Co, Ltd* (17 July 1997) Tokyo High Court, *Hanrei Jiho*, No 1628, 101 and *Mitsubishi Gas Chemical Co, Inc v Director-General of the Patent Office* (11 June 2002) Tokyo High Court, *Hanrei Jiho*, No 1805, 124.

[26] US Constitution, Art I, § 8.

[27] 35 USC § 271(a).

Infringing Acts

43.6.03 Direct infringement of a US patent can occur with several potentially infringing acts performed in the United States, which are covered in separate, generally non-overlapping, sections of the patent laws:

- making, using, selling, offering for sale, or importing an article of manufacture or method;[28]
- submitting an application for regulatory approval of a drug or veterinary biological product claimed per se, or the use of which is claimed, in a US patent;[29]
- exporting the separate components of a patented combination, for assembly and use abroad;[30]
- importing a product made abroad by a process patented in the United States.[31]

Direct infringement generally: 35 USC § 271(a)

43.6.04 Title 35 USC § 271(a) sets out the basic cause of action for direct infringement of a patent. A patentee is granted the right to exclude anyone from performing certain acts without authorization, namely from making, using, selling, or offering for sale in the United States, or importing into the United States, an invention claimed in a patent. Thus, a patentee has the right to prevent an unauthorized party to make, use, sell, offer for sale, or import a material or construct claimed in a patent (such as a chemical compound, a cell line, a nucleic acid, or a diagnostic/therapeutic kit). In the case of claims actually covering processes for making an article of manufacture, or covering methods of using an article of manufacture (for example a method for expressing a protein using a certain cell line, plasmid construct, or coding sequence, or a method of treating a disease with a certain drug), or methods for achieving a certain result comprising performing a series of steps (for example an assay, screening or diagnostic method, or a method for providing a pharmaceutical compound having a defined characteristic such as particle size distribution or level of purity), the infringing act would logically be 'using' the patented invention.

43.6.05 Infringement under § 271(a) requires an affirmative act by the accused infringer.[32] No intent to infringe is required.[33] As will be discussed below, infringement can be literal, that is, by making, using, selling, offering for sale, or importing what is literally recited in the claims, or by equivalents. The latter is referred to as infringement under the 'doctrine of equivalents', and occurs when the accused infringer is not practising precisely what is recited in a patent claim, but rather something that is the substantial equivalent of what is claimed.[34]

Products subject to regulatory approval: 35 USC § 271(e)

43.6.06 Title 35 USC § 271(e) relates to infringement which is connected to a product subject to regulatory approval, in particular drug products. Under subs 271(e)(1) acts which would

[28] Ibid.
[29] 35 USC § 271(e).
[30] 35 USC § 271(f).
[31] 35 USC § 271(g).
[32] See *Beverly Hills Fan Co v Royal Sovereign Corp* 21 F3d 1558 (Fed Cir 1994).
[33] *Warner-Jenkinson Co, Inc v Hilton Davis Chemical Co* 520 US 41 (1997), on remand 114 F3d 1161 (Fed Cir 1997).
[34] See Chapter 44.

otherwise be an infringement are exempt if they are reasonably related to obtaining regulatory approval under federal law, discussed in Chapter 51, para 51.6.03.

43.6.07 In 1984, the Hatch-Waxman Amendments added § 271(e)(2) to the US Patent Code, along with § 505(b)(2) and (j) to the Federal Food, Drug, and Cosmetic Act (FDC Act). A § 271(e)(2) action differs from other infringement actions in that it is a technical cause of action which arises upon filing an application to gain approval for the commercial manufacture, use, sale, or importation of a drug or veterinary biological product which is covered by a US patent—that is, it arises from an affirmative act (filing an application for regulatory approval) which in itself would not be considered an infringement under § 271(a). In most cases, a legal action under § 271(e)(2) is initiated before any commercial manufacture, use, sale, etc of the patented product, which would be a typical infringement under § 271(a). Instead, an action under § 271(e)(2) is based on the prospective commercial manufacture, use, sale, etc, which would occur should the application for regulatory approval in question be approved.

43.6.08 Aside from this difference, infringement under § 271(e)(2) is essentially the same as that described under § 271(a). The elements of the infringement analysis, the affirmative defences, and the respective burdens of proof of the parties are the same as in a cause of action arising under § 271(a). The product as to which the infringement determination is made is the product which the accused infringer will market after approval, namely the product which is described in the technical specifications of the application for regulatory approval.[35] When the technical specifications for the product are not dispositive of the issue of infringement, analysis of samples of the product for which approval is sought may be appropriate.[36] Because most often an action under § 271(e)(2) is commenced before an actual infringing act has occurred, the relief available is limited to injunctive relief, since no damages have accrued.[37]

43.6.09 Section 271(e)(2) is most often used in litigation involving generic pharmaceuticals. Under the 1984 amendments to the Federal Food, Drug, and Cosmetic Act (the 'Hatch-Waxman Amendments'), of which § 271(e) is a part, the holder of an approved new drug application (NDA) must list with the US Food and Drug Administration (FDA) any patent covering the NDA drug or an approved use of that drug.[38] These listed patents are identified in an FDA publication commonly known as the Orange Book.[39]

43.6.10 Any party seeking approval of an abbreviated new drug application (ANDA) or a new drug application under § 505(b)(2) ('Paper NDA') for the same drug must certify that either (1) no patent information has been filed, (2) as to each listed patent, that the patent has expired, (3) as to each listed patent, that the applicant will not market their drug until the patent has expired, or (4) as to each listed patent, that the patent is invalid, or will not be infringed by the manufacture, use, sale, or offer for sale of the ANDA or Paper NDA drug for which approval is sought.[40] It is the filing of an application with the last certification, a so-called 'Paragraph IV' certification, which will trigger the provisions of 35 USC § 271(e)(2).

[35] *Glaxo, Inc v Novopharm Ltd* 110 F3d 1562 (Fed Cir 1997).
[36] *Bayer AG v Elan Pharmaceutical Research Corp* 212 F3d 1241, 1250 (Fed Cir 2000).
[37] See 35 USC § 271(e)(4)(A)–(C).
[38] 21 USC § 355(b)(1).
[39] Official title, 'Approved Drug Products With Therapeutic Equivalence Evaluations'.
[40] 21 USC § 355(j)(2)(A)(ii).

The applicant is required to give the NDA holder notice of a Paragraph IV certification,[41] in which event the NDA holder has 45 days in which to bring an action for infringement under § 271(e).[42] If no such action is brought, the ANDA or Paper NDA may be approved and the applicant is free to market its drug if all other regulatory requirements are met. If, however, the NDA holder files a legal action under § 271(e) within the 45-day period, the FDA is automatically enjoined from giving final approval to the ANDA or Paper NDA for either 30 months, or until a final decision by the court that the patent is either invalid or not infringed, whichever is sooner.[43] This period can be shortened or lengthened by the court, at its discretion, if either party failed to reasonably co-operate in expediting the action.

43.6.11 The Hatch-Waxman Amendments provide an incentive to ANDA (but not Paper NDA) applicants to file a Paragraph IV certification when possible, by granting to a party who is first to file a complete ANDA with a Paragraph IV certification, a 180-day period of market exclusivity on the ANDA drug to run from either (1) the date of first commercial marketing of the ANDA drug, or (2) from the date on which judgment is entered by a district court in an action brought under § 355(j)(5)(B)(iii) that the listed patent(s) are either invalid or not infringed, whichever is sooner.[44]

Supply of components of patented invention: 35 USC § 271(f)

43.6.12 Section 271(f) of Title 35 provides that it is an act of infringement to supply, or cause to be supplied, to or in the United States, all or a substantial portion of the components of a patented invention. This section of the patent statute was enacted essentially to overrule a US Supreme Court decision that held that claims to a machine composed of a combination of components, which separately were not patented, was not infringed by the manufacture and export of the disassembled components of the claimed combination for assembly and use outside the United States.[45] Section 271(f) creates liability for infringement by either of two acts. Under subs 271(f)(1), it is an act of infringement to supply, or cause to be supplied, in or from the United States, all or a substantial part of the separate components of a patented invention, where such components are uncombined in whole or in part, in a manner to actively induce the combination of such components abroad, in a manner that would be infringing if performed inside the United States (for example the components of a diagnostic or therapeutic kit patented in the United States, to be assembled and used or sold by another abroad). Second, under subs 271(f)(2), it is an act of infringement to supply, or cause to be supplied, in or from the United States, any component of a patented invention which is specially made or adapted for use in a patented method or combination, and which has no substantial non-infringing use, knowing that the component will be combined outside the United States in a manner which would be infringing if performed inside the United States.

Process Patents Act: 35 USC § 271(g)

43.6.13 The importation into the United States or the use, sale, or offer to sale in the United States, of 'a product which is made by a process patented in the United States' is deemed an act

41 See 21 USC 355(j)(2)(B)(ii).
42 21 USC 355(j)(2)(B)(iii).
43 Ibid.
44 21 USC § 355(j)(5)(B)(2)(iv).
45 *Deepsouth Packing Co v Laitram Corp* 406 US 518 (1972).

of infringement.[46] Note that § 271(g) does *not* apply to the importation of a product which is made abroad using a patented *compound* or article of manufacture. Section 271(g) is not limited to the protection of a direct or unaltered product made by a patented process, but also provides protection to a product which has been subsequently subjected to further processing or manufacturing steps, as long as the subsequent modifications do not:

- 'materially change' the basic structure and/or function of the product;
- mean that the product of the process has become a trivial and non-essential component of another product.[47]

43.6.14 Note that in *Kinik Co v International Trade Commission*,[48] the US Court of Appeals for the Federal Circuit held that the two exceptions in § 271(g) do not apply to proceedings brought before the International Trade Commission under 19 USC § 1337(a)(1)(B)(ii). Refer to Chapter 46 for a detailed discussion of International Trade Commission proceedings.

43.6.15 Although at least one Federal Court of Appeals case appears to state that infringement under § 271(g) occurs upon importation of the product during the term of the patent claiming the process used to make that product, even if the process was performed *before* either the patent issued or § 271(g) went into effect,[49] a more recent case clarifies that in order for there to be infringement under § 271(g), not only must the importation of a product made by a patented process take place while the patent to the process is in force, the process in question must also have been performed while the allegedly infringed patent was issued and in force.[50] The court in *Mycogen* distinguished *Bio-Technology v Genentech* based on the fact that in that case performance of the process, as well as importation, occurred while the patent was issued and in force, albeit prior to the effective date of § 271(g).

43.6.16 A chemical modification or processing that resulted in a derivative chemical having a different molecular structure, biological property, or pharmaceutical purpose would be considered a different chemical rather than a product made by the patented process.[51] In cases where the patented process produces an intermediate that can be changed into an end product, the patent may protect the end product if it would not be possible or commercially viable to make that product but for the patented process.

43.6.17 The Federal Circuit held that infringement under 35 USC § 271(g) is limited to the importation of physical articles manufactured directly using a patented process, and does not extend to data generated, or drug products identified using an upstream research or screening method.[52]

43.6.18 Although the literal language of § 271(g) is not limited to products made outside the United States (thus appearing to provide a cause of action against a party that uses, sells, or offers for

[46] 35 USC § 271(g).

[47] See S Rep No 83, 100th Cong, 1st Sess 46, 50 (1987); H R Rep No 60, 100th Cong, 1st Sess 13–21 (1986); *Marion Merrell Dow, Inc v American Cyanamid Co* 36 USPQ2d 1036 (DNJ 1994).

[48] 362 F3d 1359 (Fed Cir 2004).

[49] See *Bio-Technology General Corp v Genentech, Inc* 80 F3d 1553, 1560 (Fed Cir 1996).

[50] *Mycogen Plant Science, Inc v Monsanto Co* 252 F3d 1306, 1319 (Fed Cir 2001).

[51] See *Eli Lilly & Co v American Cyanamid Co* 82 F3d 1568 (Fed Cir 1996); but see *Bio-Technology General Corp* 80 F3d at 1561 ('an imported protein may be viewed as having been made by the patented process for making a plasmid when the plasmid was used to make the protein and the patent explicitly contemplated that the process and its resulting plasmid be used as part of an overall process for producing protein').

[52] See *Bayer AG v Housey Pharms, Inc* 340 F3d 1367 (Fed Cir 2003).

sale a product made in the United States by a patented process, distinct from that provided by § 271(a)), § 271(g) is most often applied in the context of importation of a product made abroad using a process claimed in a US patent. The issue of whether § 271(g) applies to products made within the United States has resulted in conflicting decisions from the lower courts, and the issue thus far has not been resolved by the higher courts.[53]

Test for Infringement

43.6.19 Literal infringement requires a showing that each element of the claim, as properly construed, is present in the accused product or process.[54] A product or process that lacks even a single claim limitation cannot be found to literally infringe that claim,[55] A product or process that does not infringe an independent claim cannot be found to literally infringe a claim that is dependent upon, and thus contains all the limitations of, the independent claim.[56]

43.6.20 To determine whether any claims of a patent are infringed, a two-part enquiry is required.[57] The first step is to construe the claims as a matter of law. The second step is to determine whether the properly construed claims literally cover the accused product or process.[58] Whether an accused product literally infringes a claim is a question of fact.[59] The patentee has the burden of proving infringement by a 'preponderance of the evidence'.[60]

References

Chisum, Donald S., *Chisum on Patents* (2008), §§ 16.02 and 16.03

Europe Overview

43.7.01 A patent granted by the European Patent Office (EPO) has the same standing in a Contracting State as a national patent under the local legislation.[61] This statute must be observed even if in respect of a particular patent, there is an inconsistency in the rights conferred due to operation of the European Biopatents Directive 98/44/EG. Thus, once it is granted, a patent is interpreted and infringement is decided in the same manner, irrespective of the place of original application for the patent. The European Patent Convention came into being in order to harmonize the law for patent validity. Article 139 EPC requires Member States to harmonize the principles governing validity of its national patents with those set out in

[53] See eg *Hughes Aircraft Co v National Semiconductor Co* 857 FSupp 691 (ND Cal 1994) (§271(g) applies to products made abroad, but not to products made in the US); *Shamrock Technologies Inc v Precision Micron Powders Inc* 20 USPQ2d 1797 (EDNY 1991) (§ 271(g) applies to products made both abroad and in the US).

[54] *Telemac Cellular Corp v Topp Telecom, Inc* 247 F3d 1316, 1330 (Fed Cir 2001).

[55] *Enercon GmbH v ITC* 151 F3d 1376, 1384 (Fed Cir 1998).

[56] *Medtronic, Inc v Advanced Cardiovascular Sys* 248 F3d 1303, 1310 (Fed Cir 2001).

[57] *SmithKline Beecham Corp v Apotex Corp, et al* 403 F3d 1331, 1337 (Fed Cir 2005); *Cybor Corp v FAS Tech, Inc*138 F3d 1448 (Fed Cir 1998) (*en banc*).

[58] *SmithKline v Apotex* 403 F3d at 1337; *Cybor Corp* 138 F3d at 1454.

[59] *Tanabe Seiyaku Co v United States Int'l Trade Com'n* 109 F3d 726, 731 (Fed Cir 1997), cert denied 522 US 1027 (1997).

[60] *Laitram Corp v Rexnord, Inc* 939 F2d 1533, 1535 (Fed Cir 1991).

[61] Arts 2 and 64 EPC.

the EPC. Thus, for validity, the provisions of Art 69 and its Protocol are binding on all EPC countries as to the determination of the 'extent of protection' provided by the patent claims. See Chapter 4 for a discussion of Art 69.

43.7.02 As described above, the EPC does not determine what acts should be regarded as potentially infringing ones. However, there has been a degree of harmonization of the law of infringement by virtue of the Community Patent Convention (CPC), which was negotiated by the EU Member States in 1975.[62] It was then agreed that all countries which ratified the EPC would adjust their national laws in this respect to adopt the infringement provisions set out in the proposed CPC. Many, if not all, of the Member States did in fact adopt these changes, even though the CPC never came into force and will not now do so. The relevant provisions of the CPC are Arts 25–7 (as found in the 1979 version).

43.7.03 Article 25 states:

> Article 25—Prohibition of direct use of the invention
>
> A Community shall confer onits proprietor the right to prevent all third parties not having his consent:
>
> (1) from making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for these purposes;
> (2) from using a process which is the subject-matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within the territories of the Contracting States;
> (3) from offering, putting on the market, using, or importing or stocking for these purposes the product obtained directly by a process which is the subject-matter of the patent.

43.7.04 Article 26 deals with indirect infringement, and Art 27 provides exceptions for certain acts which would otherwise fall within the provisions of Art 25 or 26.

France

Infringing Acts and Literal Infringement

43.8.01 In France, the definition of infringing acts is set out in Art L 613-3 of the French Intellectual Property Code (IPC) which mirrors Art 25 of the CPC above.

Literal Infringement

43.8.02 In France, literal infringement requires the exact reproduction of the means of the claims of the patent: that is, structures and functions are strictly identical to those claimed in the patent. In rare cases, the identity between the alleged infringing product and the patent claims is so obvious that there is no doubt about whether infringement is constituted. However, usually an alleged infringer will have made at least some attempt to avoid the strict

[62] The Articles were renumbered in 1989—Agreement Relating to Community Patents. Done at Luxembourg on 15 December 1989 (89/695/EEC).

words of the claims. Consequently, over time, case law has loosened the criteria for literal infringement. Thus, literal infringement can be constituted by: (1) servile reproduction; (2) minor variant of execution; or (3) partial infringement.

Servile Reproduction

43.8.03 There is servile reproduction where the claimed product or process is reproduced identically in *both* form and structure. If only the structure is reproduced (albeit identically), but there is a different function, then the reproduction may be considered to involve the use of a known means and, as such, to be freely workable. Furthermore, if only the function is reproduced but not the structure, then infringement cannot be constituted literally but only by equivalents.[63] Of course, if both structure and function differ from those claimed, then there is no infringement.[64]

Minor Variant of Execution

43.8.04 Minor variants will still infringe a patent if the essential means of the patent claim are reproduced. The approach to this analysis is summarized by the phrase: 'infringement is assessed by similarities but not by differences'. While such differences may consist of modifications, additions, or deletions, they must not alter the essential structure or function claimed in the patent. The fact that the differences provide a better or worse implementation of the claimed invention is irrelevant.

Partial Infringement

43.8.05 Under French law, it has been decided by case law that a patent may be partially infringed provided that (1) the patent claims a plurality of means which are not a combination; (2) the infringing product or process must include a juxtaposition of means; and (3) this juxtaposition must itself be an essential means of the patent claim.

43.8.06 A true combination patent cannot be partially infringed because partial use will leave out crucial elements necessary for the working of the combination. In other words, in a combination patent, the elements cooperate in order to obtain a common result which is different from the sum of the results produced by each element individually.[65]

43.8.07 However, there may be partial infringement if a patent claim contains a number of means which do not cooperate together. In this situation, the means of the claim are merely added together or juxtaposed, so that there is no common result and one of these means can be deleted without consequences to the interaction between the other(s).[66]

[63] See Chapter 44.

[64] *Jean Pierre Belin v Broyeurs Bugnot SA* (Tribunal de Grande Instance de Paris, 1 October 2004) [2005] PIBD 800, III, 46–8.

[65] *New Mat SA v Scherrer, Normalu SA & Anthonioz* (Cour d'Appel de Paris, 1 December 1993) [1994] PIBD 562, III, 135–9.

[66] Ibid.

43.8.08 Finally, to constitute partial infringement, the juxtaposition of means must itself be an essential element of the patent claims.[67] An element of a patent is essential if it is required for the invention to function in such a way as to solve the technical problem: if the element reproduced is not essential, then there is no partial infringement.[68]

References

Chavanne, A. and Burst J. J., *Droit de la propriété industrielle* (5th edn, Dalloz, 1998), 241–50
Mathély, P., *Le nouveau droit français des brevets* (Journal des notaires et des avocats, 1991), 416

Germany

Infringing Acts

43.9.01 In Germany, the proscribed infringing acts are set out in s 9 Patent Act which mirrors Art 25 CPC.[69]

43.9.02 The six activities that are exclusive to the proprietor include anything relevant to commercial use. The terms in the statute are interpreted in a commonsense way. Thus, 'to make' includes all steps of production that eventually result in 'making' the product.[70] Furthermore, 'offer for trade' and 'trade' refer to any offer for or disposal of the product to third parties provided that the requisite intent can be proven.

43.9.03 There has been some debate about the extent to which products of patented biological processes are protected. This is still uncertain. If a product was not explicitly included in the regime of s 9 according to s 9a Patent Act, in force since 28 February 2005.

43.9.04 The usual rule in relation to process patents is that they cover the direct product of the process.[71] Note that a patent claiming a particular use of a product is in effect a process patent. However, such a patent does not cover the product if it is not used within this process.[72] This situation arises reasonably frequently in biotechnology patents where the product is found to be useful for a particular process (for example a restriction enzyme).

Literal Infringement

43.9.05 A patent has been infringed literally if the technical wording of the patent claim applies to the alleged infringing product or process and it contains all the essential elements of an independent claim of the patent.[73]

[67] *Poux Erik Bernard v Girard Edouard & France Japon Optique SARL* (Cour d'Appel de Paris, 19 November 2004) [2005] PIBD 804, III, 168–70.
[68] *Lely enterprises AG & Lely Industries NV v Delaval International & Delaval SNC* (Tribunal de Grande Instance de Paris, 10 December 2004) [2005] PIBD 805, III, 203–6; *Skis Rossignol v Volkl Deutschland Vertriebs GMBH & Technica France SARL* (Cour d'Appel de Paris, 11 February 2004) [2004] PIBD 786, III, 284–8.
[69] See para 43.7.03 above.
[70] BGH 14.07.1970, GRUR 1971, 78, 80—*Diarähmchen V.*
[71] BGH 30.03.1993, GRUR 1993, 651, 655—*Tetraploide Kamille* (with reference to BGHZ 57 (1972), 1, 22—*Trioxan*).
[72] BGH 16.01.1990, GRUR 1990, 508, 509—*Spreizdübel.*
[73] BGH 27.10.1998, NJW-RR 1999, 546—*Sammelförderer.*

43.9.06 To test whether literal infringement has occurred, the individual features of the patent claim are compared to the features of the allegedly infringing product or process. However, mere substitution for an element of the claim will not guard against literal infringement if the substitute is commonly used for the same purpose. For example, if the claim requires that an object be affixed to a wall with a nail, but a screw is used instead, and the differences between a nail and a screw is recognizably irrelevant in the particular case, then this is deemed a literal use.[74] Thus, if the alleged infringing product or process fully uses the technical meaning of the features of the patent claim, then there is literal infringement. Put another way, if the features of the alleged infringing product or process serve the same purpose and fulfil the same effect and function as the elements of the patent claim in dispute, then there will be literal infringement.[75]

43.9.07 However, one cannot simply ignore the technical purpose and the technical effect of a feature. The technical understanding of a patent claim, irrespective of whether it is determined in relation to a literal patent infringement or a patent infringement by equivalence, always has to depend on a technical function and effect of the individual features.[76] Thus, for example, a feature defined in a patent claim by its spatial or physical design must be used in the challenged embodiment and function according to the teaching of the patent in issue.

43.9.08 Notwithstanding that it contains all of the essential features of a patent claim, an alleged infringing product or process will not infringe that claim if its individual features do not function as claimed in the patent. Furthermore, it is irrelevant to infringement that an alleged infringing product or process contains additional features that are not claimed in the patent. A product or process that contains additional, inventive features will still infringe, even though it may be capable of separate patent protection.

References

Busse, *Patentgesetz* (6th edn, 2003), § 9
Schulte, *Patentgesetz mit EPÜ* (8th edn, 2008), § 9

Italy

Infringing Acts

43.10.01 According to Art 66 of the Code of Industrial Property (CIP), the rights conferred by a patent consist of the exclusive right to work or make use of the invention and to obtain a profit from it. In particular the following is prohibited without the patent owner's consent: the manufacture, sale, offer for sale, and/or import of the product incorporating the patent or made in accordance with a patented process. In what constitutes an act of infringement, the concept of making a profit has been extended to include intermediation by a company domiciled in Italy—where the product is patented—in the sale of the product in countries where the product is not covered by the patent.[77]

[74] BGH 22.03.1983, GRUR 1983, 497—*Absetzvorrichtung.*
[75] BGH 12.07.1990, GRUR 1991, 436—*Befestigungsvorrichtung II.*
[76] BGH 03.10.1989, GRUR 1989, 903—*Batteriekastenschnur.*
[77] For further details, see Chapter 47, para 47.10.06.

Scope of Patent Protection

43.10.02 In order correctly to assess the existence of an infringement, whether literal, non-literal, partial, or contributory, it is first necessary correctly to identify the meaning and scope of the patent claims. According to Art 52 CIP, 'the extent of the protection is determined by the terms of the claims; however the description and the drawings shall assist in the interpretation of the claims'. This rule, which is substantially identical to Art 69 EPC was not present in the Italian Patent Act which was in force until the enactment of the CIP by way of Law Decree of 10 February 2005 n 30. It is expected that the new rule will induce Italian courts to abandon the traditional approach to claim construction, according to which the meaning and scope of the exclusive right conferred by a patent consisted of the 'inventive idea', the extent of which was determined by claims, description, and drawings combined together.

43.10.03 Although the traditional approach had been gradually diluted so that claims have recently been given a prominent role in construing the scope of protection conferred by a patent, there was still some uncertainty as to whether the description and drawings were only to assist in the interpretation of the claims (that is, only in case of doubt) or to concur with the claims in the interpretation of the extent of the protection. Under the present CIP, it is plausible that claim construction will move towards reducing room for *ex post* determination of the meaning and scope of the claims on the basis of the content of the description and drawings. Instead, construction will focus on the text of the claims interpreted, and if necessary in the light of the description and drawings (provided that they are not thereby broadened).

Extent of Protection of Pharmaceutical Patents

43.10.04 The determination of the scope of protection of pharmaceutical patents deserves separate treatment. This is because there is doubt as to whether the new patented compound is protected only with respect to the use for which it has been developed (the scope of protection is limited to the specific use) or whether the new compound is protected per se. If the latter view is correct, then while new utilizations may be patentable, they would constitute dependent patents the working of which would amount to an infringement of the main patent. In *Smith Kline & French Laboratories Ltd et al v Gibipharma*,[78] the Italian Court of Cassation held that pharmaceutical inventions cannot be constituted by a simple molecular structure, but rather by the industrial product which can be obtained by the use of the compound in relation to its properties. In other words, the patent covers the new formula in conjunction with the use (or uses) claimed. In the same judgment, the court added that a patent the subject of which is a general formula, covers the compounds not specifically identified only if they are easily identifiably by a person skilled in the art without further research or experimentation. Also, importantly, chemical intermediates—that is, those substances that during a chemical process are generated by one step and used for the succeeding steps—are patentable separately from the final product and, as such, can be protected per se.

[78] Court of Cassation, 16 November 1990, No 11094, GADI, 1990 (2478) (Italy).

Extent of the Protection and Literal Infringement

43.10.05 Once the extent of the protection has been determined, there is literal infringement of a patent claim if every element recited in the claim in the patent is also present in the alleged infringing product or process. In other words, the product must contain the invention while the process must perform the patented process. As a consequence, if the accused product or process does not contain one or more of the elements of the claim, there is no literal infringement even though there can still be partial infringement or infringement by equivalents.

43.10.06 Under Italian patent law, there still is literal infringement if the accused product or process contains additional features beyond those claimed, even if the additional features are patentable improvements.[79] This type of infringement is often referred to as evolutionary infringement by Italian courts and commentators and is considered to be a variant of literal infringement.

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Netherlands

Infringing Acts

43.11.01 Article 53(1) of the Patent Act 1995 provides that a patent shall confer on its owner the exclusive right:

(1) to make, use, put on the market or resell, hire out, or deliver the patented product, or otherwise deal in it in or for business, or to offer, import, or stock it for any of those purposes;
(2) to use the patented process in or for business or to use, put on the market, or resell, hire out, or deliver the product obtained directly as a result of the use of the patented process, or otherwise deal in it in or for business, or to offer, import, or stock it for any of those purposes, with the exception of any product excluded from the grant of a patent because publication or exploitation would be contrary to public order or morality or because it concerns plant or animal varieties, or essentially biological processes for the production of plants or animals and the products thereof, with the exception of microbiological processes unless these are prohibited by or pursuant to the Act on Health and Welfare of Animals.

[79] *Maschinenfabrik Berhard Krone GmbH v Morra Macchine Agricole snc et al*, Tribunal of Milan, 18 May 1989, GADI, 1989 [2421/4].

43.11.02 A party other than the patentee which performs the acts mentioned under point (1) or point (2) above without the consent of the patentee directly infringes the exclusive right of the patentee. In both situations under points (1) and (2), the exclusive right is limited to applying the invention 'in or for his business'. The word 'business' should be interpreted broadly and does not merely involve commercial or profit-oriented activities. The word 'business' merely indicates that the patentee cannot object to the application of his invention in a purely private environment without any commercial intention.

43.11.03 In its landmark judgment in *Probel*,[80] the Supreme Court held that the wording 'put on the market' means actually making the product available to a third party in the Netherlands. In its later judgment *Organon v ARS II*,[81] the Supreme Court added that it is not relevant whether the making available involves the transfer of title or some other form, for example for testing. Article 53(1) provides that to offer, import, or stock the patent protected product or to use the patent protected process is only a direct infringement if this is done for 'any of those purposes', in other words: with the intent to make, use, or perform any of the other acts reserved to the patentee in the Netherlands. This means that products that are kept in stock in the Netherlands for further distribution outside the Netherlands do not infringe the patent.

43.11.04 It was decided in *Cordis v Cadsand*[82] that products that are kept in stock outside the Netherlands but that are intended to be marketed and sold in the Netherlands can infringe a Dutch patent. It is currently unclear whether importing or keeping in stock generic medicinal products in the Netherlands prior to expiry of a patent (or Supplementary Protection Certificate, 'SPC') in order to be able to market and sell these products immediately after the patent or SPC expires, is an infringing act. The Court of Appeals in The Hague ruled in *Glaxo v Pharmachemie*[82a] that offering a generic product for sale before the date on which the patent will lapse with the express notice that the product is not available before that date, is an infringement because it will influence the market behaviour in respect of this medicine prior to the lapse of the patent.

43.11.05 The exclusive right of the patentee as set forth in Art 53 of the Patent Act 1995 is subject to a number of limitations and exceptions. Two of the most important exceptions concern the experimental use exception and a Bolar-provision.[83]

Literal Infringement

43.11.06 Particularly in the first instance the court is taking the wording of the claims as decisive for the assessment of literal infringement. If the product or process of the defendant does not answer the letter of the claims, the Dutch courts will first construe the claims and determine whether the claims, in connection with the description and the drawings, suggest that the general inventive concept of the invention is broader than the description of the invention in the claims.[84] If the inventive concept is not broader, then there is no infringement. If the

[80] [1964] BIE 1964/141.
[81] [1995] NJ 1996/463, BIE 1997/41.
[82] [1995] BIE 1996/82.
[82a] Court of Appeals The Hague, 2 November 2010, concerning Ondansetron.
[83] See Chapters 51and 52 for a discussion of these two defences.
[84] See Chapter 4 for a discussion of the construction of claims in the Netherlands.

patent provides for a clear inventive concept, then the court will assume that the applicant intended protection in conformity with that concept and that this concept is also what the authorities intended to grant the protection for, unless there are clear indications to the contrary in the patent or in the file of grant. However, this applies only to the situation where the inventive concept follows clearly from the patent. Of course, a patentee in infringement cases will often claim a broader inventive concept than follows from the literal wording of the claims. If it is doubtful whether the concept that the patentee claims is indeed the inventive concept that the authorities have intended to grant protection for, then the extent of protection will be held to be closer to the wording of the claims.

43.11.07 In a recent judgment[85] the Supreme Court fine-tuned the criterion by which the extent of protection of a patent should be assessed. The two extremes that define the extent of protection are, according to the Protocol with Art 69 EPC, on one side the strict, literal meaning of the wording used in the claims and, on the other side, what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. In *Lely v Delaval*, the Supreme Court held that the latter should no longer be regarded, as in previous case law, as a starting point but rather as merely a point of view when assessing the scope of protection of the patent. This also implies a narrowing of the general inventive concept, lying beyond the literal wording of the claims, although recent case law has not yet confirmed this implication.

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United Kingdom

Introduction

43.12.01 The question of infringement involves consideration of two matters. The first is whether the alleged infringer has done any of the acts described in this section in relation to the product or process in the UK. The second is whether the product or process alleged to infringe falls within the claims of the granted patent. To decide this it is necessary to construe properly the claims of the patent, for which see Chapter 4.

[85] *Lely v Delaval* [2007] IER 2007/106.

Infringing Acts

43.12.02 Section 60(1)[86] of the Patents Act 1977 contains the acts of direct patent infringement, and s 60(2) the acts of indirect infringement.[87] There are different acts of direct infringement for products,[88] processes,[89] and products obtained directly from processes.[90]

Product patents

43.12.03 Section 60(1)(a)[91] concerns product patents. The following acts will infringe a product patent, provided the product falls within the claims and the patent is valid and in force: making, disposing of, offering to dispose of, using, or importing the product, or keeping it whether for disposal or otherwise.

43.12.04 There is no infringement by a supplier of a product if all of his actions are carried out abroad.[92] However, infringement will not be avoided if the supplier retains any lien over the goods after they have entered the UK.[93] A person may be liable as a 'joint tortfeasor' for actions carried out abroad if he was acting jointly (rather than at arm's length) with a person within the jurisdiction, that is, as part of a conspiracy to infringe.[94]

43.12.05 'Offers to dispose of' deserve special mention. They are interpreted in the context of the wording of the CPC, which is an offer of 'putting on the market'. This is wider than the English contract law definition of 'offer'. However, if the offer is to supply after the expiry of the patent this is unlikely to be regarded as an infringement in itself, even if made during subsistence of the patent.[95] Furthermore, both the offer and the supply of the product need to be made within the UK for there to be an infringement in the UK.

Process patents

43.12.06 Section 60(1)(b) concerns process patents and provides two heads of infringement:

- 'Uses the process'—a person infringes a patent for a process if he uses that process without the consent of the proprietor. The use has to be in the UK and the knowledge of the alleged infringer is irrelevant.
- 'Offers the process for use'—A person also infringes a process patent if he offers the process for use in the UK when he knows, or it is obvious to a reasonable person in the circumstances, that its use in the jurisdiction without the consent of the proprietor would be an infringement.

43.12.07 This second head of infringement is different to those discussed above because the defendant's knowledge, or imputed knowledge, is taken into account. It is the only type of direct

[86] Patents Act 1977.
[87] See Chapter 45.
[88] Patents Act 1977, s 60(1)(a).
[89] Ibid, s 60(1)(b).
[90] Ibid, s 60(1)(c).
[91] Ibid.
[92] *Sabaf SpA v MFI Furniture Centres Ltd and others* [2004] UKHL 45.
[93] *Morton-Norwich Products Incorporated v Intercen Limited* [1978] RPC 501.
[94] See Chapter 45.
[95] *Gerber Garment Technology Inc v Lectra Systems Ltd and another* [1995] RPC 383.

infringement where the defendant's knowledge is relevant. The test has subjective and objective elements, only one of which needs to be satisfied.

Products directly obtained from processes

43.12.08 Under section 60(1)(c)[96] a person infringes a process patent if he disposes of, offers to dispose of, uses, or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise. This head is aimed primarily at preventing the importation and use of non-patented products produced by a patented process abroad.

43.12.09 The product should be a *direct* product of the process.[97] The literal translation into English of the German text of the EPC is 'without intermediary'. If there is an extra step in the process creating the allegedly infringing product, or if it is subsequently sufficiently altered that it loses the identity of the infringing product, then the product may not infringe, but the extent of the loss of identity and whether it is sufficient to justify non-infringement is a question of fact in each case and hinges on whether the end product retains the 'essential characteristics' of the infringing product.

43.12.10 In *Monsanto v Cargill*,[98] Pumfrey J considered when a plant lost its 'essential characteristics'. The relevant claim was to a method of producing a genetically transformed plant. This transformation only occurred once. The question considered by the court was whether the progeny of that single plant were a direct product of the claimed process. Pumfrey J held that he would reserve the phrase 'directly obtained' for the original transformed plant. Even the first generation was unlikely to share the same material as the original plant and so was not a direct product of the process. Soymeal, the subject of the infringement claim, was therefore clearly not a direct product of the process.

References

Chartered Institute of Patent Agents, *CIPA Guide to the Patents Acts* (5th edn, Sweet & Maxwell, 2001), Part I, s 60

'Halsbury's Laws Direct' (online service, Butterworths)

[96] Patents Act 1977.
[97] *Pioneer Electronics v Warner Music* [1995] RPC 487.
[98] [2007] EWHC 2257 (Pat).