

The patent and indirect patent infringement

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In the amendment to the Dutch Patents Act (DPA) which came into force on 1 December 1987 the regulation of indirect patent infringement was included in art. 44A. It has now become, in the same form, art. 73 DPA 1995. This brought to an end a period in which acts which were not deemed as 'direct' infringement could only be challenged under the general rule of torts, and only then with difficulty.² In accordance with the Explanatory Memorandum, the new regulation of art. 44A follows 'in all respects' the system of the then art. 30 Community Patent Convention (now art. 26).³ However, as Schutjens rightly

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2. See in this respect inter alia: Hoyng, *Repareren in het octrooirecht*, Tilburg 1988, chapters VI-V111.

3. Art. 26 CPC states:

1. The Community patent also gives the patent proprietor the right to forbid any third party on the territories of the Contracting States who does not have his consent thereto to offer or deliver means for putting the patented invention into effect, in respect of an essential part of the invention, to others than those entitled to put the invention into effect on those territories, if the third party knows, or that it is evident considering the circumstances, that those means are suitable and intended for that application.

2. The first paragraph does not apply if the means referred to therein are generally available in commerce, unless the third party incites the person to whom he delivers to perform acts forbidden by virtue of art. 25.

3. Those who perform the acts referred to in art. 27, sub a) up to and including sub c), are not deemed in the sense of the first paragraph to be entitled to work the invention.

Art. 73 DPA 1995 states:

1. The patent proprietor may institute the same claims which are at his disposal in enforcing his patent against any third party who, in the Realm or, in the case of a European patent, in the Netherlands, offers or delivers, in or for his business, the means for working the patented invention, in respect of an essential part of the invention, in the Realm or, in the case of a European patent, in the Netherlands, to others than those who by virtue of art. 55 to 60 are empowered to work the patented invention, provided

comments, the text of the DPA shows no evidence of the intention to actually follow this provision; there are anomalies whose purpose is not clear.⁴ In this respect the German legislature for instance has done a better job. The provision of par. 10 German Patents Act thus corresponds almost literally with the CPC. Whatever, if doubt arises over the meaning of art. 73, the Dutch court must if necessary turn for guidance to the CPC regulation. The TRIPs Agreement unfortunately gives us nothing to go on since it does not include provisions on indirect patent infringement.

I wish in these remarks to examine a particular aspect of indirect patent infringement and this concerns not the indirect infringer himself but those to whom he offers or delivers the means relating to an essential part of the invention referred to in art. 73 DPA. The provision gives the patent proprietor the opportunity to take action when such means 'for working the invention' are offered or delivered 'to others than those who by virtue of art. 55 to 60 are empowered to work the patented invention', this when the condition, which I will not discuss further here, is fulfilled that the indirectly acting person knows, or that it is evident considering the circumstances, that these means are suitable and intended for that application.

The reader who sets this provision and art. 26 CPC side by side will notice that the clear language of the third paragraph of art. 26 CPC is lacking in art. 73 DPA 1995. This third paragraph provides that those stated in art. 27 under a, b and c, and these are - briefly - those acting in their private capacity, researchers and

this third party knows or that it is evident considering the circumstances that those means are suitable and intended for that application.

2. The first paragraph shall not apply if the offer or delivery takes place with the consent of the patent proprietor. Nor will this paragraph apply if means delivered or offered means are products generally available in commerce, unless the third party incites the person to whom he delivers to perform acts as specified in art. 53, first paragraph.

3. Art. 70, fifth paragraph, is similarly applicable.

4. Schutjens, Octrooirecht en geneesmiddelen, p. 326. An example of a difference: in art. 26(1) CPC there is no requirement that the indirect infringing actions must be performed 'in or for his business'.

pharmacies, are not deemed as entitled parties as in the first paragraph. This rule is however also included in the Dutch regulation because in art. 73(1) DPA 1995 reference is made only to art. 55-60 and therefore *not* to art. 53 DPA 1995, in which the category mentioned here are referred to as non-infringing persons, which means that offer or delivery of means to them can constitute the indirect infringement referred to in art. 73.⁵ At first glance this is understandable. The intention of art. 26 CPC is precisely to give the patent proprietor a reliable means of taking action himself against the indirect acts. In other words, it does not matter whether or not direct infringement is committed as a consequence of the indirect actions, as for instance used to be the case in Germany.⁶ On closer consideration however, it does seem somewhat strange that someone who may carry out research into the patented subject-matter or a pharmacist who prepares the medication prescribed by a doctor cannot have delivered a means as referred to in art. 73. Particularly as a result of this consequence the provision has been criticised *inter alia* by Mulder and van der Kooij and Schutjens in the Netherlands, and earlier by Hoffmann in Germany.⁷ Helbach however sees the provision as being desirable with a view to an adequate protection of the patent holder.⁸ Schutjens sees two possible solutions, being either removal of art. 26(3) CPC (and amendment of the national laws on this point) or wide-ranging application of art. 26(2) CPC (or: art. 73(2) DPA 1995). This latter provision allows delivery of generally available products, unless the supplier or offering person incites the third party to (direct) infringing acts. Schutjens rightly

5. That this is so intended is also shown in the Explanatory Statement. See also Helbach et al., *Industriële eigendom en mededingingsrecht*, Arnhem 1989, no. 376.

6. See for instance Mes, *Die mittelbare Patentverletzung*, GRUR 1998, p. 281.

7. Schutjens, *loc. cit.*, p. 330-331, Mulder and Van der Kooij, *Directe en indirecte octrooiinbreuk in het voorstel tot wijziging van de Rijksoctrooiwet*, IER 1986, p. 44-45, and Hoffmann, *Die mittelbare Patentverletzung*, GRUR Int. 1975, p. 228-229.

8. *Loc. cit.* (See note 6).

hesitates however as to whether the provision of art. 73(2) is indeed the means of achieving that the persons referred to in art. 53 can be freely supplied without the possibility of the suppliers being accused of indirect infringement. In the first place reference is made in art. 73(2) to only the infringing acts of art. 53(1), so that the research and private activities fall outside this. She further states that in accordance with the Explanatory Memorandum it is the intention to interpret the concept 'means generally available in commerce' in a limited sense.

Should then the provision of art. 26(3) disappear? My opinion is that this should not be allowed to happen, at least not in respect of offer or delivery of means to private individuals. Where researchers are concerned, the provision does indeed seem to me to be undesirable insofar as the operation of the research exception would be limited thereby. In respect of the pharmacists it appears to me that the rights of the patent proprietor are already sufficiently guaranteed by the provision that the exception only applies for the preparation of medicines for *direct* use for the purpose of *individual cases on medical prescription*. Mulder and Van der Kooij also seem to have particular difficulty with the possibility of indirect infringement in the case of deliveries to researchers and pharmacists. In respect of private individuals they are of the opinion that large-scale deliveries to such persons could sometimes have far-reaching consequences for the patent proprietor. Similar considerations can be found in Hoffmann's article where reference is made to the example of the delivery of construction kits to hobbyists. The patent proprietor will indeed not become very agitated about the fact that the person building a machine, which falls under a patent, in his garage for private purposes receives delivery of a component in respect of an essential part of the machine, but cases can be envisaged where the patent proprietor may well indeed have reason to take action in the matter of indirect infringement. It is possible to envisage patients who have medications administered which are converted in the body into a substance covered by a patent.

An example from English jurisprudence can demonstrate

this. This is the Terfenadine case which resulted in the decision of the House of Lords of 1996.⁹ Terfenadine is an anti-histamine. The patent on this substance had lapsed. Only after the patent was granted was it discovered that the anti-histamine activity of terfenadine results from the acid metabolite formed in the liver as a consequence of terfenadine. A new patent was granted, of which claim 24 was used against companies which supplied (the patent-free) terfenadine to patients. Claim 24 relates to products containing the acid metabolite. This substance is first made in the body and not by the supplier of terfenadine. The patent proprietor argued that the supply of terfenadine to pharmacists and the like who supply it to patients constitutes indirect patent infringement. Terfenadine is after all a means in respect of an essential part of the invention and the invention is 'put into effect' (as stated in the English text of the CPC and art. 60 Patents Act) by the conversion of this substance into the patented substance in the body of patients. The court did not get around to an assessment of the infringement, since the patent failed through lack of novelty. Lord Hoffmann did however devote some interesting considerations to the role of the patient. Referring to the exclusive rights of the patent proprietor he states:

(p. 82) 'For this purpose it does not matter how the product is made or what form it takes. The monopoly covers every method of manufacture and every form which comes within the description in the claim. So claim 24 includes the making of the acid metabolite in one's liver just as much as making it by synthetic process, in the body as well as in isolation;'

and further on, concerning the question of whether a particular description ('*a part of the chemical reaction in the human body produced by the ingestion of terfenadine and having an antihistamine effect*') is novelty destroying, he states:

(p. 90) 'It enabled the public to work the invention by making the acid metabolite in their livers. The fact that they would not have been able to

9. Merrel Dow/Norton (1996) RPC, p. 76.

describe the chemical reaction in these terms does not mean that they were not working the invention. Whether or not a person is working a product invention is an objective fact independent of what he knows or thinks about what he is doing. ... The volunteers in the clinical trials who took terfenadine were doing exactly what they would have done if they had attended Merrell Dow's Strasbourg symposium and decided to try making the acid metabolite.'

While these statements were not made in the context of a decision on indirect infringement, they do illustrate strikingly that a patient can play a crucial part in putting 'into effect' a patent and therefore in indirect infringement by the supplier of the per se patent-free substance, assuming at least that the supplier knows, or that it is evident considering the circumstances, that - in this case - terfenadine is suitable and intended for that application. In a case such as this, various matters will not be too difficult to infer from the information leaflet provided with the product. For the sake of certainty, I note that the fact that the patient is not supplied with the means by the manufacturer thereof but by the doctor, pharmacist or hospital does of course not in any way alter the fact that the manufacturer is indirectly infringing by offering and delivering the means.¹⁰

It is also possible in such cases to envisage that, although the means to be supplied do not themselves fall under the patent, there is even direct infringement by the supplier, so that the course of indirect infringement, which is trickier on account of the subjective elements, does not have to be followed. Another English case can illustrate this. This was the decision of the House of Lords of 1997.¹¹ The patents in question related to the substance ampicillin and its preparations methods. Ampicillin is an antibiotic. The alleged infringer supplied the substance hetacillin, which itself exhibits no antibiotic activity and resembles ampicillin in chemical structure but, because it lacks a free NH²-

10. See Benkard/Bruchhausen, Patentgesetz, Gebrauchsmustergesetz, 1993, p. 4-17 and the jurisprudence cited there.

11. Beecham/Bristol (1978) RPC, p. 153.

group, displays an essential difference. When hetacillin is introduced into water or into the body fluid of the patient it is converted into ampicillin. Whether delivery of the hetacillin, which in itself did not fall under the patent, constituted indirect infringement was not a subject of discussion. The court decided that hetacillin was no more than a chemical equivalent of ampicillin. When hetacillin is sold this substance does not comply with the characteristics of the claimed ampicillin, but this ends as soon as hetacillin is administered. There is only a temporary masking. This case shows that, where one may think in terms of indirect infringement (and where the actions in question are possible to qualify as such) direct infringement by equivalency can be assumed. In Germany the production and supply of particular parts can also constitute direct infringement.¹²

Whichever way one looks at it however, I am of the opinion that the removal of art. 26(3) CPC as advocated by Schutjens would be mistaken, certainly in respect of private individuals. The chemical reactions in the human body can cause the creation of compounds which fall under patents. When the elements administered for this purpose cannot be viewed as equivalents of the compounds resulting from these reactions, whereby they do not constitute a direct patent infringement, the remedy of indirect infringement is of great importance to the patent proprietor.

12. See e.g. Hoffmann, GRUR Int. 1975, p. 229-230 with reference to the 'Dia-Rämchen V' case decided by the Bundesgerichtshof.