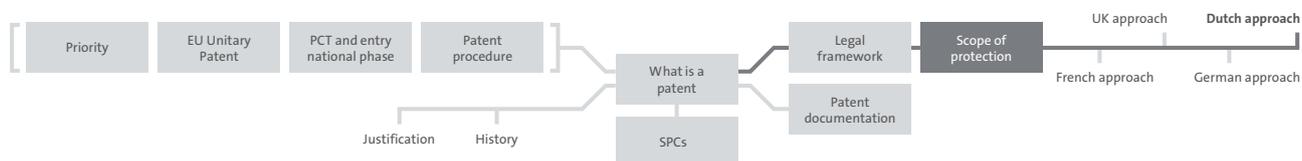

The Dutch approach (Supplementary reading)



Introduction

Determining the scope of protection of a patent is relevant not only with respect to establishing infringement, but also with respect to assessing validity. The Dutch courts assess actions for patent infringement and counterclaims in which the validity of the patent is contested at the same time in the same proceedings, i.e. there is no bifurcated patent system in the Netherlands.

In the Netherlands, patent cases are exclusively litigated before the courts of The Hague. The district court and the appeals court decide the facts and the law. The Dutch Supreme Court's task is in principle limited to reviewing how the lower court has applied the law, and thus it will not review the facts. The interpretation of a (specific) patent is regarded as a matter of fact by the Supreme Court. However, it has nonetheless repeatedly shed light on how the scope of protection of a patent should be established in general.

The Dutch Supreme Court's approach to the scope of protection of patents

In 1930, the Dutch Supreme Court ruled in the case *Philips v Tasseron* that the law is violated when a judge does not take the essence of the invention ("*het wezen van de uitvinding*") as a starting point for establishing the scope of protection of a patent. This doctrine remained established case law for a long time. Under this approach, it was possible for a judge to accord a broader scope to the patent than would follow from the exact wording of the claims. The determination of the scope of protection on the basis of this doctrine was unchallengeable on appeal before the Supreme Court because of its factual nature.

Supreme Court of the Netherlands, 20 June 1930, *NJ* 1930, p. 1217 with commentary from PS (*Philips v Tasseron*).

See e.g. Supreme Court of the Netherlands 23 June 1972, *NJ* 1972, 451 with commentary from LWH, BIE 1972, 228 (*Fruitsortermachine*); opinion of advocate general Franx at Supreme Court of the Netherlands, 10 June 1983, *NJ* 1984, 32 with commentary from LWH (*Pfizer v Pharmon*).

The Supreme Court's doctrine of the essence of the invention was heavily criticised, because the scope of protection, when determined by applying this doctrine, was not foreseeable by third parties. The legal certainty of third parties was thus at issue, since third parties (i.e. competitors) could

not rely on the substance of the patent claims when determining the scope of protection of the patent.

In 1978, when incorporating changes resulting from the ratification of the European Patent Convention, the Netherlands also adapted its national patent law to the provisions of the Strasbourg Convention. As a result, the Dutch Patent Act 1910 (*Rijksoctrooiwet 1910*) stated in Article 30(2) that the claims determine the scope of protection of a patent and that the description and drawings serve to interpret those claims. The Dutch courts did not, however, immediately align their judgments with the uniform European provisions on the determination of the scope of protection.

Nowadays, this provision is included in Article 53(2) of the Dutch Patent Act 1995.

It was argued that the Dutch approach had to give way to the European provisions on the determination of the scope of protection of European (national) patents. In other words, Article 69 EPC – and not national laws – should be applied when determining the scope of protection.

See Pieroen, Diss. 1988; see also Huydecoper, BIE 1992, 34; Hamaker, *IER* 1994, 161; Wien, *NJB* 1995, 1035; Hoijtink, BIE 1995; Brinkhof, BIE 1995, 6.

It was only in 1995 that the Supreme Court changed its approach as regards the determination of the scope of protection, and then only slightly. In *Ciba Geigy v Oté Optics*, it took, as usual, the essence of the invention as a starting point for establishing the scope of protection of a patent. It then went on, however, to clarify “the essence of the invention” by introducing a new wording, namely “the inventive concept behind the wording of the claims” (“*de achter de woorden van de conclusies liggende uitvindingsgedachte*”). The Supreme Court further acknowledged that application of the doctrine of the essence of the invention does not make any allowance for a reasonable degree of certainty for third parties. For this reason, a court, once it has determined the essence of the invention, must assess whether sufficient justice has been done for the legal certainty of third parties. According to the Supreme Court, a lack of clarity for the average person skilled in the art would justify an interpretation that is more in line with the wording used. However, the extent of the innovation would in turn provide scope for protection extending beyond the actual words of the claims.

Supreme Court of the Netherlands, 13 January 1995, *NJ* 1995, 391 (*Ciba Geigy v Oté Optics*).

In 2007, the Supreme Court made it clear in *Lely v Delaval* that the essence of the invention is not to be considered as a “starting point,” but as a “viewpoint” (“*gezichtspunt*”). In *AGA v Occlutech* (2012) and, more recently, *Medinol v Abbott* (2014), the Supreme Court again mentioned the viewpoints to be taken into account when determining the scope of protection. The effect of the Supreme Court’s use of these viewpoints may not be noticeable in the case law of the lower courts, which does not mention the essence of the invention as an important element in determining the scope of protection of European and national patents.

Supreme Court of the Netherlands, 7 September 2007 (*Lely v Delaval*).

Supreme Court of the Netherlands, 25 May 2012 (*AGA v Occlutech*).

In **Medinol v Abbott**, the Supreme Court also referred to the viewpoints to be taken into account when determining the scope of protection. In this case, Medinol argued that, when determining the scope of protection of a patent, the literal wording of the claims must prevail and that the scope of protection of a patent can (be broadened, but) not be limited by the description and the drawings. According to Medinol, the context of the claims (i.e. the description and the drawings) is of importance only when the wording of the claims is not clear. The Supreme Court ruled that Medinol's argument ignored the fact that Article 1 of the Protocol puts beyond doubt that the scope of a European patent is not exclusively determined by the literal wording of the claims, and that Article 69 EPC should not be construed as meaning that the description and drawings may only serve to eliminate any ambiguities. If from reading the description the skilled man comes to that conclusion, the extent of the protection conferred by the claims can be even more limited than might appear when reading the claims out of context.

Supreme Court of the Netherlands,
4 April 2014 (*Medinol v Abbott*).

Relevance of the prosecution file for determining the scope of protection

Defendants may rely on the prosecution file when arguing the scope of protection. The Supreme Court ruled in **Meyn v Stork** (1989) that third parties may assume that the patentee wanted to limit himself by the chosen wording of the claims, if good reasons existed for that assumption having regard to the patent specification in the light of any other known data, such as the prosecution file.

Supreme Court of the Netherlands,
27 January 1989, NJ 1989, 506, GRUR Int.
1990, 386; IIC 1992, 533 (*Meyn v Stork*),
para. 3.5.

According to the Supreme Court in **Ciba Geigy v Oté Optics** (1995), the prosecution file only plays a role in determining the scope of protection if, after consideration of the description and the drawings, reasonable doubt exists as to the interpretation of the claims. This approach was confirmed by the Supreme Court in **Dow v Stamicarbon** (1997) and **Van Bentum v Kool** (2002).

Supreme Court of the Netherlands,
13 January 1995, NJ 1995, 391 (*Ciba Geigy
v Oté Optics*).

Supreme Court of the Netherlands,
5 September 1997, BIE 1998, 85 (*Dow v
Stamicarbon*) and Supreme Court of the
Netherlands, 29 March 2002, RvdW 2002,
64 (*Van Bentum v Kool*).

The Supreme Court also ruled in *Ciba Geigy v Oté Optics* that ambiguities which result from an inaccurate formulation are in principle at the patentee's own risk. According to the Court, arguments from the prosecution file in favour of the patentee may be used to a limited extent only. The defendant in infringement proceedings, however, may always derive arguments from the prosecution file.

In **Saier v Dijkstra** (2006), the Supreme Court ruled that third parties are not limited to using arguments based on the prosecution file.

Supreme Court of the Netherlands,
22 December 2006, RvdW 2007/25 (*Saier
v Dijkstra*).

Indirect infringement

The patentee may enforce its patent against any party which, in or for its business, offers or supplies means relating to an essential element of the patented invention to parties which are not entitled to use the patented invention (Article 73 Dutch Patent Act). A patent is infringed only when both the offering or supplying and the application of the invention take place in the Netherlands. It does not matter whether the means relating to an essential element of the patented invention are offered or supplied from the Netherlands or from abroad. Furthermore, the party supplying the means must know that those means are suitable and intended for application of the patented invention, or that such is evident in view of the circumstances.

Pres. District Court The Hague, 13 December 1988, BIE 1991, 135 (*mixers*);
Pres. District Court The Hague, 8 September 1998, BIE 1999, 244 (*Rustibus*);
Court of Appeal The Hague, 30 March 2010, I 2010, 70 (*Van Beelen v Otter*).

In the case *Sara Lee v Intergro* (2003), the Supreme Court decided that the mere necessity of a certain element for the purposes of the invention does not in itself render it essential to the patented invention: the relevant feature must, in addition, distinguish the invention from the prior art.

Supreme Court of the Netherlands, 31 October 2003, BIE 2004, 47 with commentary from JdH (*Sara Lee v Intergro*), para. 3.4.2.

Equivalence

The Dutch courts also take into account infringement by way of equivalence. In the event that a product or process does not fulfill one or more features of a patent claim, the court will establish whether or not the product or process contains equivalent measures.

Following on from the Supreme Court's decision in *Dreizler v Remeha* (1995), the Dutch courts usually apply the so-called "function-way-result test". In patent cases relating to chemical inventions, the lower courts may also apply the "insubstantial differences test" or assess whether it is "obvious to a person skilled in the art that substantially the same result as that achieved by means of the element as expressed in the claim can be achieved by means of the equivalent element." In this test, the court assesses whether a difference between a product (or process) and a claim is material.

Supreme Court, 13 January 1995, NJ 1995, 392 (*Dreizler v Remeha*).

See District Court The Hague, 28 October 1998 (*Yamanouchi v Biogen*).

In its decision in *Stamicarbon v Dow* (1998), the Supreme Court acknowledged that a product or process could fall within the scope of protection of a patent by way of equivalence, but ruled that equivalence does not pertain where application of the alleged infringing process leads to a significantly inferior result.

Supreme Court of the Netherlands, 5 September 1997, BIE 1998, 85 (*Stamicarbon v Dow*).

The lower Dutch courts have become very reluctant to accept equivalence, since more and more attention is being paid to legal certainty for third parties. In recent years, there have been hardly any cases where the lower courts have accepted infringement by way of equivalence. Furthermore, it has been held in lower-court decisions that inventive variants, i.e. products or processes which are protected by an independent patent, cannot be considered equivalents.

The most recent patent cases where the Dutch courts accepted infringement by way of equivalence are: District Court The Hague, 31 March 2010 (*Ezendam v Lommers*), para. 4.23, District Court The Hague, 2 July 2008 (*Novartis v Actavis and Pharmachemie*), para. 4.99, Court of Appeal The Hague, 24 May 2007 (*Air Force v Smillie*), para. 15-16, and Court of Appeal The Hague, 23 February 2006 (*Multifase Schroef-spilpomp*), para. 33. In the latter case, however, the Supreme Court decided (25 April 2008) that the Court of Appeal's judgment as regards infringement by way of equivalence could not be upheld, since the Court of Appeal, contrary to Article 24 of the Dutch Code of Civil Procedure, complemented the factual basis of the defendant's infringement claim (para. 4.4.1–4.5).

Date at which the claims must be interpreted for the purpose of infringement proceedings

The Supreme Court ruled in *Medinol v Abbott* (2014) that, when determining the scope of protection of a patent, the knowledge of the skilled person at the filing date or priority date serves as a guide. Within the framework of establishing infringement, in addition to the knowledge of the skilled person on the filing or priority date, significance can also be attached to the knowledge of the skilled person at the infringement date, especially when infringement by way of equivalence has to be assessed.

Supreme Court of the Netherlands, 4 April 2014 (*Medinol v Abbott*), para. 3.5.2.

Defences to infringement

In the Netherlands, the research exemption is laid down in Article 53(3) DPA. This article states that acts serving solely for research on the patented subject-matter, including the product obtained directly as a result of using the patented process, do not infringe the exclusive right of the patent owner.

Research exemption: Article 53(3) DPA

According to the legislative history of the Dutch Patent Act, this research exemption must be interpreted restrictively. It is designed only for acts that serve exclusively for investigating the patented invention. It follows from the doctrine and case law that only research having a purely scientific character is considered to fall under the research exemption. Market research or large-scale manufacture is not allowed. Performing clinical trials within the context of obtaining market authorisation for a generic medicinal product does not fall under the research exemption either.

Kamerstukken 2005–2006, 30 663 (R 1812), nr. 3, p. 3.

Supreme Court, 18 December 1992, IER 1993, 17, BIE 1993, 310, (*Medicopharma v ICI*); Supreme Court, 23 June 1995, BIE 1997, 235 (*ARS v Organon*); District Court The Hague, 17 January 2007, BIE 2007, 474 (*Conor v Angiotech*).

The Bolar exemption set out in Article 10(6) of Directive 2001/83/EC (as amended) was implemented in Article 53(4) DPA. This provision states that conducting the necessary studies, tests and trials within the context

Bolar exemption: Article 53(4) DPA

of obtaining market authorisation for a generic medicinal product (hybrid generics and biosimilars included) is not to be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Article 53(4) DPA refers to the studies, tests and trials that must be performed in order to obtain marketing authorisation for either of the generic medicinal products referred to in Article 10(1-4) of Directive 2001/83/EC (i.e. “true” generics, hybrid generics and biosimilars). This means that both the bioavailability studies which are required within the context of true generic applications and the preclinical tests and clinical trials which are required within the context of hybrid applications and biosimilar applications are permitted to be performed. Such studies, tests and trials are hence not considered to infringe the exclusive rights of a patentee. There is no Dutch case law specifically dealing with the Bolar exemption.

If a challenged product belongs to the prior art, or is a non-inventive variant of that art, it cannot infringe a later patent. After all, a patent cannot be interpreted such that the prior art falls within the scope of protection: the patent would then be (partially) invalid. This fundamental principle was first clearly formulated by Lord Moulton of the British House of Lords in 1913, in *Gillette v Anglo American Trading Company*, and has since been known as the “Gillette defence”.

House of Lords, *Gillette v Anglo-American* [1913] 30 RPC 465.

The Gillette defence is acknowledged by the Dutch courts. In Dutch proceedings, it may also be applied in cases of alleged “literal” infringement – i.e. equivalence is not a condition. Examples of Dutch case law in which the Gillette defence played a role are *SKB v FAL Duiven* (2006), *Fort Vale v Pelican* (2007), *MSD v Generieken* (2008) and *B+R v Van den Berg* (2010).

District Court The Hague, 22 March 2006, BIE 2006, 83 (*SKB v FAL Duiven*), para. 4.20, District Court The Hague, 30 May 2007, IEPT 20070530 (*Fort Vale v Pelican*), para. 4.19–4.21, District Court The Hague, 13 February 2008, IEPT 20080213 (*MSD v Generieken*), para. 5.14, and District Court The Hague, 27 April 2010, IEPT 20100427 (*B+R v Van den Berg*), para. 4.12.