3 November 2017

First Chamber

15/04934

RM/EE

Supreme Court of the Netherlands

Judgment

in the matter of:

the legal entity incorporated under foreign law
MERCK SHARP & DOHME CORP.,
formerly called Schering Corporation,
having its present corporate domicile in White Station, New Jersey, United States of America,
The Appellant in Cassation,
Counsel: T. Cohen Jehoram and V. Rörsch,

v:

1. TEVA PHARMA B.V.
having its corporate domicile in Haarlem, the Netherlands,

2. PHARMACHEMIE B.V.
having its corporate domicile in Haarlem, the Netherlands,

The APPELLEES in Cassation,

Counsel: R.P.J.L. Tjittes.

The Parties shall also be referred to as MSD and Teva. The plaintiff is referred to as Schering in the contested judgment.

1. The proceedings in the fact-finding instances

The Supreme Court refers to the following documents for the history of the proceedings in the fact-finding instances:

a. ruling in the case 358401/HA ZA 10-437, issued by the District Court of The Hague on 10 November 2010;

b. judgment in the case 200.082.008/02, issued by the Appellate Court of The Hague on 14 July 2015.

The judgment by the Appellate Court is attached to this Judgment.

2. The proceedings in cassation

MSD filed a cassation appeal against the judgment by the Appellate Court. The notice of appeal in cassation is attached to this judgment and constitutes a part of it.

Teva moved to dismiss the appeal.

The case was argued orally for the parties by their counsel; Teva [sic] also provided a written commentary on the case.

The statement of the Advocate-General M.H. Wissink proposes that the contested judgment should be annulled.

Counsel for MSD responded to that statement in a letter dated 23 June 2017; counsel for Teva also did so in a letter of the same date.

3. Assessment of the appeal in cassation

3.1 The Supreme Court may proceed on the basis of the facts and circumstances stated at 2.1-2.11 of the Advocate-General's statement, for the purposes of the cassation appeal. This is what the facts and circumstances amount to:

(i) Chronic hepatitis C is a serious viral infectious disease. There are a number of variants of Hepatitis C virus (HCV), referred to as genotypes 1 to 6.

(ii) In European patent EP 0 707 855 (hereinafter "**Grint**"), published on 24 April 1996, the combination of ribavirin and interferon alpha was disclosed in the form of a 'Swiss-type' claim for the treatment of (*inter alia*) naive chronic hepatitis C patients for a period of 6 to 12 months, without any differentiation as to genotype of the hepatitis virus. Naive patients are patients who were not previously treated.

(iii) MSD holds European patent 0 956 861 (hereinafter: EP 861 or the patent), which was granted to it on 24 April 2002 for (inter alia) the Netherlands on the basis of an application dated 13 May 1999, claiming priority since 15 May 1998 of US 79566. The description of EP 861 (hereinafter also "**the EP 861 Description**") states (inter alia) the following, [*translation note*: *in the "undisputed Dutch translation" quoted in original Dutch document*]:

> "Background to the invention
> (...)
> Interferon alpha-interferon monotherapy is commonly used to treat chronic hepatitis C infections. (...). However, this monotherapy treatment has been found ineffective. Combination therapy of interferon alpha and ribavirin has been proposed (...). However, no-one has described methods using interferon alpha and ribavarin which eradicate HCV-RNA in the long term and are effective for antivirally naive patients having a genotype specific HCV infection.
> (...)
> Summary of the invention
> (...)
> We have discovered that if the antiviral treatment naive patient has an HCV genotype 1 infection, or if the antiviral treatment naive patient has an HCV genotype 1 infection and a viral load of greater than 2 million copies per ml of HCV-RNA by quantitative PCR, then the administration of the combination therapy is effected for a time period of 40-50 weeks, preferably 48 weeks.
> (...) . "

Claim 1 of EP 861, as granted reads as follows [*in the – so far as relevant – undisputed Dutch translation*]:

> "The use of ribavirin for the manufacture of a pharmaceutical composition for treating a patient having chronic hepatitis C infection to eradicate detectable HCV-RNA wherein the pharmaceutical composition is for administering an effective amount of ribavirin in association with an effective amount of interferon alpha, characterized in that the ribavirin in association with the interferon alpha, is for administration for a time period of 40-50 weeks, the patient is an antiviral treatment naive patient, and the patient is one having a HCV genotype 1 infection and a viral load of greater than 2 million copies per ml of serum as measured by HCV-RNA quantitative PCR."

Claim 2 assumes the use of interferon for the manufacture of the pharmaceutical composition named in claim 1; claim 3 assumes the use of ribavirin and interferon together. The claims of EP 861 are 'Swiss-type' claims, as are those of Grint.

(iv) Following opposition before the Opposition Division of the European Patent Office (EPO) and two appeals in opposition before the Technical Board of Appeal of the EPO, EP 861 was maintained unaltered.

(v) MSD markets capsules and tablets in accordance with EP 861 under the respective brand names of 'Rebetol' and 'Copegus'.

(vi) Pursuant to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (hereinafter "Directive 2001/83"), Member States that place medicinal products on the market for human use must have a marketing authorisation (Article 6). Pursuant to Article 8, the application for the marketing

authorisation must be accompanied by the test results of clinical and pre-clinical trials (Article 8(3)(i)) and a summary of the product characteristics (hereinafter SmPC). Article 10 provides that, in derogation of Article 8(3)(i), the applicant is not required to provide the results of clinical and pre-clinical trials if he can demonstrate that the medicinal product is essentially similar to a medicinal product authorised in the Member State. Article 11 sets forth the information to be included in the SmPC, and the order in which this must be done. The following categories are important in this matter:

- 4.1 = Therapeutic indications;
- 4.2 = Posology and route of administration;
- 4.3 = Contra-indications;
- 4.4 = Special precautions for use;
- 5.1 = Pharmacological particulars.

Article 11 also contains the following passage:

> "For marketing authorisations pursuant to Article 10, it is not necessary to mention the parts of the summary of product characteristics of the reference medicine that refer to the indications or to dosage forms and that came under the patent right when a generic medicinal product was marketed."

If parts of the SmPC of the reference product are left out in the SmPC of a generic product on this basis, this is referred to as a carve-out. An SmPC of a generic product containing carve-outs is also referred to as a 'skinny label'.

(vii) In 2009, via the central European registration procedure and with Rebetol and Copegus as reference products, Teva B.V. obtained the following two marketing authorisations for marketing of generic ribavirin:

- for capsules on March 31, 2009 ('RIbavirin Teva', marketing authorisation EU 1/09/509), amended on 16 November 2009 via a 'Type II variation';
- for tablets, on October 19, 2009 ('Ribavirin Teva Pharma B.V.', marketing authorisation EU 1/09/527), amended on 22 January 2010 via a 'Type II variation'.

(viii) Pharmachemie is designated in the SmPCs and product information leaflets of Teva B.V.'s generic ribavirin as the 'Manufacturer' and 'Manufacturer responsible for release' of Ribivarin Teva and Ribavirin Teva Pharma B.V. in the European Union.

(ix) Categories 4.1 and 4.2 of the SmPC for the amended marketing authorisations for the Teva capsules state the following (where the passages underlined by the Appellate Court relate to indications or dosage forms that may be classified as 'carved out'):

> **"4.1 Therapeutic indications**
> (…)
> Naive patients

> Adult patients: Ribavirin is indicated, in combination with interferon alpha 2b, for the treatment of naive adult patients with all types of chronic hepatitis C except genotype 1 (…)
> Children and adolescents: Ribavirin is intended for use, in combination with interferon alpha 2b, for the treatment of naive children and adolescents aged 3 and up with all types of chronic hepatitis C except genotype 1 (…).
> (…)
> Patients who did not respond to previous treatment
> Adult patients: Ribavirin is indicated, in combination with interferon alpha 2b, for the treatment of adult patients with chronic hepatitis who previously responded to monotherapy with interferon alpha (…) but who later relapsed.
>
> **4.2 Posology and manner of administration**
> (…).
> Ribavirin capsules in combination with interferon alpha 2b:
> On the basis of results of clinical studies, it is advised to treat patients for at least six months.
> (…)
> Duration of treatment - naive patients
> - Other than genotype 1: a decision to carry out treatment for one full year in patients with negative HCV-RNA after six months of treatment must be based on other prognostic factors (e.g. Age > 40, male, septal fibrosis)
> Duration of treatment - repeated treatment
> - Genotype 1: the treatment must be continued for a subsequent period of six months (i.e. one year in total) in patients who exhibited a negative HCV-RNA after six months of treatment.
> - Other than genotype 1: the decision to carry out treatment for one full year in patients with negative HCV-RNA after six months of treatment must be based on other prognostic factors (…)."

Categories 4.3 and 4.4 of the aforementioned SmPC do not contain warnings for side effects and do not urge that caution should be exercised in administering the capsules to the category of naïve patients with HCV genotype 1 who have been 'carved out' in categories 4.1 and 4.2. Category 5 of the SmPC describes (*inter alia*) three clinical studies relating to combinations of ribavirin and interferon alpha 2b in naïve patients infected with all genotypes of HCV. Category 5.1 states the following in relation to one such study, C/198-580:

> "In this study the combination of ribavirin and peginterferon alpha 2b (…) was significantly more effective than the combination of ribavirin and interferon alpha 2b, particularly in patients with a genotype 1 infection."

A table is also shown in which the results for genotype 1 are broken down into categories such as viral loads of more and less than 600,000 IU/ml.

The parts/passages of the SmPC for Teva's capsules included above have the same content as the corresponding parts/passages of the SmPC for the Teva tablets.

(x) Paragraph 1 of the product information leaflet for Teva's generic ribavirin tablets according to the amended marketing authorisation states the following:

> "Ribavirin Teva Pharma B.V. is used in adults in combination with peginterferon alpha 2b or interferon alpha 2b for the treatment of patients with chronic hepatitis C. The situations in which Ribavirin Teva Pharma B.V. can be used in adults are stated below:
> ● In combination with alpha 2b interferon or peginterferon alpha 2b in adults not previously treated for chronic hepatitis C (…)."

The product information leaflet for the generic Teva capsules does not differ essentially from the leaflet for tablets.

(xi) In June or October 2011 Teva introduced its generic ribavirin tablets on the Dutch market. It does not market ribavirin capsules in the Netherlands, nor did it in the past.

3.2.1 In the original proceedings, MSD sought (among other claims) a declaratory decision stating that Teva´s generic products fell within the scope of protection of EP 861, an injunction against infringement of the Patent in the Netherlands and an order for compensation, the amount to be determined by the court, or surrender of profits.
In the counterclaim, Teva sought (among other claims) a declaratory decision of non-infringement of the Dutch part of EP 861 and, subject to the condition that an infringement was established, invalidity of the Dutch part of the Patent.

3.2.2 The District Court dismissed the claim in the original proceedings and issued a declaratory decision in the counterclaim that Teva was not infringing the Dutch part of EP 861.
The District Court's deliberations to this end were that there had been no activities by Teva that brought it within the scope of protection of the Swiss-type claims being relied upon, so that there was no infringement of the Patent by Teva (para. 4.1). Teva had adequately ensured, by means of a 'carve-out', that it remained outside the scope of protection of the Swiss-type claims of the Patent (para. 4.4). Teva had excluded the specific patient category claimed by MSD (naive and with genotype 1 infection). That was sufficient to remain outside the scope of protection of the Patent (para. 4.6).

3.2.3 The Appellate Court ratified the District Court ruling and dismissed MSD's claims on appeal.

3.2.4 The Appellate Court made the following findings in relation to the extent of protection of the Patent.

> "4.2 The claims of EP 861 are formulated as 'Swiss-type' claims that were deemed necessary under the 'old' European Patent Convention (EPC) – in connection with its Article 53(c) – in order to patent a new therapeutic use of a substance for which a therapeutic use was already known. A therapeutic use may be new in (*inter alia*) the following cases:
> - the substance is applied for a different indication (the 'new' indication) than the indication for which it was used in the prior art: the classical second medical indication (hereinafter "**2M-I**");
> - the substance is – as in EP 861 – used in a sub-group of the group for which the known indication was already used, hereinafter called: the sub-group indication ("**SG-I**").
> Teva rightly emphasised (…) the fact that there is an essential difference between the two categories of inventions. In a 2M-I invention, the substance is used for an indication for which it was not previously used, and the invention lies in this new use. In an SG-I invention, the substance is used for an indication for which the substance was previously used, and the invention rests in identifying the

sub-group, in this selection. This difference has consequences for the extent of protection of the patent (including the acts reserved to the patent owner), see also the passage in the protocol on the interpretation of Article 69 of the EPC, to the effect that the interpretation of a patent is in part determined by the 'reasonable' protection accruing to the patent owner, which also brings to expression that the protection of the patent owner ought to go no further than justified by his invention.

4.3 A 2M-I patent protects against the use of the substance for the treatment of a 'new' indication. If a substance is marketed by a third party without specifically mentioning this 'new' use, but also without a (consequential) restriction being made for its use, then it is possible that the substance marketed by that third party is also used for the treatment of the 'new' indication, and in this way that the benefits of the invention are utilised by someone other than the patent owner. For this reason, the extent of protection of a 2M-I patent may extend to the substance being marketed by a third party, even if it is not specifically stated that it is meant for the 'new' use. This idea lies at the basis of the judgment delivered by this Court on January 27, 2015 in the *Novartis v Sun* case (case no. 200.150.713/01; *IEF* 14599; *BIE* 2015, no. 15, p. 79.

4.4 An SG-I patent protects against the use of the substance for the selected sub-group of patients. If the substance is marketed by a third party without specifically stating that this is a 'new' use, but also without any restriction being made with regard to its use, then it is possible that the substance will also be used for the treatment of the sub-group, but this does not yet mean – in contrast to a 2M-I patent – that the benefits of the patented invention are utilised by someone other than the patent owner. It was already known in the prior art that the substance could be used for the group of patients to which the sub-group belongs, so that the substance could also be used for treatment of the sub-group. To utilise the benefits of an SG-I invention, it is therefore necessary that the substance is used *specifically* for the sub-group (and in this case, also for a specific duration of treatment). As a result (…) the extent of protection of an SG-I patent is limited to the situation in which it is *specifically* indicated by the third party that the substance is intended for the sub-group (and in this case also for the specific duration of treatment).

4.5 From these findings it follows that the case law that focuses on the characteristics of 2M-I patents lacks relevance in this case. For this reason, Schering's line of reasoning, which is based on this (…), will be disregarded."

3.2.5 The Appellate Court held (para. 5.2), in relation to direct infringement, that it would in any event be required that the average person skilled in the art would consider, based on the SmPC and/or the product information leaflet accompanying Teva's generic ribavirin, that it was specifically intended for the sub-group mentioned at 4.1 (the Genotype 1 naive sub-group, abbreviated to G1N sub-group). 'Naive patients with a genotype 1 infection' are carved out in sections 4.1 and 4.2 of the Teva SmPCs and there is no mention of patients with a 'viral load of more than 2 million copies per ml of serum'. These sections, which relate to the indications, the dosage and the route of administration and which must therefore be regarded as the most important sources of information regarding the purpose of the medicinal product, do not therefore give any reason to assume that Teva's generic products are meant specifically for the G1N sub-group. (para. 5.3) The Teva product information leaflets do not mention a 'genotype I infection' or a 'viral load of more than 2 million copies per ml serum/600,000 IE/ml' at all. There is accordingly no reason to assume that the man skilled in the art will read a specific purpose for the G1N sub-group into this. (para. 5.4) The findings under para. 5.3 and 5.4 mean that the minimum requirement stated in para. 5.2 for direct infringement is not satisfied (para. 5.5). As

regards indirect infringement, the Appellate Court concludes, proceeding from the assumption that there is an indirect infringement situation, that generic ribavirin is not a 'means' as defined in section 73 of the Dutch Patents Act 1995 ('DPA 1995') relating to an essential element of the invention in EP 861 (para. 6.5).

Proceeding on the basis of the said SmPCs and product information leaflets, there is accordingly no direct or indirect patent infringement by Teva, irrespective as to whether Teva's generic ribavirin is prescribed, sold and supplied by doctors or pharmacists for the application patented in EP 861 (treatment of the G1N sub-group) and irrespective as to whether that substance is used by naive genotype 1 patients (para. 7.1). MSD provided no different facts for its reliance upon general tort law, other than those used for its reliance upon direct and indirect patent infringement. Taking account of the fact that the concept of indirect patent infringement in particular is essentially part of the general tortious act tenet in situations such as this one ("Patentgefährdung"), there is no scope for making findings about the tort claims that differ from those regarding the patent infringement claims (para. 7.3). MSD's offer to furnish evidence that doctors and pharmacists were applying the invention in EP 861 by prescribing Teva's ribavirin and/or patients were doing so by using it is of no consequence in the light of the foregoing deliberations and is accordingly bypassed for that reason (para. 7.4).

3.3.1 Cassation ground 1 targets paras. 4.2, 4.4 and 4.5 and the consequent deliberations in the contested judgment. This cassation ground argues that the distinction drawn in terms of the extent of protection of patents in relation to the 'classic second medical indication' mentioned by the Appellate Court at para. 4.2 of the contested judgment and the 'sub-group indication' is incorrect. After all, the scope of protection of the European patent is, in brief, determined by the content of the claims and not by the question of whether an invention is part of a specific category. The Appellate Court established the scope of protection of patents such as the one involved here *in abstracto*, and was wrong in categorically according them a more limited scope of protection or alternatively categorically setting a different standard for the scope of protection. In so doing, the Appellate Court breached Article 69 of the European Patent Convention ("EPC") or at least did not supply sufficient justification for its opinion on this point.

3.3.2 The other cassation grounds focus complaints against the findings by the Appellate Court relating to direct infringement (cassation ground 2) and indirect infringement (cassation ground 3). Appeals are also made against wrongly disregarding of MSD's offer to furnish evidence (cassation ground 4) and the rejection of the tort claim (cassation ground 5). Cassation ground 6 contains a complaint that expands on the previous grounds for appeal.

3.4.1 The following are the prime considerations in the assessment of the cassation grounds.

3.4.2 Put briefly, the EPC excludes patents for methods for medical treatment (currently Article 53, preamble and at c EPC; formerly Article 52(4) (old) EPC). Article 54(4) EPC (formerly article 54(5) (old) EPC; cf. section 4(5) DPA 1995) opens up the possibility, however, of obtaining a patent for known substances for application in a method for medical treatment, provided this application is not part of the prior art. This possibility deals with the 'first medical indication'. However, this provision offers no solace for the need to be able to patent a second medical indication of a known substance, having regard on the one hand to the exclusion referred to in Article 53, preamble and at c EPC, and on the other hand Article 54(1) EPC (the requirement for novelty). A second medical indication includes the case where a new medical application is found for an already known substance, which already has a known medical application. Swiss-type claims, as in the Patent, were permitted by the Enlarged Board of Appeal of the EPO (EBoA 5 December 1984, G 0001/83, G 0005/83 and G 0006/83) so as to be able to protect a second medical indication as a patent. Swiss-type claims are formulated as purpose-limited process claims, such that "the use of substance X for the preparation of a medicinal substance for the treatment of disease Y" is placed under protection.
Pursuant to Article 64(2) EPC and section 53(1) preamble and at b DPA 1995, the extent of protection of these process claims extends to the results directly obtained by such process.
With the review of the EPC in 2000 (Treaty Series 2002/9 and 2002/62), coming into effect on 13 December 2007 (Treaty Series 2007/233), second medical indication patents became possible (the current Article 54(5) EPC; cf. section 4(6) DPA 1995). The Enlarged Board of Appeal subsequently decided that, as a result of this regulation, Swiss-type claims could no longer be used for European patent applications (EBoA 19 February 2010, G 0002/08). The ruling is not retrospective in effect, so that earlier Swiss-type claims, including the present EP 861 continue in force.

Extent of protection of patents

3.4.3 The extent of protection of the European patent is regulated in Article 69 EPC and the associated interpretation protocol (hereinafter the 'Protocol'). The interpretation thereof is based on the criteria set out in Articles 31 and 32 of the Vienna Convention on the Law of Treaties of 23 May 1969 (Treaty Series 1972, 51 and Treaty Series 1985, 79). Article 69(1) EPC specifies that the extent of protection of a patent is determined by the claims of the patent application, with the description and drawings serving to interpret those claims. Article 1 of the Protocol pertaining to Article 69 EPC reads as follows:

> "Article 1
>
> General principles

> Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties."

A summary of the case law of the Supreme Court relating to Article 69 EPC and to the Protocol is set out in Supreme Court 5 February 2016, ECLI:NL:HR:2016:196, NJ 2016/496 (*Bayer v Sandoz*).

Extent of protection of Swiss-type claims

Direct infringement

3.4.4 The difficulty arises with a patent containing a Swiss-type claim, which is formulated by its nature as a process claim (see 3.4.2), since as a result of the effect of Article 64(2) EPC or section 53(1) preamble and at b DPA 1995 (cf. above in 3.4.2), the extent of protection would also extend to the manufacture or application of the substance for the first medical indication if that patent has expired. This would be incompatible with the principle underlying patent law to the effect that anyone is at liberty to apply the doctrine of a patent that is no longer in effect, and also with the principle expressed in Article 69 EPC that the extent of protection of a patent should not extend beyond what is justified by the invention. For this reason, it must be assumed that a manufacturer or seller will only then directy infringe a patent with a Swiss-type claim if he foresees or ought to foresee that the generic substance he manufacturers or offers will intentionally be used for treatment covered by the second medical indication patent. This requires that the average person skilled in the art, on the basis of the SmPC and/or the product information leaflet or some other circumstance, will consider that the substance is (also) intended for or suited to that treatment. The manufacturer or seller will then have to take all effective measures that can reasonably be required of him to prevent his product from being dispensed for the patented second medical indication. The mere circumstance of a carve-out in the SmPC and product information leaflet of the generic drug – as in the present case – is generally not sufficient to rule out direct infringement. (Cf. Supreme Court 14 April 2017, ECLI:NL:HR:2017:692, NJ 2017/296, para. 3.5.2).

3.5 Against the background of all of the foregoing factors, cassation grounds 1.1, 1.2 and 1.3 correctly complain that the distinction drawn by the Appellate Court in the scope of protection of

patents for the 'classic second medical indication' and the 'sub-group indication', mentioned at 4.2 of the contested judgment, is an incorrect distinction. As follows from the deliberations at 3.4.4 above, it is necessary in all cases of Swiss-type claims for (direct) infringement, and also sufficient, that the average person skilled in the art will consider that the substance is (also) intended for or suited to the treatment covered by the second medical indication patent, that the manufacturer or seller foresees or ought to foresee that the generic drug he manufactures or offers will intentionally be used for that treatment and that he does not take the steps specified above in 3.4.4. There is no place in the system of the EPC for a categorical distinction between the two types of second medical indications, introduced *in abstracto*, as done by the Appellate Court at the end of 4.4 – in relation to the specifically indicated use. The remaining complaints in cassation ground 1 require no discussion. The same applies to cassation ground 2.

Indirect infringement

3.6.1 Cassation ground 3 contests the findings at 6.2-6.5 of the contested judgment, where the Appellate Court investigated whether Teva was indirectly infringing EP 861. It appears from 6.1 that the Appellate Court was proceeding on the assumption that an indirect infringement of a Swiss-type claim was conceivable. Teva argues that this is not the case, so that MSD has no interest in cassation ground 3. The following deliberations pertain to this aspect.

3.6.2 According to section 73 DPA 1995 there is an indirect patent infringement if, put briefly, a person in or for his business supplies or offers to supply means relating to an essential element of the invention for putting the invention into effect, provided that the person knows or it is obvious given the circumstances that those means are suitable and intended for that use.

3.6.3 As already held at 3.4.2 above, Swiss-type claims are recognized in order to be able to protect a second medical indication as a patent and they take the form of purpose-limited process claims. It could be argued that, taken literally, there cannot be an indirect infringement of such a patent, for instance by an intermediary, since he would after all not be supplying or offering to supply means that could be used for the process in the manner specified in section 73(1) DPA 1995, consisting of the use of the substance mentioned in the claim for the preparation of a pharmaceutical product. Against the background of the reason that gave rise to recognition of the Swiss-type claims, and also having regard to the possibility available in the EPC since the revision in 2000 of linking a product-bound *result claim* to a patent for the protection of a second medical indication (Article 54(5) EPC incorporated in the DPA 1995 as Section 4(6)) – a revision that did not intend to break with the patentability of substances or combinations, as developed in case law, by means of a Swiss type claim (see EBoA 19 February 2010,

G 0002/08, at 5.10.1-4 and the Preparatory Documents MR/18/00 and MR/24/00 quoted therein) – the reasonable protection of the patent proprietor prescribed by Article 1 of the Protocol justifies accepting that there can be an indirect infringement of a Swiss-type claim, on the same basis as for a claim in accordance with the current Article 54(5) EPC. A finding along the same lines was made by the *Bundesgerichtshof* (BGH 14 June 2016, no. X ZR 29/15, GRUR 2016/921 (Eli Lilly v Actavis), paras. 83-85). The possibility of an indirect infringement of a Swiss-type claim has also been acknowledged by the Supreme Court of the United Kingdom (UKSC 12 July 2017, no. [2017] UKSC 48 (Actavis v Eli Lilly), paras. 103-112).

3.6.4 This means that, as is the case with a patent containing a claim such as those rendered possible by Article 54(5) EPC, an indirect infringement of a Swiss-type claim is possible. With a purpose-limited product claim, the purpose given to the product (the drug) is after all "an essential element of the invention" as specified in section 73 DPA 1995. The foregoing deliberations mean that the manufacturer of a generic medicine can also indirectly infringe a patent for a second medical indication, namely if he supplies or offers to supply the drug to persons not entitled to work the invention and where he knows or it is obvious given the circumstances, that the drug is suitable and intended for the patented second medical indication. It is not an objection to this that he can therefore both directly and indirectly infringe such a patent. The UKSC has also held, as is apparent from the case law cited at 3.6.3, that the same conduct may amount to both direct and indirect infringement.

3.6.5 Teva's defense, quoted at 3.6.1 above, is therefore ineffective. Cassation ground 3, in whose disposal MSD therefore has an interest, also requires no disposal.

3.6.6 With a view to the disposal following referral, it should further be noted that the decision in SC 31 October 2003, ECLI:NL:HR:2003:AI0346, NJ 2006/600 ('Senseo') should not be understood such that there can only be 'means relating to an essential element of the invention' as specified in section 73(1) DPA 1995, if it concerns an element in the patent claims, let alone in that part of the claims (often introduced with words such as 'characterized in that') containing a description of how the invention differs from the prior art. The formulation of the passage in question must be read in the light of the debate between the parties in that case and the findings made by the Appellate Court on that point. What is understood by 'a means relating to an essential element of the invention' requires interpretation of the patent and is strongly intertwined with assessments of a factual nature. Neither Dutch nor foreign case law and literature provide any clear description in general terms of what is understood by this. It may be inferred from the judgement of the BGH dated 4 May 2004, cited by the Appellate Court at 6.4, as well as the formulation by Benyamini quoted in that case, that the means

must be able to serve the concept of the invention, that which the invention is based upon, and must contribute to the realization of the teachings in the patent. In each individual case, based on his interpretation of the patent, the judge must ask himself whether this is the case, which may involve asking whether the contentious means plays such a part in the application of the doctrine in the patent that the ratio behind the existence of the notion of indirect patent infringement is satisfied; in the words of the Advocate-General in his statement for the *Senseo* judgment (at 3.4), preventing third parties from directly making unauthorized use of the invention through the supply of (unprotected) material.

Other cassation grounds

3.7 Following on from the findings that cassation grounds 1.1, 1.2 and 1.3 are successful, the consequent complaint in ground for appeal 6 also succeeds. The remaining grounds for appeal do not require to be decided upon.

Costs of the proceedings

3.8 As the party found to be in the wrong in the cassation appeal, Teva should be ordered to pay the costs of the proceedings. As MSD has claimed payment of the costs of the cassation appeal on the basis of Article 1019h of the Dutch Code of Civil Procedure, and as the parties have reached agreement on the amount to be awarded, the decision will reflect this.

4. Decision

The Supreme Court hereby:

- annuls the judgment by the Appellate Court of The Hague dated 14 July 2015;
- refers the case back to the Appellate Court for further disposal and judgment;
- orders Teva to pay the costs of the cassation appeal, estimated for MSD at the date of this pronouncement at €936.02 for disbursements and €100,000 for other procedural expenses.

This judgment is issued by the Vice-President, E.J. Numann, as presiding judge and by Judges G. Snijders, M.V. Polak, C.E. du Perron and M.J. Kroeze, and is pronounced in open court by Judge T.H. Tanja-van den Broek on 3 November 2017.

[signed] [signed]

[stamp]

Issued as a true copy

The Clerk of the Supreme Court of the Netherlands