JUDGMENT

DISTRICT COURT OF THE HAGUE

Civil Law Section

case number / cause list number: 245396/HA ZA 05-2019

Judgment of 17 May 2006

in the matter of

1. the private limited company
TEVA PHARMACEUTICALS EUROPE B.V.,
having its registered office in MIJDRECHT,
2. the private limited company
TEVA PHARMA B.V.,
having its registered office in MIJDRECHT,
3. the private limited company
PHARMACHEMIE B.V.,
having its registered office in HAARLEM,
claimants in the main action,
defendants in the counterclaim proceedings,
local counsel M.A.A. van Wijngaarden,

versus

the legal person under foreign law
MSD OVERSEAS MANUFACTURING CO. (IRELAND),
having its registered office in BERMUDA,
defendant in the main action,
claimant in the counterclaim proceedings,
local counsel P.J.M. von Schmidt auf Altenstadt,
attorney L. Oosting of Amsterdam.

The parties will hereinafter be called Teva and Merck.

1. The proceedings

1.1 The course of the proceedings appears from:
- the summons,
- the statement of defence in the main action and the counterclaim,
- the statement of reply in the main action and the statement of defence in the counterclaim proceedings,
- the pleading notes and the documents presented during oral arguments.

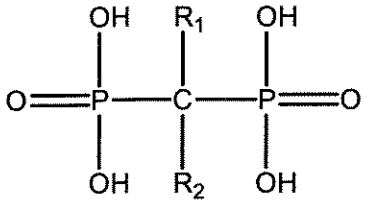
1.2 Judgment was passed on 3 May 2006.

2. The facts

in the main action and in the counterclaim proceedings

2.1 After transfer, Merck became the proprietor of Dutch patent 192562 (hereinafter: the patent or NL '562) granted on 3 October 1997 on the basis of an application of 15 April 1983, claiming priority as of 15 April 1982 for a *pharmaceutical preparation comprising an NH_2-$(CH_2)_3$-$C(PO_3H_2)_2OH$ compound.*

2.2 Said compound belongs to the group of bisphosphonates with the general structure formula:



Bisphosphonates contain two C-P compounds and have a bone resorption inhibiting effect.
Bone replacement is a continuous process. The removal of old bone is called resorption, the forming of new bone is called mineralisation. The two processes are normally in equilibrium. With bone diseases this equilibrium is disrupted and on balance there is more resorption than mineralisation. Osteoporosis is a well-known bone disease which occurs relatively frequently in women after the menopause. Paget's disease is another bone disease which is treated with bisphosphonates.
The compound which is central to the patent has a carbon chain of four C atoms with a hydroxy group at the 1 position and an amino group at the end of the carbon chain (thus $R_1 = (CH_2)_3$-NH_2 and $R_2 = OH$) and, in accordance with the terminology used by the parties, will hereinafter be called alendronate or the C-4 compound (4-amino-1, hydroxybutane-1, 1-bisphosphonic acid or the salt thereof). Other related substances known on the priority date are etidronate, a C-2 compound without an amino group (in English trade literature also referred to by the abbreviation EHDP), clodronate, with a C-Cl_2 compound (also known as Cl_2MDP, whereby R_1=R_2=Cl), also without an amino group at the end of the chain, pamidronate, a C-3 compound with, just like alendronate, an NH_2 group at the end of the chain and an OH group at the 1 position, also called AHPDP, and neridronate, a C-6 compound with an OH group at 1 and an NH_2 group at 6. A C-5 compound was also known on the priority date, for which no common derivative name is used.

The patent was granted pursuant to the Patent Act 1910 and therefore relates to a pre-examined patent. The Applications Department of the Patent Council originally refused it in a decision of 10 November 1987, which decision was quashed by decision of 28 February 1997 (sent on 3 March 1997) after an appeal was presented to the Board of Appeal. The patent was then granted on 3 October 1997, after final amendments suggested by the Board of Appeal were implemented. The patent expired

on 15 April 2003, but Merck is still claiming rights under this patent because of a supplementary protection certificate ('SPC') granted to it under this patent under number 970038, based on NL '562 and valid up to and including 14 April 2008. This SPC was granted to Merck for: *alendronic acid, if so desired in the form of a (...) salt with an alkali metal, an organic base or a basic amino acid or in the form of a hydrate, in particular Natrii Alendronas Trihydric.*

2.3 The claims of NL '562 read:

1. Pharmaceutical preparation comprising an NH_2-$(CH_2)_3$-$C(PO_3H_2)_2OH$ compound, characterised in thatthe preparation is suitable for the treatment of bone diseases,wherein the 4-amino-1-hydroxybutane-1, 1-bisphosphonic acid is present as such or in the form of a salt with an alkali metal, an organic base or a basic amino acid, under the proviso thatwhen the 4-amino-1-hydroxybutane-1, 1-bisphosphonic acid is not present in the form of a salt, it is the only pharmaceutically active ingredient present in the preparation.
2. Pharmaceutical preparation according to claim 1, characterised in that the preparation is in a solid form for oral admininstration.

2.4 In 2002 Merck brought preliminary relief proceedings against Teva in respect of a (threatened) infringement of the patent. The case was dropped because, in short, Teva agreed, for the time being, not to put a generic alendronate against bone diseases on the market, and, if it were to intend to do so in the future, to announce six weeks in advance that it had such intention. At the beginning of March 2005, in accordance with was agreed in 2002, Teva announced it intended to put a generic alendronate on the market. Merck once again instituted preliminary relief proceedings for infringement, which resulted in a judgment of 25 April 2005 of the preliminary relief judge of this district court (BIE 2005, 104, KG ZA 05/354, case number 239877). As the judge was of the opinion that there was a good chance that the patent (and thus the SPC) would not survive a revocation procedure because of lack of inventive step, the preliminary relief judge dismissed the case. An appeal was lodged against this judgment. Also the courts of Hamburg and Dusseldorf (in cancellation proceedings of an "einstweilige Verfügung" and the application for the same, respectively) were of the opinion that the German (parallel) patent/SPC probably lacked inventive step (judgments of 1 June and 6 December 2005, respectively). The President of the Tribunal de Grande Instance de Paris passed a similar judgment on 6 May 2005. Stockholm's Tingsrätt, on the other hand, did not deem it likely on 6 February 2006 that the Swedish patent would be held invalid. The conclusions of the foreign parallel patents differ from each other on some points.

2.5 In proceedings on the merits the English court held the British sister patent - at least, in the eyes of Teva - of NL '562 invalid for lack of inventive step, both at first instance and in appeal (judgments of 21 January and 6 November 2003). The United States District Court of Delaware, on the other hand, held the patent (with extended protection term) valid on 4 November 2002 (and assumed that Teva infringed it), which was confirmed in appeal by the United States Court of Appeals, Federal Circuit, on 30 October 2003.

3. The dispute

in the main action

3.1 Teva is seeking, briefly put, that the Supplementary Protection Certificate with number 970038 in the name of Merck will be declared invalid, increased by costs.

3.2 Merck has presented a defence. Insofar as relevant, the parties' claims will be discussed below.

in the counterclaim proceedings

3.3 Merck is seeking, summarized, an injunction prohibiting Teva from infringing the aforementioned SPC in the Netherlands, with additional claims and compensation/transfer of profits, the exact amount to be determined in subsequent damage proceedings, also increased with costs.

3.4 Teva has presented a defence. Insofar as relevant, the parties' claims will be discussed below.

4. The assessment

in the main action and the counterclaim proceedings

4.1 Both in the main action and the counterclaim proceedings Teva has taken the position that the patent and the SPC are invalid, which position the court will now review first.

4.2 Teva has, in the context, put the question whether the disclaimer, which was added to the claim of NL '562 when the patent was granted, being *" under the proviso that when the 4-amino-1-hydroxybutane-1, 1-bisphosphonic acid is not present in the form of a salt, it is the only pharmaceutically active ingredient present in the preparation"*, is in conflict with Article 75 Paragraph 1.c of the Patent Act, because it forms impermissible added matter. This disclaimer was introduced in the procedure before the Board of Appeal of the BIE. Insofar as the court is aware, this disclaimer has only been included in the Dutch patent and not in the parallel foreign patents. The court considers as follows.

4.3 It is stated *a priori* that the court, when answering – under Dutch patent law – the question whether a disclaimer such as the one at issue is permissible, seeks alignment with the case law of the Enlarged Board of Appeal of the EPO, as developed in G1/03 (OJ EPO 2004, 413) and G2/03 (OJ EPO 2004, 448) of 8 April 2004. In said judgments the Enlarged Board of Appeal of the EPO held that a disclaimer without basis in the original documents was only allowed in three cases: (i) as an exclusion of the fictitious state of the art, (ii) as an exclusion of an accidental anticipation and (iii) by exclusions of patenting for non-technical reasons.

4.4 Merck's argument, referring to the BIE Guideline (p. 9-6), that such a disclaimer was accepted under the old law if there was "ordinary" anticipation, is rejected. Aside from the question whether the civil court who has to evaluate the validity of a patent

is bound by said Guideline, said passage does not state in so many words that anticipations other than accidental or fictitious ones could be disclaimed. On the contrary, it is claimed that a disclaimer for an "accidental anticipation" will as a rule not result in problems, while with a disclaimer for known state of the art "relating to the same application area" problems generally can be expected. The decision of the Enlarged Board of Appeal of the EPO does not in any other sense constitute such a break from previous case law (to the extent there is actually any "break", in any event not so far as Dutch case law is concerned), that such should be deemed to form grounds for derogation.

4.5 The court furthermore considers that Merck did not contest Teva's claim that the disclaimer referred to under 4.2 does not have any basis in the original documents, so that it can be assumed that there is no such basis. The basic principle is furthermore that the disclaimer has been included with an eye on EP 0039033 A1 in the name of Henkel Kommanditgesellschaft auf Aktien in Dusseldorf, published on 4 November 1981 (*i.e.* prior to the priority date of the patent), hereinafter also "Blum". The question to be answered is thus whether Blum is to be deemed an accidental anticipation. According to the above-mentioned decisions of the Enlarged Board of Appeal of the EPO, there will only be an accidental anticipation if the document is so little related and so remote that the average skilled person would never have taken the document into consideration when creating the invention. The court agrees with this interpretation. It is then important that it has become sufficiently clear that Blum does not meet that requirement, whereby the following circumstances have been taken into consideration.

4.6 (1) It is not in dispute that the general expertise of the average skilled person on the priority date included the knowledge that there was wide-spread interest for the clinical use of biphosphonates, to which alendronate belongs, for the treatment of bone diseases. (2) The average skilled person in search of other biphosphonates for bone diseases (such as is suggested in Fleisch) will also look for a synthesis route of these biphosphonates and thus come to Blum, because it discloses a preparation method of ω-amino-1-hydroxyalkyl-1, 1-biphosphonic acids (including alendronate). (3) It was also clear that on the priority date it was already known that biphosphonates (Etidronate, Clodronate and Pamidronate) used in the treatment of bone diseases, found their origin in the washing detergents industry (cf. no. 41 statement of defence in the main action, counterclaim) to which technical area Blum relates, according to Merck. These two technical fields consequently started to overlap and justified the assumption that the average skilled person in search of new medicines for bone disorders also followed the developments of biphosphonates for detergents. (4) Finally, it is important that Blum itself, possibly not completely unambiguously, includes a reference to the use of the aminoalkanediphosphonic acids (like alendronate) in the preparation of pharmaceutical preparations (p. 5, lines 16-18).

4.7 The above leads the court to the conclusion that Blum is not so unrelated and remote that the average skilled person never took this document into consideration when searching for other biphosphonates, which could be used in the treatment of bone disorders. This means there is no accidental anticipation and the disclaimer forms unauthorised added matter. This disclaimer cannot, *e.g.* by means of partial revocation, be removed from the claim because this would result in abroadening of the scope of protection. Consequently, this ground for invalidity of NL '562 is

effective, whereby as a result of the provisions of Article 15, Paragraph 1.c Regulation 1786/92 the SPC based on said invalid, but expired, patent is also invalid, so that the claim in the main action can be awarded. The other grounds for invalidity as presented by Teva need not be dealt with.

4.8 Merck, as the party held to be in the wrong, will be ordered to pay the costs of the main action. The costs on the part of Teva are fixed at:

- summons	EUR	71.93
- court fees		244.00
- local counsel's salary		1,152.00 (3.0 points x rate EUR 384.00)
Total	EUR	1,467.93

in the counterclaim proceedings

4.9 No injunction can be claimed on the basis of an invalid SPC, so that the claims in the counterclaim proceedings must be dismissed.

4.10 .Merck, as the party held to be in the wrong, will be ordered to pay the costs of the main action. The costs on the part of Teva are fixed at:

- local counsel's salary		576.00 (3.0 points x factor 0.5 x rate EUR 384.00)
Total	EUR	576.00

5. The decision

The court

in the main action

5.1 declares the Supplementary Protection Certificate with number 970038 invalid.

5.2 orders Merck to pay the costs of the proceedings, fixed to date on the part of Teva at EUR 1,467.93,

5.3 declares this judgment in the main action to be immediately enforceable with regard to the order for costs,

5.4 dismisses any further and other claims,

in the counterclaim proceedings

5.5 dismisses the claims,

5.6 orders Merck to pay the costs of the proceedings, fixed to date on the part of Teva at EUR 576.00,

5.7 declares this judgment in the counterclaim proceedings to be immediately enforceable with regard to the order for costs.

This judgment is passed by Chr.A.J.F.M. Hensen, E.F. Brinkman and D. van Oostveen and pronounced in public on 17 May 2006.