IN THE NAME OF THE QUEEN

9 March 2006

AMSTERDAM COURT OF APPEAL
FOURTH THREE-JUDGE SECTION FOR CIVIL MATTERS

JUDGMENT
in the matter between:

the private company with limited liability
MERCK SHARP & DOHME b.v.,
with its registered office in Haarlem, the Netherlands,
APPELLANT,
local counsel: *mr*. L. Oosting,

and

the private company with limited liability
PHARMACHEMIE B.V.
with its registered office in Haarlem,
RESPONDENT,
local counsel: *mr*. G.W. Kernkamp.

1. The appeal case

The parties shall hereinafter be referred to as MSD and Pharmachemie.

By a notice dated 21 October 2005, MSD filed an appeal against a judgment in preliminary relief proceedings by the preliminary relief judge of the Haarlem District Court, rendered in this matter under case/cause-list number 116813/KG ZA 05-495 between Pharmachemie as the claimant in the original action, respondent in the (conditional) counterclaim, and MSD as the defendant in the original action, claimant in the (conditional) counterclaim, and pronounced on 23 September 2005.
The notice of appeal contains the grounds for appeal.

In accordance with its notice of appeal, MSD submitted a statement with the grounds for appeal and produced exhibits, moving that the Court of Appeal must reverse the judgment of the court below – insofar as the claims in the original claim were granted – and must after all reject Pharmachemie's claims, and, succinctly put, order Pharmachemie, on pain of a penalty, to send out letters of rectification and place a message of rectification on its website, while sending copies of the letters of rectification to MSD's local counsel, and order Pharmachemie to pay the costs of the proceedings in both instances.

Pharmachemie submitted a defence on appeal disputing the grounds for appeal and produced exhibits, moving that the Court of Appeal must uphold the judgment of the court below and

reject MSD's claims on appeal, rendering an immediately enforceable judgment and ordering MSD to pay the costs of the appeal (as interpreted by the Court of Appeal).

The parties argued their case at the court session of 10 February 2006, MSD represented by its local counsel and Pharmachemie by *mr*. M.A.A. van Wijngaarden, attorney practising in The Hague, both based on the written arguments submitted. At the oral arguments, both parties submitted more exhibits to the proceedings.

In conclusion, the parties requested a judgment on the documents of both instances, the contents of which are considered to be inserted here.

2. Grounds for appeal

For the grounds for appeal, we refer to the notice of appeal.

3. Facts

In the judgment being appealed, the preliminary relief judge enumerated the facts on which he based the assessment of the parties' dispute under 2.1 through 2.11. These facts were not disputed in the appeal and thus the Court of Appeal also bases its judgment on them.

4. Assessment

4.1. MSD markets the medicine Fosamax in the form of 10 mg and 70 mg tablets. This medicine, whose active substance is sodium alendronate trihydrate, is used to treat osteoporosis.
The Dutch basic patent, granted at the time to the Instituto Gentili S.p.a. in Pisa, Italy, was transferred to MSD Overseas Manufacturing Co. (Ireland), a company affiliated with MSD, and expired on 15 April 2003. The Supplemental Protection Certificate no. 970038 granted to MSD Overseas Manufacturing Co. (Ireland) is at issue in proceedings initiated by Pharmachemie at The Hague District Court, claiming its nullification.
On 21 April 2005 and 6 July 2005, respectively, Pharmachemie received registrations from the Medicines Evaluation Board (hereafter MEB) for the medicines alendronic acid 10 PCH and alendronic acid 70 PCH (active substance: sodium alendronate monohydrate). These are generic variants of Fosamax. The 70 PCH variant was marketed on 22 July 2005, and the 10 PCH variant in August 2005.

In letters dated 23 June, 29 June and 13 July 2005, MSD addressed a large number of pharmacists and (dispensing) physicians and, succinctly put, pointed out possible disadvantages of the prescription and use of recently registered generic variants of Fosamax, as well as the merits of the products it markets. Also, MSD placed the letter of 13 July on the part of its website www.mds.nl accessible to the public.
On 30 September 2005, the MEB cancelled the registration of alendronic acid 70 PCH at Pharmachemie's request. This was done because doubts had arisen as to whether Pharmachemie had followed the right procedure for obtaining the authorisation of the medicine in the Netherlands, since the medicine had already been registered in the United Kingdom in the name of an affiliated company.
On 20 December 2005, Pharmachemie obtained a new registration for alendronic acid 70 PCH and it has marketed the medicine since late December under this registration.

4.2. In these proceedings, Pharmachemie claims a prohibition against MSD from making any statements such as the ones, succinctly put, in the aforementioned letters dated 23 June, 29 June and 13 July 2005, as well as an order for MSD to rectify all this by means of a letter of rectification sent to the recipients of those letters and by placing a rectification on its website. The preliminary relief judge granted the main part of Pharmachemie's claims (in amended form). In its grounds for appeal, MSD is disputing this decision and the grounds on which it is based.

4.3. The letters disputed by Pharmachemie started with a reference to "generic variants of Fosamax" or "generic alendronic acid preparations" recently registered in the Netherlands. It is an established fact that the registration for alendronic acid 10 PCH was granted on 21 April 2005 and the one for alendronic acid 70 PCH on 6 July 2005. In its oral arguments in the appeal, MSD pointed out that on 6 June 2005, two registrations were granted in the name of Kromme Rijn Apotheek, but it can reasonably be assumed that the registrations granted to Pharmachemie at the time – a major player in the (generic) medicines market – will have been noticed by the relevant market parties. Thus, the preliminary relief judge rightly assumed that the addressees of the letters and/or the relevant public will have linked the statements made to Pharmachemie's products registered at that time and subsequently marketed, and that therefore the statements constituted (implicit) comparative advertising. The fact that these products had not yet been marketed at the time the letters were sent is not relevant in this respect: it is sufficiently likely that the market parties approached by MSD knew which generic medicine the reference concerned.
Grounds for appeal I through III therefore fail.

4.4 The preliminary relief judge rightly assumed that in its letters MSD creates the impression that Pharmachemie's registration applications are solely based on bioequivalence studies and that they are misleading in that respect. The fact that all this is allegedly customary for generic medicines, and that MSD, at the time the letters were sent, did not know that additional safety studies had been performed into the tablet characteristic of Pharmachemie's products and that these had been included in the dossier to be assessed by the MEB (at the MEB's initiative) is at MSD's risk and does not detract from the imputability of its course of action. In principle, it is up to the party using comparative advertising to ensure that they have all the relevant information and that they do not imprudently criticise their competitor's product or make insinuations about it.

In its statements, MSD at least created the suggestion that the MEB's assessment had been insufficient and that the registration had wrongly been granted. The fact that the addressees were expected to know that this was only MSD's opinion, even if it were correct, does not detract from the misleading character of those statements, all the more since MSD definitely refers to research ('Studies have shown…').
This entails that grounds for appeal IV through VI also fail.

4.5. In the explanation of its seventh ground for appeal, MSD argues that it submitted various reports to support its point of view, including studies which had not been previously assessed by the MEB. MSD has not sufficiently clarified that these studies – insofar as they were performed independently – prove the suggestion which was raised with respect to the safety of Pharmachemie's products to be true/well-founded (in its oral arguments on appeal, MSD mentions "possibly deviating" characteristics). Nor is this sufficiently decisive, in the light of the fact that the MEB definitely paid attention to the tablet characteristics. This ground for appeal also fails.

In this respect, the Court of Appeal wishes to point out that the study submitted by MSD as exhibit 44 (Abbreviated Clinical Study Report) only pertains – as was stated by the parties in the court session – to the 10 mg tablets to be taken daily, involving higher risks due to harmful side effects (especially damage to the oesophageal wall), and that this study did not entail a direct comparison with Fosamax 10 mg.

4.6. In its eighth ground for appeal, MSD addresses the preliminary relief judge's opinion that MSD's statements in its letter of 13 July 2005 regarding the medicine's packaging were in violation of the provisions of Book 6, Section 194(a) (c) of the Dutch Civil Code. The Court of Appeal also believes that the suggestion made in that letter, that the "other types of alendronic acid packaging" do not sufficiently tackle the risk of incorrect use, is as yet insufficiently supported by the facts presented by MSD and that its statement that the packaging and information leaflet of Fosamax 70 mg "distinguishes itself from other types of alendronic acid packaging in its clearly patient-oriented packaging and information leaflet, which promotes correct use, proper compliance and minimises the risk of inadvertent overdosing" must therefore be qualified as a subjective and non-verifiable statement.
With respect to MSD's argument that there can be no question of comparative advertising with Pharmachemie products since the products had not yet been marketed at the time the aforementioned letter was sent, the Court of Appeal refers to its findings above under 4.3 regarding the traceability of the reference. Nor does MSD at all illustrate how the recipients of its letters should have interpreted the statements with respect to the characteristics of the retail packaging of Fosamax 70 mg, compared to that of "the other types of alendronic acid packaging": there is no dispute about Pharmachemie having entered the market with the generic variants shortly thereafter.

4.7. The fact that Pharmachemie only (actually) addressed its objection against the letter of 13 July 2005 (there dated 12 July 2005) being placed on MSD's website in its increase of claim – which was received by MSD on the night of 14 September 2005 – and that MSD removed the disputed letter from its website the following day, does not entail that the preliminary relief judge wrongly ordered MSD to place a rectification on the website. After all, it must already have been clear to MSD when it received the draft summons – which explicitly mentioned the letter's publication on the website – that Pharmachemie objected to the contents of this letter and therefore against its publication through (for example) MSD's website, without this having prompted MSD to remove it. In this light, it is impossible to maintain that Pharmachemie has no interest in the relevant relief. Therefore, ground for appeal IX is also unsuccessful.

4.8. In its tenth ground for appeal, MSD argues that Pharmachemie no longer has an interest in the relief granted by the district court, now that the 70 mg product has been cancelled by the MEB at Pharmachemie's request and that in the given circumstances there is no room for a "clearance sale" as referred to in Article 22 of the Pharmaceuticals Registration Decree. Apart from the fact that such does not prejudice the interest in the relief insofar as it also concerns the 10 mg product and that MSD's statements can still be harmful if the 70 mg product (already registered in the United Kingdom) were re-introduced in the Netherlands only some time, Pharmachemie undisputedly argued in its oral arguments on appeal that the product was as yet registered in December 2005 and has been marketed under a new registration number since 20 December 2005. The last fact entails that this grounds for appeal also fails.

4.9. The general ground for appeal XI lacks any independent meaning and shares the same fate as the grounds discussed above.

4.10. It is clear from the above that none of the grounds for appeal asserted by MSD are successful. The judgment of the preliminary relief judge will be upheld, with an order for MSD to pay the cost of the appeal proceedings. MSD's claims on appeal will be rejected.

5. Decision

The Court of Appeal:

upholds the judgment of the court below, insofar as subjected to the opinion of the Court of Appeal;

orders MSD to pay the costs of the appeal proceedings, which for Pharmachemie until now amount to EUR 2,973;

rejects MSD's claims on appeal;

declares the order to pay the costs to be immediately enforceable.

This judgment was rendered by *mr*. N. van Lingen, *mr*. J.H. Huijzer and *mr*. E.E. van Tuyll van Serooskerken-Roëll and was pronounced in public by the cause-list justice on 9 March 2006.

[signed] [signed]

mr. T.A.C. van Hartingsveldt

ISSUED FOR TRUE COPY
TO: *mr*. G.W. Kernkamp
THE REGISTRAR
[initialled]