IN THE NAME OF THE QUEEN

JUDGMENT

DISTRICT COURT OF HAARLEM

Civil Law Sector

Cause-list number: 116813/KG ZA 05-495

Judgment in preliminary relief proceedings of 23 September 2005 (accelerated)

in the case of

the private limited company **PHARMACHEMIE B.V.**,
having its registered office in Haarlem,
plaintiff in the claim proceedings,
defendant in the counterclaim proceedings,
court-registered lawyer M. Middeldorp,
attorney M.A.A. van Wijngaarden of The Hague,

versus

the private limited company **MERCK SHARP & DOHME B.V.**,
having its registered office in Haarlem,
defendant in the claim proceedings,
plaintiff in the counterclaim proceedings,
court-registered lawyer H.K. Garvelink,
attorney L. Oosting of Amsterdam

The parties will hereafter be referred to as Pharmachemie and MSD.

1. The course of the proceedings

1.1 The course of the proceedings is set out in:
- the summons
- the oral arguments
- Pharmachemie's notes on oral arguments
- MSD's notes on oral arguments
- the claim in the counterclaim proceedings.

1.2 Finally, the judgment was passed.

2. The facts

2.1 Pharmachemie develops, produces and sells medicines in various therapeutic areas, in particular "generic" medicines.

2.2 MSD brings the medicine Fosamax on the market in the form of 10 mg and 70 mg tables. Fosamax' active ingredient is sodium alendronate trihydrate, and is indicated for the treatment of osteoporosis.

2.3 On 21 April 2005 the Medicines Evaluation Board (hereafter: "MEB") granted Pharmachemie a registration under number RVG 31768 for the medicine with the registration name "alendronic acid 10 PCH, tablets 10 mg" (hereafter: "Alendronic Acid 10 PCH"). The active ingredient of this medicine is sodium alendronate monohydrate and is indicated for the treatment of osteoporosis. On 6 July 2005 the MEB granted Pharmachemie a registration for the medicine with the registration name "alendronic acid 70 PCH, tablets 70 mg" (hereafter: "Alendronic Acid 70 PCH").

2.4 On 16 June 2005 MSD lodged an objection with MEB against the decision of 21 April 2005, referred to under 2.3, because – in short – it does not believe Alendronic Acid 10 PCH (in accordance with Article 10(1)a(iii) of Directive 2001/83/EC) is "in essence the same as" Fosamax 10 mg.

2.5 By petition of 16 June 2005 MSD asked the preliminary relief judge of the District Court of Haarlem (Administrative Law sector) to suspend the registration / trade permit which the MEB granted to Pharmachemie in relation to Alendronic Acid 10 PCH up to and including six weeks after the decision. The preliminary relief judge dismissed MSD's petition by judgment of 11 August 2005 with cause-list number 05/2502.

2.6 On 23 and 29 June 2005 MSD sent the following letter to an unknown number of pharmacies and/or (dispensing) doctors:

"(...) As you may have heard from your wholesaler, recent generic variations of FOSAMAX® (sodium alendronate, MSD) have been registered in the Netherlands.

We have lodged an objection with the Medicines Evaluation Board against the registration of the various forms of alendronic acid.

The registration applications for alendronic acid are based on bioequivalencies in comparison with FOSAMAX® among volunteers. It is assumed in this respect that two medicines with comparable absorption have comparable effectivity and safety characteristics. However, in addition to the absorption, tablet characteristics such as dissolution and disintegration rate also play a role. Studies have shown that generic alendronic acids can have other tablet characteristics than FOSAMAX®, such as a shorter and longer disintegration time.1

The effectivity and the safety profile of FOSAMAX® have been extensively studied. In 2004 the ten-year data were published which showed that long term treatment with FOSAMAX® is very effective and well-tolerated.2
MSD does not possess clinical effectivity or safety data of alendronic acid of other manufacturers.

As you may know, patent rights are of vital importance for an innovative pharmaceutical company like MSD. We will defend our patent rights in respect of FOSAMAX®.
We reserve the right to hold you liable for the damage which MSD suffers by substitution of FOSAMAX® with alendronic acid. (...)"

2.7 Pharmachemie summoned – inter alia – MSD to appear in preliminary relief proceedings on 28 June 2005 and – in short – argued that MSD had acted wrongfully vis-à-vis Pharmachemie by sending the letter dated 7 June 2005 to customers of MSD and Pharmachemie.
The preliminary relief judge (for the greater part) awarded the claims by judgment of 12 July 2005, cause-list number 05/322.

2.8 On 13 July 2005 MSD sent the following letter to pharmacies and/or (dispensing) doctors:

"(..) As you may have heard, recent generic alendronic acid preparations have been registered in the Netherlands.

These generic registrations are based on bioequivalencies in comparison with FOSAMAX® (sodium alendronate, MSD) among healthy volunteers. It is assumed in this respect that two medicines with comparable absorption have comparable effectivity and safety characteristics. However, with bifosfonates, tablet characteristics such as disintegration and dissolution rate are important for optimal effectivity and safety, as these characteristics can influence the contact time of alendronic acid with the oesophagus and consequently the risk of local side effects. Side effects such as oesophagitis and oesophageal ulcers occur before absorption in the gastrointestinal tract and possible risk differences will therefore not be expressed in bioequivalency tests.

Study has shown that generic alendronic acid can have other tablet characteristics than the original, such as a slower of faster disintegration rate.1
The effectivity and safety of FOSAMAX® have been extensively researched. In 2004 the ten-year data were published which showed that long term treatment with FOSAMAX® is effective and is well-tolerated.2
There are no published data on the clinical effectivity or safety of alendronic acid of other manufacturers.

Furthermore, the packaging of a medicine, including the related consumer information leaflet, is of great importance for the correct use of a medicine. FOSAMAX® 70 mg once a week distinguishes itself from the other alendronic acid packagings by clear patient-friendly packaging and consumer information leaflet, which contributes to proper use and good compliance and minimises the risk of erroneous overdosing.

As a practitioner you play an important role with regard to reporting noted side effects and medicines. We would like to point out to you that it is of importance when noting a side effect (including overdosing or insufficient effectivity) when using alendronic acid, to in specific determine what preparation your patient uses and since when, and to include this information in the notification information to the LAREB.

You can also report possible side effects of FOSAMAX®, Pharmacological Vigilance department, tel. 023-5153836.
(…)
Reference:
1 Epstein, S. et al: Disintegration/dissolution profiles of copies of Fosamax (alendronate Curr Med Res Opin 19 (8): 781-789, 2003
2 Bone, H.G. et al: Ten Years' Experience with Alendronate for Osteoporosis in Postmenopausal Women, New Engl J Med: 12, 2004.

2.9 MSD has placed the letter referred to under 2.8 on the part of its website which is accessible by the general public, www.msd.nl, under products -> fosamax -> "Letter to GPs on FOSAMAX® alendronic acid and pharmacological vigilance".

2.10 On 22 July 2005 Pharmachemie introduced Alendronic Acid 70 PCH on the Dutch market.

2.11 On 2 August 2005 MSD lodged an objection with the MEB against the decision of the MEB referred to under 2.3 of 6 July 2005, whereby Pharmachemie was granted a registration for Alendronic Acid 70 PCH.

3. The dispute in the claim proceedings

3.1 Pharmachemie claims, after an increase in the claim against which MSD has objected – in short – that the preliminary relief judge order by judgment, which is immediately enforceable:

1. to prohibit MSD with immediate effect as of the day of service of this judgment to act wrongfully vis-à-vis Pharmachemie, in specific by prohibiting it from making statements to market parties and the general public, or making suggestions in any way, in writing, verbally, via the internet, or otherwise, such as those made in its letters of 23 June, 29 June and 13 July 2005, or comparable statements, whereby failure to comply with this order is subject to a fine of € 1,000,000 for every individual breach of this injunction or, at Pharmachemie's election, for each day (a part of a day is counted as a whole day) which MSD carries out an action or omission in contravention of this injunction.

2. to order MSD within 7 days after service of this judgment to inform every party who received one or more of the litigious letters dated 23 or 29 June, or 13 July 2005, or any other comparable notice, by recorded mail (with confirmation of receipt), signed by a duly authorised representative, on the company's letterhead, and without any accompanying letter, as follows:

   _____ *2005 [date of the letter]*
   RECTIFICATION BY COURT ORDER

   Dear _____ [name of addressee of the litigious letter/letters].

   By judgment of _____ 2005 [date] the preliminary relief judge of the District Court of Haarlem determined that we have acted <u>wrongfully</u> vis-à-vis Pharmachemie by making the statements in our letters of 23 June, 29 June and 13 July 2005 to pharmacists and (dispensing) doctors, and our letter of 12 July 2005

on our website www.msd.nl. These letters, or at least one or two thereof, have also been sent to you, or you can view them on our website.

In the letters in question we presented, inter alia, unauthorised, misleading comparative advertising, in favour of our product Fosamax, and to the detriment of Pharmachemie's Alendronic Acid 70 PCH, tablets 70 mg and Alendronic Acid 10 PCH, tablets 10 mg.

The court has prohibited us with immediate effect from making this type of statement, or comparable statements, to you and to other market parties.

We have misled the addressees of said letters by suggesting that the effectivity and safety profile of Pharmachemie's alendronic acid medicines is not the same as that of Fosamax, and that the disintegration/dissolution rate of Pharmachemie's products does not with that of Fosamax. Nor should we have suggested that the decision of the MEB to grant a market registration for both of Pharmachemie's medicines was incorrect, and based on an insufficient evaluation of the products. The preliminary relief judge stated the same in his judgment of 11 August 2005. We based our wrongful statements on publications which are in no way relevant for determining the safety and effectivity profile of Pharmachemie's alendronic acid medicines.
Furthermore, we have exaggerated the effectivity of our Fosamax 70 mg product, in comparison with Pharmachemie's alendronic acid products.

We have furthermore wrongly suggested that the packaging of Fosamax 70 mg distinguishes itself from the packaging of Pharmachemie's alendronic acid products by a clear patient-friendly packaging and consumer information leaflet, which contributes to proper use and good compliance and minimises the risk of erroneous overdosing.
There are no relevant differences between the packagings and the consumer information leaflets of these products.
Furthermore we hereby wish to rectify the misconception we have created, that the packaging of Pharmachemie's alendronic acid products do not have a clear, patient-friendly packaging and consumer information leaflet, which contributes to proper use and good compliance and minimises the risk of erroneous overdosing.

In our letters we also failed to mention the list prices of Fosamax and Pharmachemie's alendronic acid products. These are:

Fosamax 70 mg, 4 tablets	*Euro 32.40*
Alendronic Acid 70 PCH, 70 mg tablets, 4 tablets	*Euro 19.44*
Fosamax 10 mg, 30 tablets	*Euro 34.43*
Alendronic Acid 10 PCH, 10 mg tablets, 30 tablets	*Euro 20.66*

Finally, with regard to the patent (infringement) claims which we made in our letters of 23 and 29 June, the court ordered us to inform you that the court prohibited us by judgment of 12 July 2005 to state or suggest to you and other market parties that the trading of Pharmachemie's alendronic acid is an infringement, without always stating
- that in proceedings between Pharmachemie and MSD Overseas Manufacturing with regard to an Additional Protection Certificate (APC) 970038, the

preliminary relief court of the District Court of The Hague held by judgment of 25 April 2005 that there is a good chance that the Dutch patent NL 192562 on which said APC is based will be held void in proceedings on the merit, on the basis of which rights cannot be enforced under this APC, and that the court has dismissed MSD Overseas Manufacturing's claims of infringement based on this ABC;
- that the Opposition department of the European Patent Office revoked the European Patent EP 0.998.292 on 20 July 2004.

The court has also prohibited us from hereafter claiming that we have exclusive rights by virtue of the Dutch Patent NL 192562.

The court ordered us to send you this letter, with these contents.

MERCK SHARP & DOHME B.V., Haarlem
_____ [signature]
_____ [name of authorised representative]

or a statement which the preliminary relief judge deems fair, and furthermore to order MSD, on the day of dispatch of the aforementioned letters, to send a copy of each letter to Pharmachemie's counsel (M.A.A. van Wijngaarden, Sweelinckplein 1, 2517 GK The Hague), whereby failure to comply is subject to a fine of € 1,000,000 for each individual breach of this order or, at Pharmachemie's election, for each day (part of a day being counted as a whole day) that MSD continues to fail to comply with this order in full;

3. to order MSD within 7 days after service of this judgment to rectify the notice dated 12 July 2005 (titled: "letter to GPS regarding Fosamax alendronic acid and pharmacological vigilance") on its website www.msd.nl by placing a notice signed by the duly authorised representative, and to keep said notice on the website for a period of 2 months, without further comment in word or in image, in or around the rectification or elsewhere on a website managed by it or in another publication, with the following contents:

RECTIFICATION BY COURT ORDER

By judgment of _____ 2005 [date] the preliminary relief judge of the District Court of Haarlem determined that we have acted <u>wrongfully</u> vis-à-vis Pharmachemie by means of the statements in our letter of 12 July 2005 entitled "letter to GPs regarding Fosamax alendronic acid and pharmacological vigilance" on our website www.msd.nl; just as with the comparable statements in our letters of 23 June, 29 June and 13 July 2005 to pharmacists and (dispensing) doctors.

In the letters in question we presented, inter alia, unauthorised, misleading comparative (public) advertising, in favour of our product Fosamax, to the detriment of Pharmachemie's Alendronic Acid 70 PCH, tablets 70 mg and Alendronic Acid 10 PCH, tablets 10 mg.

The court has prohibited us with immediate effect from making this type of statement, or comparable statements, to you and to others.

By placing our letter of 12 July 2005 entitled "letter to GPs regarding Fosamax alendronic acid and pharmacological vigilance" on our website we publicly advertised Fosamax. Public advertising for medicines like Fosamax, which is exclusively available on prescription, is not permitted on the grounds of the applicable advertising rules.

Aside from this, with this letter we also misled the reader by suggesting that the effectivity and safety profile of Pharmachemie's alendronic acid medicines is not equal to that of Fosamax, and that the disintegration/dissolution rate of Pharmachemie's products might not correspond with that of Fosamax.
Nor should we have suggested that the decision of the MEB to grant a market registration for both Pharmachemie medicines was incorrect, and was based on an insufficient evaluation of the products.
We also based our wrongful statements on publications which are in no way relevant to determining the safety and effectivity profile of Pharmachemie's alendronic acid medicines.
Furthermore we have exaggerated the effectivity of our Fosamax 70 mg product, in comparison to Pharmachemie's alendronic acid.

We have furthermore wrongly suggested that the packaging of Fosamax 70 mg distinguishes itself from the packaging of Pharmachemie's alendronic acid products by clear patient-friendly packaging and consumer information leaflet, which contributes to proper use and good compliance and minimises the risk of erroneous overdosing.
There are no relevant differences between the packagings and the consumer information leaflet of these products.
Furthermore we hereby wish to rectify the misconception we have created, that the packaging of Pharmachemie's alendronic acid products do not have a clear, patient-friendly packaging and consumer information leaflet, which contributes to proper use and good compliance and minimises the risk of erroneous overdosing.

In our letters we also failed to mention the list prices of Fosamax and Pharmachemie's alendronic acid products. These are:

Fosamax 70 mg, 4 tablets	*Euro 32.40*
Alendronic Acid 70 PCH, 70 mg tablets, 4 tablets	*Euro 19.44*
Fosamax 10 mg, 30 tablets	*Euro 34.43*
Alendronic Acid 10 PCH, 10 mg tablets, 30 tablets	*Euro 20.66*

MERCK SHARP & DOHME B.V., Haarlem
_____ *[signature]*
_____ *[name of authorised representative]*

whereby the rectification is placed in a "pop-up window" which automatically appears on screen when an internet user calls up the MSD home page in any way, which is of such scope that it covers at least half of the home page, in which the text of the rectification is laid out in such way that it is properly and prominently readable, and can be read by the reader by means of "scrolling" from beginning to end, or a notice which the court holds to be fair, whereby failure to comply with

this order is subject to forfeiture of a fine of € 1,000,000 for each individual breach of this order or, at Pharmachemie's election, for each day (part of a day is counted as a whole day) that MSD continues to fail to comply with this order in full;

4. to order MSD within 2 days as of the day of service of this judgment, to furnish Pharmachemie's counsel with a complete list, certified (after an independent audit) by an independent registered accountant, encompassing:
   - the name and address details of all parties who received the litigious letter dated 23 June 2005, or who have received any other comparable notice, stating by separate notice the name and address details of the relevant parties and of the date of dispatch, and to hand over a copy of each of the separate notices,
   - the name and address details of all parties who received the litigious letter dated 29 June 2005, or any other comparable notice, stating by separate notice the name and address details of the relevant parties and of the date of dispatch, and to hand over a copy of each of the separate notices,
   - the name and address details of all parties who received the litigious letter dated 13 July 2005, or any other comparable notice, stating by separate notice the name and address details of the relevant parties and of the date of dispatch, and to hand over a copy of each of the separate notices,
   - the date of introduction by (or on behalf of) MSD on the website www.msd.nl of the publication dated 12 July 2005 and titled "letter to GPs regarding Fosamax alendronic acid and pharmacological vigilance",
   whereby failure to comply with this order is subject to forfeiture of a fine of € 1,000,000 for each individual breach of this order or, at Pharmachemie's election, for each day (part of a day is counted as a whole day) that MSD continues to fail to comply with this order in full;

5. to order MSD to pay the costs of the proceedings.

3.2 MSD presented a defence. The positions of the parties shall be discussed hereafter insofar as relevant.

4. The dispute in the conditional counterclaim

4.1 MSD claims – in short – that the preliminary relief judge order by judgment which is immediately enforceable:

A. to order Pharmachemie to immediately after the service of this judgment to discontinue the publication in whatever form and/or in whatever manner of statements/notices as described under 8 of the claim in the conditional counterclaim and/or statements/notices with a similar intent and/or effect and to keep such discontinued, whereby failure to comply with this order is subject to forfeiture of a fine of € 1,000,000 for each whole or partial breach of this order and for each day (part of a day is counted as a whole day) when a whole or partial breach continues whereby for each individual breach said penalty shall be forfeited each time anew;
B. to order Pharmachemie within 7 days after service of this judgment to send to all persons and/or institutions to whom the introduction letter and/or the information leaflet was sent or otherwise furnished, a recorded letter (with confirmation of

receipt) drawn up on Pharmachemie's ordinary letterhead, with exclusively the following contents, without any addition and/or accompanying letter:

Dear [name],

By judgement dated [date] the preliminary relief judge of the District Court of Haarlem held that we have acted wrongfully vis-à-vis Merck Sharp & Dohme B.V. by including statements in our introduction letter for alendronic acid 70 PCH and in the enclosed information leaflet.

In this letter and the information leaflet we included, inter alia, inaccurate comparative claims between our products Alendronic Acid 70 and 10 PCH and Fosamax 70 mg and 10 mg. Among other things, we wrongly stated that the dissolution profiles of our products were comparable with those of Fosamax. Furthermore, we wrongly stated that the disintegration of our products was comparable to that of Fosamax. We also wrongly stated that Alendronic Acid 70 PCH disintegrated even faster than Fosamax. The preliminary relief judge of the District Court of Haarlem held that these statements were misleading, inaccurate and wrongful vis-à-vis MSD.

The preliminary relief judge of the District Court of Haarlem has furthermore held that the following statements are inaccurate, misleading and wrongful vis-à-vis Merck Sharp & Dohme B.V.:
- Alendronic Acid PCH: no increased risk of oesophageal irritation;

- even if the tablet were to stick to the side of the oesophagus after incorrect use (e.g. ingestion in a prone position), it will quickly disintegrate at that point;

- Alendronic Acid 10 and 70 PCH (7.5 and 8 mm) are comparable size-wise to the medium-round tablets from the research of Channer et al. A very favourable speed of passage through the oesophagus is thus likely.

- with the 70 mg no signs of irritation were seen in 160 people in the bioequivalency study.

We therefore ask you to ignore all these statements in our introduction letter and the information leaflet. We furthermore ask you to return the introduction letter and the information leaflet to us, whereby we will naturally reimburse you for all the costs which you make in this respect.

We apologise for the above inaccurate and misleading notices.

Yours sincerely,

PHARMACHEMIE B.V.
[name]
[function]

C. to order Pharmachemie within 2 days after service of this judgment to furnish the MSD counsel with a full list, certified by an independent registered account, of all name and address details of all persons and/or institutions to whom the introduction letter for Alendronic Acid 70 PCH of July 2005 and/or the information leaflet was sent or otherwise furnished, stating per party the date of dispatch and/or presentation and with a copy of each separate letter;
D. to order Pharmachemie to pay the costs of these proceedings.

4.2 Pharmachemie has presented a defence. The positions of the parties will be discussed hereafter insofar as relevant.

5. The evaluation the counterclaim proceedings

Admissibility

5.1 MSD argues in the first place that Pharmachemie's claim is inadmissible, as the dispute should be presented to Stichting Code Geneesmiddelenreclame [Code of Conduct on Medicine Advertising Board] (hereafter: "CGR"). Toward this end it argues that the umbrella organisations, of which both parties are a member, have agreed that their members will present complaints on medicine advertising to (at first instance) CGR's Code Commission and that the statements of the CGR are to be deemed a binding advisory opinion.

5.2 This position is rejected. The documents presented by MSD and the history of the (Code Commission of the) CGR cited do not support the position that the CGR allegedly has exclusive jurisdiction to adjudicate this dispute. Moreover, Pharmachemie has an interest in bringing its claim before the civil court, as in proceedings before the CGR Code Commission there is no option of making failure to comply with injunctions subject to a monetary fine.

5.3 That, as MSD argues, the competence of the civil court allegedly only arises if a party continues, after a decision of the CGR, with the action which has been prohibited by the CGR, is incorrect. MSD wrongly refers in this respect to the Sanofi/Navartis case (District Court of 's-Hertogenbosch dated 17 December 2002, Court of Appeal of 's-Hertogenbosch, 9 September 2004 and Supreme Court 1 April 2005, LJN: AS5825). In said case the Court of Appeal of 's-Hertogenbosch did not follow the position accepted by the preliminary relief judge that the (preliminary relief) judge would only be competent to attach sanctions to concrete complaints which had been presented to and evaluated by the CGR. The advocate-general affirmed the accuracy of the judgment of the Court of Appeal on this point in his conclusion (the Supreme Court, pursuant to Article 81 of the Judiciary Organisation Act, held the appeal filed against the judgment of the Court of Appeal unfounded with regard to this point).

Unauthorised (comparative) advertising

5.4 The parties do not dispute that the letters of 23 June, 29 June and 13 July 2005 (which hereafter also includes the letter published on the MSD website of 12 July 2005), are to be deemed advertising, to which Article 6:194 of the Netherlands Civil Code et seq., the Medicines Act, and the Medicines Advertising Decree and the Code

of Conduct on Medicine Advertising apply. However, MSD contests Pharmachemie's statement that the first sentence of the letter contains a clear, implicit reference to Pharmachemie, so that there is comparative advertising as referred to in Article 6:194a of the Civil Code and Article 5.8 of the Code of Conduct. MSD argues in this respect that Pharmachemie at the time of writing the letters had not yet brought Alendronic Acid 70 PCH onto the market. According to MSD, the addresses cannot have viewed the first sentence of the letters as a reference to (products of) Pharmachemie.

5.5 This defence fails. The first sentence of the letters refers to recent registrations of generic variations of Fosamax, and of generic alendronic acid preparations in the Netherlands and not to bringing alendronic acid products onto the market. MSD acknowledges that at the time of the dispatch of the letters, two recent registrations have been made, which were also the only registrations for alendronic acid in the Netherlands, and that these registrations were made on behalf of Pharmachemie (and Merck Generics, a company not affiliated with MSD). These facts can be assumed to be known to the addressees of the letters, being pharmacists and doctors. The basic principle in this respect is the average informed, prudent and alert pharmacist/doctor (hereafter: "the average practitioner"). It is therefore plausible that the average practitioner will read the first sentence of the letter as a reference to Pharmachemie and Merck Generics. MSD's defence that pharmacists and doctors were not aware of the registration by Pharmachemie, as they did not hear of the registration via the wholesale trade, cannot be followed. MSD does not contest that the wholesalers at the time of the dispatch of the letters of 23 June, 29 June and 13 July 2005 were aware of the registration of Pharmachemie's alendronic acid products. On 7 June and 21 June 2005 MSD even sent various wholesalers letters in which the alendronic acid products of Pharmachemie were explicitly mentioned. MSD did not explain why pharmacists and doctors could not have been informed of these registrations via the wholesalers.

5.6 Insofar as the letters of 23 June, 29 June and 13 July 2005 refer to recent registrations, the preliminary relief judge assumes a priori on the basis of the above that there is comparative advertising as referred to in Article 6:194a of the Civil Code, Article 5.8 of the Code of Conduct.

5.7 The question must then be answered whether the letters of 23 June, 29 June and 13 July 2005 satisfy the provisions of Article 6:194 and 6:194a of the Civil Code and the Code of Conduct and the Medicines Advertising Decree. Hereafter the structure used by Pharmachemie will be applied with regard to the statements made in the letters. The intelligence and the imagination of the average practitioner are relevant criteria in this respect.

Statements regarding the safety and characteristics of Fosamax and Alendronic Acid 10 and 70 PCH

5.8 Pharmachemie refers to the following statements in the letters of 23 June and 29 June 2005:

"The registration applications for alendronic acid are based on bioequivalencies in comparison with FOSAMAX® among volunteers. It is assumed in this respect that two medicines with comparable absorption have comparable effectivity and safety

characteristics. However, in addition to the absorption, tablet characteristics such as dissolution and disintegration time also play a role. Studies have shown that generic alendronic acids can have other tablet characteristics than FOSAMAX®, such as a shorter and longer disintegration time." (followed by reference to a footnote, in which a publication of S. Epstein et al. is mentioned, Preliminary Relief Judge)

and in the letter of 13 July 2005:
"These generic registrations are based on bioequivalencies in comparison with FOSAMAX® (sodium alendronate, MSD) among healthy volunteers. It is assumed in this respect that two medicines with comparable absorption have comparable effectivity and safety characteristics. However, with bifosfonates, tablet characteristics such as disintegration and dissolution rate are important for optimal effectivity and safety, as these characteristics can influence the contact time of alendronic acid with the oesophagus and consequently the risk of local side effects. Side effects such as oesophagitis and oesophageal ulcers occur before absorption in the gastrointestinal tract and possible risk differences will therefore not be expressed in bioequivalency tests.

Study has shown that generic alendronic acid can have other tablet characteristics than the original, such as a slower of faster disintegration time." (followed by reference to a footnote, in which a publication of S. Epstein et al. is mentioned, Preliminary Relief Judge)

It claims that MSD suggested with the cited statements that registrations were wrongly granted for Alendronic Acid 10 and 70 PCH of Pharmachemie, that the evaluation by the CGR prior to the granting of the registrations was insufficient for concluding that the effectivity and safety of Pharmachemie's Alendronic Acid 10 and 70 PCH is equal to the effectivity and safety of Fosamax, and that the effectivity and safety of Pharmachemie's Alendronic Acid 10 and 70 PCH does not in fact correspond with the effectivity and safety of Fosamax.

5.9 The cited statements refer to the recently registered alendronic acid preparations and consequently, on the basis of what has already been considered in point 5.5, inter alia to Alendronic Acid 10 and 70 PCH of Pharmachemie. Contrary to what MSD argues, there is thus comparative advertising. By speaking of a specific assumption with regard to effectivity and safety characteristics and by stating in the following sentence that "*however*" other characteristics are of importance, this implies a contrast between the studies on which the registrations are based and the characteristics which are also important for the effectivity and safety of the products. It is likely that this use of language will create the impression among the average practitioner that the registration applications are only based on bioequivalency studies and not on tablet characteristics. According to Pharmachemie's position, which has not been contested and which has been substantiated with documents, this is incorrect. In this respect the statements cited in point 5.8 are, in the preliminary opinion of the preliminary relief judge, misleading.

5.10 It is furthermore of importance that MSD acknowledges that the addresses of the letter will deduce from the statements cited under point 5.8 that MSD is of the opinion that the evaluation carried out by the CGR for the registration was not sufficient. According to MSD it is free to express its opinion to third parties. By referring to

research in its claim (which in any event does not relate to Pharmachemie's Alendronic Acid), it is likely that the impression will have been created among the average practitioner that this concerns a position substantiated by research and is thus objectified. In this context MSD must prove the accuracy of this position. Pharmachemie has contested such, and pursuant to Article 6:195 of the Civil Code, the burden of proving the accuracy of the statements cited in point 5.8 lies with MSD.

5.11 To substantiate its position that the statements in point 5.8 are accurate, MSD has presented the grounds of objections against the registration of Pharmachemie's Alendronic Acid 10 and 70 PCH, as well as various publications, statements and reports and the notes on oral arguments of its counsel for the session of 28 July 2005 in the proceedings before the preliminary relief judge of the Administrative Law sector of this District Court. However, the documents presented by Pharmachemie show that the documents which MSD has presented to substantiate its position are the same as the documents already evaluated by CGR, and with regard to which the CGR has already stated in the proceedings which the parties brought before the preliminary relief court of the Administrative Law sector of this District Court (according to the notes on oral arguments of the CGR attorney presented by Pharmachemie):
"(...) The CGR has evaluated the findings of MSD and concluded that the dissolution tests conducted by MSD do not correspond with the requirements which apply for the conducting of these tests in the European policy rules, the European Pharmacopee (...). (...) The dissolution tests conducted are in this respect only of relevance if the data are read in conjunction with results of bioequivalency research.
(...)
MSD did not conduct such research with the Pharmachemie products, or in any event has not presented the results of these studies.
(…)
According to MSD, the Pharmachemie medicine has a different safety profile than Fosamax. Animal research would have shown that considerably more side effects occur. The CGR also took note of this research in April 2004. The CGR did not see grounds in the results of the research (rabbit and dog study) to deny recognition of the registration of the Danish authorities. The value of these studies for the safety of the use of alendronic acid PCH by humans is not clear from these studies. In view of the dissolution speed of the Pharmachemie product and the precautionary measures to be taken when swallowing the tablet (...), the CGR does not believe there are any indications that the Pharmachemie tablet would cause more or more serious side effects than the MSD tablet (which in any event should be taken with the same precautionary measures) (...).
(...)
There are no concrete indications that alendronic acid can form a risk to health."

5.12 MSD has stated that it possesses reports which specifically relate to Pharmachemie's Alendronic Acid and (countering Pharmachemie's contesting thereof), that it can demonstrate that the tests which form the basis of those reports are accurate. However, it did not present any documents to substantiate this statement. In view of the contesting thereof by Pharmachemie, MSD should have done so. As the CGR has already rejected MSD's position, contrary to the documents currently presented, following any further substantiation by MSD in these proceedings, it is not likely that the statements made in point 5.8 are accurate.

5.13 The foregoing leads to the preliminary opinion that the statements made in point 5.8 are misleading as referred to in 6:194a of the Civil Code and Article 4 of the Medicines Advertising Decree and that they are contrary to the provisions of Article 4.2 of the Code of Conduct on Medicines Advertising. In view of the recent introduction of Pharmachemie's Alendronic Acid 10 and 70 PCH on the Dutch market, it is furthermore likely that Pharmachemie will suffer loss due to these misleading statements of MSD. Insofar as Pharmachemie's claim relates to these statements, it will also be awarded.

5.14 Pharmachemie furthermore states that the letters of 23 June and 29 June 2005 are misleading with regard to the following statements:
"The effectivity and the safety profile of FOSAMAX® have been extensively studied. In 2004 the ten-year data were published which showed that long term treatment with FOSAMAX® is very effective and well-tolerated. (followed by reference to a study of H.G. Bone et al., preliminary relief judge).
MSD does not possess clinical effectivity or safety data of alendronic acid of other manufacturers."

as is the letter of 13 July 2005 in the following statements:
"The effectivity and the safety profile of FOSAMAX® have been extensively studied. In 2004 the ten-year data were published which showed that long term treatment with FOSAMAX® is very effective and well-tolerated. (followed by reference to a study of H.G. Bone et al., preliminary relief judge).
MSD does not possess clinical effectivity or safety data of alendronic acid of other manufacturers."

It claims that the relevant statements entail comparative advertising, which is subject to the requirement that the accuracy of such statements must be demonstrated by means of two studies.

5.15 However, in the opinion of the preliminary relief judge, the statement in question does not encompass a comparison. Although the statement does form part of letters which contain comparative advertising, due to the formulation of the statements, partly by the explicit statement that MSD does not possess clinical effectiveness or safety data of alendronic acid of other manufacturers, or that there are no published data thereon respectively, it is likely that the average professional (like the average informed, prudent and alert ordinary consumer who reads the letter of 13 July 2005 on the internet), will read the statement as an independent claim relating to Fosamax. The accuracy of this claim has for the time being been sufficiently substantiated by Bone's publication.

Statements regarding the packaging and consumer information leaflet

5.16 MSD states in its letter of 13 July 2005:
Furthermore, the packaging of a medicine, including the related consumer information leaflet, is of great importance for the correct use of a medicine. FOSAMAX® 70 mg once a week distinguishes itself from the other alendronic acid packagings by a clear patient-friendly packaging and consumer information leaflet, which contributes to proper use and good compliance and minimises the risk of erroneous overdosing.

According to Pharmachemie, this wrongly suggests that the packaging of Fosamax 70 mg weekly distinguishes itself from Pharmachemie's packaging of alendronic acid products by the clear patient-friendly packaging and consumer information leaflet, which contributes to proper use and good compliance and minimises the risk of erroneous overdosing and the statement – in short – is detrimental to Pharmachemie's alendronic acid products.

5.17 MSD's defence that there is no comparison, as only the MSD product is described, is dismissed. By using the passage *"Fosamax (...) distinguishes itself from the other alendronic acid packagings"*, it is clear that MSD is comparing its product to the products of other parties. In view of the considerations under point 5.5, this includes Pharmachemie's alendronic acid products.

5.18 As proof of the accuracy of the statement cited in point 5.16, MSD presented the packaging of Fosamax 70 mg and the packagings of Alendronic Acid 70 PCH (70 mg) of Pharmachemie and Merck Generics at the session. The Fosamax packaging which was presented is characterised, contrary to the packagings of Pharmachemie and Merck Generics which were presented, by instructions for use with a space on which the user can mark on what day he takes the tablets every week, a space next to each tablet where the user can note the date of ingestion, and stickers which the user can stick in his agenda or on his calendar, while furthermore the text of the consumer information leaflet is printed in bigger letter type than the text of the consumer information leaflet of Pharmachemie and Merck Generics which have been presented. In that sense, the packaging and consumer information leaflet of Fosamax 70 mg are clearly distinct from those of Alendronic Acid 70 PCH (70 mg) of Pharmachemie (and Merck Generics). However, this does not as such present a sound argument that the MSD packaging and consumer information leaflet, as MSD claims, "*contributes to proper use and good compliance and minimises the risk of erroneous overdosing*". Although this, in view of the contesting of the accuracy of this statement and the provisions of Article 6:195 of the Civil Code would have been MSD's responsibility, it failed to substantiate this statement. It has been neither stated nor shown that there is any research which confirms that position. Consequently it is the preliminary opinion of the preliminary relief judge that this is a subjective comparative statement which cannot be verified, which is contrary to the provisions of Article 6:194a.c of the Civil Code. In this case too, in view of the recent introduction of Pharmachemie's Alendronic Acid 70 PCH on the Dutch market, it is likely that Pharmachemie will suffer loss due to this unauthorised statement on the part of MSD. Insofar as Pharmachemie's claim relates to these statements, the claim will be awarded.

Statements regarding the objection to the CGR registrations

5.19 Pharmachemie also bases its claim on the ground that the (mere) mention by MSD in its letters of 23 and 29 June 2005 that it has lodged an objection with the CGR against the registration of the various forms of alendronic acid is wrongful. Contrary to what Pharmachemie argues, the fact that MSD can lodge an objection against the registration with the CGR and can petition for suspension of the registration in preliminary relief proceedings does not, however, mean that it cannot inform third parties that it has lodged an objection with the CGR. As Pharmachemie has not presented any other facts and circumstances on the basis of which MSD's announcement that it had lodged an objection against the registration with the CGR

can be held to be wrongful, the claim, insofar as it relates to said announcement, is dismissed.

Statements regarding MSD's patent rights

5.20 Insofar as Pharmachemie's claim relates to the suggestion raised in the letters of 23 June and 29 June 2005 that MSD can enforce patent rights in respect of Fosamax, Pharmachemie has no interest in its claim. In the judgment in preliminary relief proceedings before this Court which was passed between the parties on 12 July 2005, MSD was already ordered to place an ad with a rectification in the Nederlands Tijdschrift voor Geneeskunde with regard to statements MSD had made regarding its patent rights. Although the letters of 23 and 29 June 2005 have other addressees (pharmacists and doctors) than the letter of 7 June 2005, which was the subject-matter of the preliminary relief judgment of 12 July 2005, these addressees will also have been reached by means of the rectification ad.

Conclusion

5.21 The injunction claimed under 3.1.1 will be awarded on the grounds of the above, as set out hereafter. MSD's defence that the use of the passage "*or to suggest in some other way*" is too vague to be awarded, is dismissed. Although it is feasible that there is more likely to be a difference in interpretation regarding breach of the injunction on suggesting certain facts, than regarding breach of the injunction on claiming certain facts, the term is not so vague that, as MSD argues, the provisions of Article 10 Paragraph of the ECHR are not complied with. This already appears from the fact that the legislature in Article 6:195 of the Civil Code also speaks of facts which are suggested by an announcement.

5.22 The claim for rectification by letter and on the MSD website will also be awarded on the grounds of the above. However, this is on the understanding that the texts suggested by Pharmachemie will be adjusted in a manner that the preliminary relief judge deems fair and that the rectification letter is also to be dispatched within a term which the preliminary relief judge deems fair.

5.23 Contrary to what MSD argues, Pharmachemie has sufficient interest in dispatch of the rectification letters by recorded mail and presentation of the rectification on the website. By means of its wrongful statements and announcements MSD has created a specific, inaccurate, impression among the addressees of said statements and announcements. Pharmachemie has an interest in having this inaccurate impression eliminated. In view of this, MSD can be demanded, by means of recorded mail or the use of a clear reference on the homepage of the MSD website, to draw the attention of the addressees to the rectification of its wrongful statements and announcements. That MSD stated at the session that it placed the letter on the website by mistake and that it has in the meantime removed it, does not mean that Pharmachemie no longer has an interest in this part of the claim being awarded. Despite having received the summons at the beginning of September 2005 and therefore being aware of Pharmachemie's objection to the publication of the letter of 12 July 2005 on the website as of the receipt of the summons, MSD only removed the letter from the website the day before the session. The letter was thus on the website for several weeks and it was only removed under pressure of the preliminary relief proceedings. Under the

circumstances, the mere fact that MSD now states that the letter has been removed from the website, is insufficient to refuse to award the requested rectification on the website.

5.24 The preliminary relief judge deems the claim to place a "pop-up" window on the homepage of the MSD website too far-reaching a measure, taking account of the fact that the letter of 12 July 2005 can only be found on the website, from the MSD homepage, by clicking several times. A clear reference in a box on the website, in the form set out hereafter, will be sufficient to draw attention to the rectification letter.

5.25 The requested notification of the prices is rejected. Pharmachemie did not provide all information which on the basis of the Medicines Advertising Decree should be mentioned with the prices. Moreover, the purpose of the rectification is to rectify inaccurate statements of MSD as much as possible by making accurate statements, not to provide (hidden) advertising.

5.26 The presentation of documents sought under 3.1.4 will be awarded, but not the certification (after an independent audit) by an independent registered accountant. Pharmachemie did not clarify the added value thereof.

5.27 The fine requested will be mitigated and maximised as set out hereafter.

5.28 MSD, as the party held (to the greater extent) in the wrong, will be ordered to pay the costs of the proceedings. The costs on the part of Pharmachemie are fixed at:

- summons	€ 71.93
- court fee	€ 244.00
- court-registered lawyer fee	€ 816,00

Total	€ 1,131.93

6. The evaluation in the conditional counterclaim

6.1 As the condition on which the counterclaim was presented has been met, the preliminary relief judge will evaluate this claim.

6.2 Pharmachemie objects to the counterclaim, as it was only first made aware of the contents thereof on 15 September 2005 at 15.42 hours, while the session started on 16 September 2005 at 9.00 hours. It claims that this meant it did not have the opportunity to have sufficient internal consultation, nor sufficient consultation with its counsel.

6.3 The fact that, pursuant to Article 137 of the Code of Civil Procedure, a counterclaim can be presented up to the time of presentation of the defence, does not detract from the fact that in preliminary relief proceedings the consideration of a counterclaim, the contents of which are only first announced shortly before the session, can be contrary to the requirements of proper procedural order. The preliminary relief judge is of the preliminary opinion that the latter is the case. It has been established that MSD was in any event already familiar, on 31 August 2005, with Pharmachemie's letter of July 2005, that it furthermore on 5 September 2005 had already received Pharmachemie's draft summons and was therefore familiar with Pharmachemie's claim, and that finally it informed the District Court of the dates it

could not appear, so that – although the session date was only fixed on 13 September 2005 – it had plenty of time to take into account that the session could take place on 15 September 2005. In this light, MSD's argument that it only announced its counterclaim late, as it itself only had a short preparation time for the session of 16 September 2005, must fail. MSD did not present any other arguments to support its position that the it could not give earlier notice of its counterclaim. On the other hand, it is sufficiently likely that the late notice was detrimental to Pharmachemie's defence. MSD claims, inter alia, that Pharmachemie's statements in the letter of July 2003 are inaccurate and cannot be substantiated in accordance with the 2-studies criterion. It is likely that Pharmachemie will need more time than the period between 15 September 2005 at 15.42 hours and 16 September 2005 at 9.00 hours to be able to prepare the substantiation of its statements.

6.4 On the basis of the above, the preliminary relief judge believes that consideration of the counterclaim would be contrary to proper procedural order. MSD's counterclaim will therefore be held inadmissible.

6.5 MSD, as the party held in the wrong in the counterclaim proceedings, will be ordered to pay the costs of the counterclaim proceedings, which in view of the nature of Pharmachemie's defence are fixed at nil on the part of Pharmachemie.

7. The decision

The preliminary relief judge

in the claim proceedings

7.1 prohibits MSD with immediate effect as of the day of service of this judgment from making statements to market parties and the general public, or suggesting in any other way, in writing, verbally, via the internet, or otherwise:

- that the effectivity and safety profile of Pharmachemie's Alendronic Acid 10 and 70 PCH are in essence not the same as that of Fosamax, and that the disintegration and dissolution rate of Pharmachemie's products does not correspond with that of Fosamax,
- that the decision of the CGR to grant a market registration for Pharmachemie's Alendronic Acid 10 and 70 PCH was incorrect, and based on insufficient evaluation of the products,
- that the packaging of Fosamax 70 mg contributes to proper use and good compliance and minimises the risk of erroneous overdosing.

7.2 orders MSD within 7 days after service of this judgment to make the following statement to every party who received one or more of the litigious letters dated 23 or 29 June or 13 July 2005, by recorded mail (with confirmation of receipt), signed by a duly authorised representative, on letterhead, without any accompanying letter:

> _____ *2005 [date of the letter]*
> ***RECTIFICATION BY COURT ORDER***
>
> *Dear _____ [name of addressee of the litigious letter/letters].*

By judgment of 23 September 2005 the preliminary relief judge of the District Court of Haarlem determined that we have acted wrongfully vis-à-vis Pharmachemie by making the statements in our letters of 23 June, 29 June and 13 July 2005 to pharmacists and (dispensing) doctors, and our letter of 12 July 2005 on our website www.msd.nl. These letters, or at least one or two thereof, have also been sent to you, or you were able to view them on our website.

The court has prohibited us with immediate effect from making the following statements to you and to other market parties:
- that the effectivity and safety profile of Pharmachemie's Alendronic Acid 10 and 70 PCH is in essence not equivalent to that of Fosamax, and that the disintegration and dissolution rate of Pharmachemie's products do not correspond with those of Fosamax,
- that the decision of the CGR to grant a market registration for Pharmachemie's Alendronic Acid 10 and 70 PCH was incorrect, and based on insufficient evaluation of the products,
- that the packaging of Fosamax 70 mg contributes to proper use and good compliance and minimises the risk of erroneous overdosing.

The court ordered us to send you this letter, with these contents.

MERCK SHARP & DOHME B.V., Haarlem
_____ [signature]
_____ [name of authorised representative]

7.3 orders MSD on the day of dispatch of the letters referred to under 7.2 to also send a copy of each letter to Pharmachemie's counsel (M.A.A. van Wijngaarden, Sweelinckplein 1, 2517 Gk The Hague).

7.4 orders MSD within 7 days after service of this judgment to rectify the notice dated 12 July 2005 (titled: "letter to GPs regarding Fosamax alendronic acid and pharmacological vigilance") which is on its website www.msd.nl by placing a notice signed by a duly authorised representative, which will remain on the website for a period of 1 (one) month, without further comment in word or image, in or around the rectification or elsewhere on a website managed by it or in another publication, with the following contents:

RECTIFICATION BY COURT ORDER

By judgment of 23 September 2005 the preliminary relief judge of the District Court of Haarlem determined that we have acted wrongfully vis-à-vis Pharmachemie by making the statements in our letter of 12 July 2005 title "letter to GPs regarding Fosamax alendronic acid and pharmacological vigilance" on our website www.msd.nl; just as we did by means of similar statements in our letters of 23 June, 29 June and 13 July 2005 to pharmacists and (dispensing) doctors.

The court has prohibited us with immediate effect from making the following statements to you and to other market parties:
- that the effectivity and safety profile of Pharmachemie's Alendronic Acid 10 and 70 PCH is in essence not equivalent to that of Fosamax, and that the disintegration and dissolution rate of Pharmachemie's products do not correspond with those of Fosamax,
- that the decision of the CGR to grant a market registration for Pharmachemie's Alendronic Acid 10 and 70 PCH was incorrect, and based on insufficient evaluation of the products,
- that the packaging of Fosamax 70 mg contributes to proper use and good compliance and minimises the risk of erroneous overdosing.

MERCK SHARP & DOHME B.V., Haarlem
_____ [signature]
_____ [name of authorised representative]

whereby a reference to the rectification must be placed in a box at the top of the MSD home page with dimensions of at least 3 by 6 centimetres (measured on a 17 inch screen) and with the clearly readable text "click here for rectification of letter of 12 July 2005", and whereby the rectification letter should be of the same size as the letter of 12 July 2005.

7.5 orders MSD within 2 days as of the day of service of this judgment, to furnish Pharmachemie's counsel with a complete list encompassing:
- the name and address details of all parties who received the litigious letter dated 23 June 2005, or any other comparable notice, stating in a separate notice the name and address details of the relevant parties and the date of dispatch, with presentation of a copy of each of the separate notices,
- the name and address details of all parties who received the litigious letter dated 29 June 2005, or any other comparable notice, stating in a separate notice the name and address details of the relevant parties and the date of dispatch, with presentation of a copy of each of the separate notices,
- the name and address details of all parties who received the litigious letter dated 13 July 2005, or any other comparable notice, stating in a separate notice the name and address details of the relevant parties and the date of dispatch, with presentation of a copy of each of the separate notices,
- the date of introduction by (or on behalf of) MSD on the website www.msd.nl of the publication dated 12 July 2005, and titled "letter to GPs regarding Fosamax alendronic acid and pharmacological vigilance",

7.6 stipulates that MSD will forfeit € 100,000 for each individual breach or, at Pharmachemie's election, for each day (part of a day being counted as a whole day) that MSD fails to comply with the injunction and order set out under 7.1 through 7.5, up to a maximum of € 10,000,000.

7.7 orders MSD to pay the costs of the proceedings, which on the part of Pharmachemie have to date been fixed at € 1,131.93.

7.8 declares this judgment in the claim proceedings to be immediately enforceable.

7.9 rejects any additional or other claim.

in the counterclaim proceedings

7.10 orders MSD to pay the costs of these counterclaim proceedings, which to date are fixed at nil.

This judgment is passed by J.I. Rood and pronounced in public on 23 September 2005.

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issued by M. Middeldorp
the court clerk

Conc.: 216/754