# JUDGMENT

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**THE HAGUE DISTRICT COURT**

Civil Law Section

Case Number / Docket Number: 249911 / HA ZA 05-2877

**Judgment of 13 September 2006**

in the case of

1. the company under foreign law
**RANBAXY UK.LTD.**,
established in London, United Kingdom,
2. the company under foreign law
**RANBAXY LABORATORIES LTD**,
established in Ropar-Punjab, India,
claimants in the principal action,
defendants in the cross-action,
attorney-of-record *mr*. P.J.M. von Schmidt auf Altenstadt,
attorneys-at-law *mr*. R.E. Ebbink and *mr*. M.G.R. van Gardingen in Amsterdam,

versus

the company under foreign law
**WARNER-LAMBERT COMPANY**,
established in Morris Plains, New Jersey 07950, United States,
defendant in the principal action,
claimant in the cross-action,
attorney-of-record *mr*. C.J.J.C. van Nispen,
attorneys-at-law *mr*. C.J.J.C. van Nispen and S.C. Dack, barrister,
registered under Article 16h *Advocatenwet*, both in The Hague.

Hereinafter the parties will be called Ranbaxy and Warner-Lambert.

The District Court has taken cognizance of the following documents:

- The decision of the Preliminary Relief Judge of this court of 28 July 2005;
- the writ of summons of 22 august 2005;
- the brief concerning exhibits 1 to 6 of Ranbaxy;
- the statement of reply in the principal action and claim in the cross-action, with exhibits 1 to 9;
- the statement of reply in the cross-action;
- the brief submitting a few more exhibits regarding the writ of summons (exhibits 7 to 9), also exhibit 10 of Ranbaxy;
- the statement of reply in the cross-action, with exhibits 13 to 20;
- the brief submitting exhibits 10 to 15 of Warner-Lambert;
- the brief submitting exhibits 21 to 37 of Ranbaxy;

At the session of 7 July 2006 the parties had their positions pleaded on the basis of oral pleading notes by, on the one hand, *mrs*. Ebbink and Van Gardingen, assisted by patent attorney *drs*. K.M.L. Bijvank and, on the other hand, by *mr*. Van Nispen and Mr. Dack, assisted by the patent attorney *dr*. R. Jorritsma. The oral pleading notes are among the briefs.

**AS TO THE LAW**

*In the principal action and in the cross-action:*

*The following facts can be assumed*

1.1. Warner-Lambert is the proprietor of several patents which relate to the substance atorvastatin. One of these patents is European patent 0 409 281, hereinafter EP 281. EP 281 invokes a right of priority derived from the American application US 384187 of 21 July 1989. The European application was filed on 20 July 1990 and published on 23 January 1991. The grant was published on 31 October 2001. EP 281 expires on 20 July 2010.

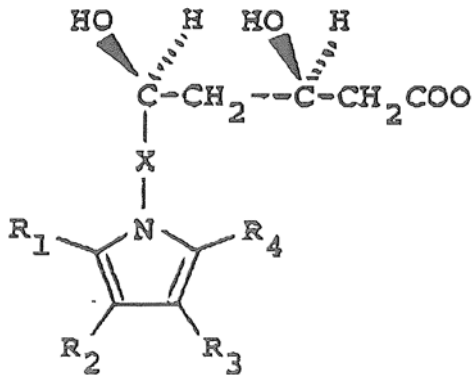
1.2. EP 281 holds four claims, the first three read, in the authentic English language, as follows:

1. *The hemicalcium salt of [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl-3-phenyl-4[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid.*
2. *A pharmaceutical composition comprising the compound of Claim 1 and a pharmaceutically acceptable carrier.*
3. *Use of the compound of claim 1 for the preparation of a pharmaceutical composition useful for treating hypercholesteremia or hyperlipidemia.*

Claim 4 concerns a method claim to obtain the substance referred to in claim 1.

1.3. The substance mentioned in the first claim, to put it briefly calcium atorvastatin, is the active ingredient in the medicine bearing the brand name Lipitor which is marketed worldwide by Pfizer (a company associated with Warner-Lambert). Atorvastatin is, like other statins also, a cholesterol inhibitor.

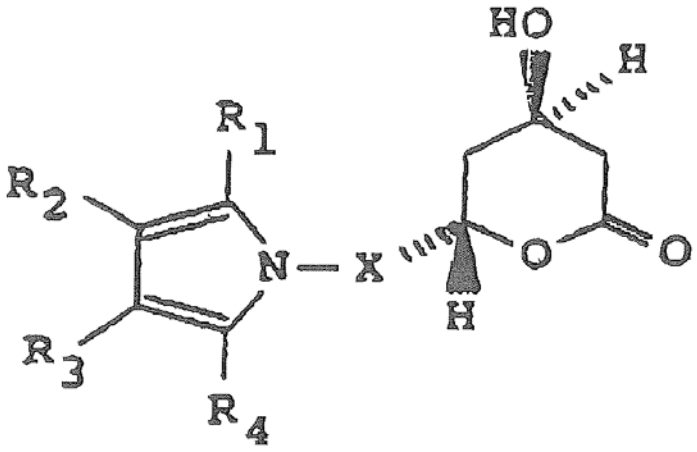
1.4. The acid remainder associated with the salt calcium atorvastatin has the following structural formula.



in which X is $-CH_2CH_2-$;
$R_1$ is 4-fluorphenyl;
$R_2$ is phenyl;
$R_3$ is –CONHPh and
$R_4$ is $-CH(CH_3)_2$.

1.5. As to the substance atorvastatin Warner-Lambert is also proprietor of European Patent 0 247 633, hereinafter 633. EP 633 bears the title, in English: Trans-6-[2-(3- or 4-carboxamid-substituted pyrrol-1-yl)-alkyl]-4-hydroxypyran-2-one inhibitors of cholesterol synthesis. The priority date of EP 633 is 30 May 1986.

1.6. The main claim of EP 633 regards substances according to the following general structural formula (Formula I):




1.7. Ranbaxy intends to launch a medicine having atorvastatin as active ingredient.

1.8. This intention was reason for Ranbaxy to bring cases concerning the scope of protection of EP 633 and the validity of EP 281. In the Netherlands this court will decide by today's judgment regarding both patents.

## 2. The dispute

*in the principal action*

2.1. Ranbaxy initially claimed – provisionally and on the condition that this judgment is not a final judgment – that Warner-Lambert be enjoined from upholding its rights resulting from EP 281 (the claims 1 to 3). At the oral pleading Ranbaxy withdrew this claim.

2.2. In the case on the merits Ranbaxy claims invalidation of claims 1, 2 and 3 of EP 281, and that Warner-Lambert be ordered to pay the costs of the proceedings.

2.3. Warner-Lambert pleads a defence. The allegations of the parties will, as far as relevant, be discussed in more detail below.

*in the cross-action*

2.4. Warner-Lambert claims in the cross-action, to put it briefly, that Ranbaxy be enjoined from infringing EP 281, while imposing a civil fine and ordering Ranbaxy to pay the costs of the proceedings.

2.5. Ranbaxy pleads a defence. The allegations of the parties will, as far as relevant, be discussed in more detail below.

## 3. The examination, introduction

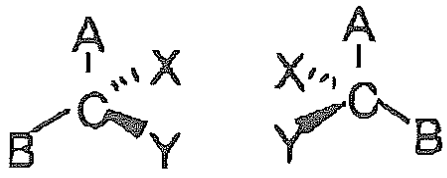
*in the principal action and in the cross-action*

3.1. Ranbaxy takes the position that the subject-matter as claimed in claims 1, 2 and 3 of EP 281 was not new on the priority date (21 July 1989) in respect of the international patent application WO 89/07598 (belonging to the fictive state of the art in the sense of Art. 54(3) EPC) and that the subject-matter as claimed in claims 1, 2 and 3 of EP 281 is not inventive in respect of American patent US 4,681,893, combined with common general knowledge. In this introductory part several topics relevant to the examination are discussed and explained in more detail.

*stereochemistry*

3.2. The molecule to which the invention of EP 281 relates may occur in principle in four different configurations, so-called stereoisomers. This aspect was discussed in particular in the prosecution of EP 281. In the following the notions used in that respect are explained.

3.3. The carbon atom (C-atom) is able to make four bonds. Three-dimensionally these links are oriented to the four angles of tetraeder with the C-atom in its point of gravity. The bonds can be made with four different groups. In that case the phenomenon of stereochemistry occurs. This means that the molecule can adopt two configurations which are identical as to chemical structural formula but not three-dimensionally. The figure below shows both configurations.




3.4. The molecules shown contain a central C-atom to which groups A, B, X and Y are bonded. The C-atom then is the asymmetrical centre. As to chemical structure the molecules are identical but stereometrically they are configured differently. In the drawing this is shown by means of a closed wedge-like connection line which indicates that the group bonded to the C-atom comes towards the observer from the plane of the drawing and a dotted wedge-like connection line which indicates that the group is

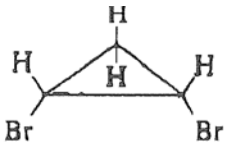
situated below the plane of the drawing. Both molecules drawn are each other's mirror-image, but they are not identical. It is not possible to make the left molecule coincide with the right one by means of rotation and shifting. Compare the left and right hand; they are each other's mirror-image but are not identical.

3.5. An asymmetric C-atom to which four different groups have been bonded is referred to as a chiral centre. Both configurations which are each other's mirror-image are called enantiomers. Enantiomers mainly have the same chemical and physical properties. Physically they can be distinguished by their optical activity. Polarized light is turned in opposite direction by both enantiomers. By way of distinction one sometimes uses the signs + and - , or the letters d and l (for dexter and laevus) or R and S (for Rectus and Sinister).

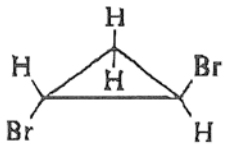
3.6. The biochemical properties of enantiomers are usually different. This fact is relevant to the development of medicines. In the body the desired action appears often to be linked to one of the enantiomers. The other enantiomer does not have such action or to a lesser degree or even has an undesirable effect.

3.7. Upon synthesis of chiral substances (substances having a chiral centre in the molecule) a mixture of the enantiomers is always formed in equal proportions, if non-chiral basic substances are started from. Such a mixture is called a racemic mixture or a racemate. There are techniques known to split racemates or convert them into one of the enantiomers. The pure enantiomer is also described as optically pure.

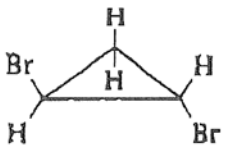
3.8. If the stereoisomers are not each other's mirror-image, then they are referred to as diastereomers. Diastereomers occur if there is more than one chiral centre. This can be illustrated on the basis of three possible three-dimensional configurations of 1,2-dibromecyclopropane:



V



VIa



VIb

3.9. The molecules VIa and VIb are each other's mirror-image and so they are enantiomers. Between molecules V and VIa there is no mirror-image relationship, V is diastereomeric in respect of molecules VIa and b. Diastereomers differ as to chemical and physical activity.

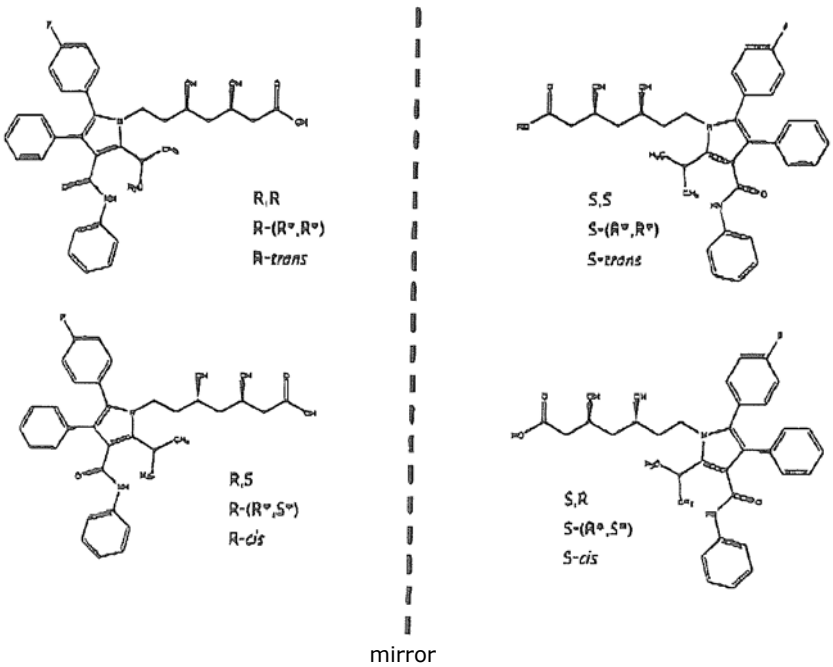
3.10. The figure also illustrates the notions cis and trans. In molecule V the significant substituents are on the same side of the plane of the ring formed by the three C-atoms. This molecule has the so-called cis-configuration. Molecules VI a an and VI b have the trans-configuration with the substituents bonded cross-wise. If there is no ring or double binding which can serve as reference point for the cis/trans nomenclature it is not really correct to use these notions. However, if a derived compound is described which can be obtained with a simple step from a

compound which does for instance contain a ring structure, as is the case upon conversion of atorvastatin from lacton-form into acid-form, the cis/trans nomenclature is used. The designations then refer to the situation as it is in the molecule in which the reference plane (i.e. the ring) is still present.

3.11. A molecule can contain more than one chiral centre. In case of two chiral centres four stereomers are possible. To its identification, the so-called absolute configuration is decisive. By this the configuration (R or S) of the second asymmetrical centre is meant in relation to the configuration (R or S) of the first asymmetrical centre. So in the case of two chiral centres the following configurations are possible R,R S,S R,S and S,R. In nomenclature one also uses the notions cis and trans discussed above. The R-trans enantiomer then is the absolute configuration which corresponds with the R,R-form.

*The stereochemistry of atorvastatin*

3.12. The general chemical structural formula by which inter alia atorvastatin is referred to has two chiral centres. Within the general structure there are as a result four stereoisomers possible in the form of two pairs of enantiomers. The enantiomer pairs are each other's diastereomers. The diagram below shows the possible absolute configurations of the acid. The R,R-configuration is the enantiomer of the S,S-configuration, since they are each other's mirror-image. The same goes for the R,S and S,R-configurations. Both trans-configurations are diastereomers of the cis-configurations, since they cannot be brought to cover each other by means of translation or rotation and are not mirror-images.




3.13. Atorvastatin, in full and in English: R-(R*,R*)]-2-(4-fluorophenyl)-ß,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt, is the molecule in trans-

configuration which is reproduced in the figure below 3.12 at the top left. Below this molecule will be described as the R,R-molecule or R,R in short. Its enantiomer will be referred to as S,S. In all cases the court refers to the absolute configuration.

*The effect of atorvastatin*

3.14 Cholesterol is produced in the human body in the liver from acetyl-co-enzyme A (acetyl-CoA) in a series of about twenty individual enzymatic reactions. In one of these reactions, which takes place rather in the beginning of the series, the substance 3-hydroxy-3-methylglutaryl co-enzyme A (HMG-CoA) is converted into mevalonic acid by means of the enzyme HMG-CoA reductase. Of this reaction it is known that it is the rate determining step of the entire synthesis of cholesterol. Statins (molecules having a dihydroxyheptane acid chain) are substances which compete with HMG-CoA as substrate for the enzyme HMG-CoA reductase. They bind with the active position of the enzyme, and as a result the enzyme cannot do its work and the conversion of HMG-CoA into mevalon acid, and so the production of cholesterol, is inhibited. Thus statins are known as inhibitors of HMG-CoA reductase.

*The prosecution history of EP 281*

3.15. In the original application which resulted into EP 281 claim 1 read as follows:

> *1. [R-(R*,R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-((1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid or (2R-trans)5-(4-fluorophenyl)-2-(1-methylethyl-N,4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide; and pharmaceutically acceptable salts thereof .*

The original application therefore regards atorvastatin regardless of its form: as lactone, as acid and as salt. For the salt-form the pharmaceutically acceptable cation is not specified.

3.16. In the search report of 9 October 1990, as "background to the state of the art" (qualification "A") was stated inter alia patent publication US 4,681.893 (D1 in the prosecution file, hereinafter US 893). Us 893 is the American counterpart of EP 633.

3.17. US 893 has as subject-matter a group of compounds which is referred to in the title of said document as *trans-t-[2(3- or 4-carboxamino-substituted pyrrol-1-yl)alkyl]-4-hydroxypyran-2-one inhibitors of cholesterol synthesis*. Of the compounds belonging to this group it is described that they inhibit cholesterol production by inhibition of HMG-CoA reductase.

3.18. In his report of 23 November 1993 the Examiner of the EPO pointed out that both the acid-form and the lactone-form of atorvastatin seemed to have been disclosed in US 893. The structural formula present in claim 1 of US 893 seemed to the Examiner to be identical to the substance claimed in EP 281. The claims in which the salts of atorvastatin were claimed, were considered not to be inventive by the Examiner. According to the Examiner it was obvious to the skilled person to expect that the salts of atorvastatin would show the same activity as hypocholesteremic and as hypolipidemic medicine as atorvastatin itself.

3.19. Next Warner-Lambert states by letter of 25 May 1994 that US 893 only discloses a racemate and that one should not forget that the R-trans-enantiomer has a ten times higher activity than the racemate. The Examiner maintained his objections in his communication of 15 December 1994 and stressed that the structure formulas in US 893 seemed to indicate the R-trans-enantiomer claimed in EP A 281. The Examiner also invited Warner-Lambert to demonstrate that the methods described in US 893 actually did not result into the pure R-trans-enantiomer, none of them. As to the difference in activity the Examiner pointed out that under set case-law of the Technical Board of Appeal it is not inventive to look for and invent which enantiomer is the most active one of an enantiomer, since it is always such that one enantiomer is more active than the other one.

3.20. In its reply of 20 June 1995 Warner-Lambert explained that the methods described in US 893 all can actually only produce the racemate. As to the structural formulas occurring in US 893 Warner-Lambert alleged that the wedge-shaped and striped drawn links reproduced in said structural formulas were only used to represent relative stereochemistry and not absolute stereochemistry. In other words, the configuration on both asymmetric carbon atoms is the same, either both S or both R. As to the inventive step Warner-Lambert alleged that US 893 discloses four different isomers, and so the choice in EP A 281 for only one of the four should be considered inventive.

3.21. Next the EPO scheduled a hearing. As his preliminary opinion (9 May 1996) the Examiner indicated that he did not maintain the prejudices to novelty, but he did maintain the prejudices to the inventive step. The Examiner accepted that in US 893 only a racemate was disclosed, but the Examiner did not accept that the choice of one of both enantiomers of such racemate could be considered as an inventive step. The Examiner stated on that account that

*the skilled person would be aware from general knowledge that one of the isomers in a racemic mixture would have a quantitatively superior effect to the other isomer or the racemate. Therefore, the solution to the problem of finding one enantiomer with an improved activity compared with another enantiomer or compared to the original racemate is not considered to be inventive, since the testing of two enantiomers to see if one or the other is more active than the racemate is considered to be routine. An enhanced effect can not be adduced as evidence of inventive step, if it emerges from obvious tests (...). The above arguments hold also in the case of a large difference in activity of the enantiomers and are equally applicable to the results achieved in the present case.*

3.22. At the hearing Warner-Lambert repeated its view. The Examiner persisted in his prejudice to inventive step and rejected the patent application (5 September 1996).

3.23. Warner-Lambert lodged an appeal from this decision. To the invitation of 13 January 2000 for the hearing the Technical Board of Appeal joined as preliminary opinion, that it agreed with the Examiner that the patent lacked an inventive step in respect of US 893. The stand of the TBA was that it does not require any inventive activity for the skilled person to split a racemate into enantiomers, and next to identify which enantiomer is the most active. Any major difference in activity between the enantiomers, does not alter the "obviousness": *The Board concurs*

*with the Appellant that the man skilled in the art would have expected that one of both enantiomers, resulting from splitting the racemic mixtures of D1 exhibit a higher hypocholesterolemic activity than the racemic mixture. Nevertheless, in the Board's preliminary opinion, it seems difficult to regard the extent of that expected increase in activity as an indication of inventive step when following the approach in T296/87 cited above. Therefore, in the Board's preliminary view it appears doubtful that the claimed subject-matter involves an inventive step.*

3.24. Next Warner-Lambert amended its claims. In the accompanying letter (20 June 2000) Warner-Lambert argued that the calcium salt of the racemate described in Example 2 of US 893 should be considered to be closest prior art. Warner-Lambert alleged that specifically the hemi calcium salt-form of the enantiomer has several advantages in respect of the sodium salt-form of the racemate. The advantages which were pointed out, were reduced hygroscopicity and improved solubility. They were illustrated on the basis of several comparative experiments the results of which were submitted to the TBA. According to Warner-Lambert the improved properties of the hemi calcium salt of the enantiomer in respect of the sodium salt of the racemate were surprising, and for that reason there is an inventive step in respect of US 893.

3.25. The TBA accepted this reasoning of Warner-Lambert in its decision of 20 July 2000 (T229/97). The TBA regarded the problem which was solved by the choice of the hemi calcium salt of the R-trans-enantiomer, in respect of the sodium salt of the racemate, as *providing a hypocholesterolemic compound having improved handling properties, in particular improved hygroscopicity and solubility*. In the view of the TBA this problem is not discussed in US 893, nor does the document give the skilled person any incentive to replace the sodium salt by the calcium salt.

## 4. The further assessment

*Novelty*

4.1. Ranbaxy substantiates its novelty objections with a reference to WO 89/07598 of Warner-Lambert. This patent, hereinafter WO 598, has as priority date 22 February 1988 and bears the title *Improved process for trans-6-[2-(substituted-pyrol-1-yl)alkyl]pyran-2-one inhibitors of cholesterol synthesis*. WO 598 is part of the fictive state of the art. The patent was not taken into account by the TBA.

4.2. In its examination the court starts from EP 281 as granted after the prosecution summarized above. This implies that the novelty of EP 281, as to claims 1 to 3, lies in the choice of specifically the hemi calcium salt as pharmaceutically acceptable salt-form of the therapeutically active substance. The active substance is described as heptanoic acid and in English, [R-(R*R*)]-2-(4-fluorophenyl)-ß,δ-dihydroxy-5-(1-methylethyl-3-phenyl-4[(phenylamino)-carbonyl]-1H-pyrrolle-1-heptanoic acid. The acid described is optically pure but seen the prosecution history the invention claimed in claims 1 to 3 does not lie (anymore) in this aspect. The court will not go into the question of whether a rephrased problem as accepted

by the TBA is admissible by law or not given the ratio of Article 123(2) EPC.

4.3. WO 598 starts from a general structural formula I which corresponds with Formula I described in EP 633 and reproduced above in 1.6. Formula I concerns the lactone-form. This can be converted into the acid-form shown in the figure at 1.4, by opening the ring at the right. In the substance in which the variable X equals $-CH_2CH_2-$, as in the case of atorvastatin, a chain of seven carbon atoms comes about. This acid is therefore designated as heptanoic acid. The acid can be converted into salts thereof. WO 598 therefore discloses – and even as particularly preferred compounds – (p. 21 read up to p. 22) substances derived from Formula I (the lactone-form), including also the optically pure substance mentioned on p. 21, l. 28, the dihydroxy acid of these substances which came about by opening the ring and the pharmaceutically acceptable salts of the dihydroxy acid. All this against the background that the preferred embodiment is the (optically pure) 4R,6R isomer (p. 44, l. 33-35). The court points out that the dihydroxy acid derived from Formula I corresponds with the acid remains of atorvastatin reproduced above in 1.4. The same acid is also represented on page 43 of WO 598. On page 43 it is next disclosed that as *pharmaceutically acceptable salts* of this acid can be considered the salts formed with inter alia the ions of sodium, potassium and calcium. Thus there is no combination of *separate items* from different embodiments within one and the same document, like Warner-Lambert alleges, because atorvastatin and its acceptable salts are not *separate items*, but precisely belong to each other.

4.4. The invention laid down in EP 281 exclusively lies in the choice of the calcium salt as pharmaceutically acceptable salt-form. This calcium salt has been made accessible, in the view of the court, directly and unambiguously with the description in WO 598. The fact that WO 598 also mentions other substances which could be considered a pharmaceutically acceptable salt does not alter this. The hemi calcium salt-form claimed in EP 281 therefore is not new. Nor is EP 281 new as selection invention, because the metal ions mentioned in WO 598 are common in the production of pharmaceutically acceptable salts.

*Inventiveness*

4.5. If the conclusion that the invention disclosed in EP 281, claims 1 to 3, is not new, were incorrect, then this invention is not inventive in any case in the light of US 893.

4.6. Also when examining inventive step it should be taken into account that the inventive level of EP 281 lies in the claimed salt-form, the hemi-calcium salt.

4.7. US 893 discloses, to put it briefly, the sodium salt of the acid the structural formula of which, as acid remains, has been reproduced above in 1.4. The court characterized this document as closest prior art.

4.8. And so it must be examined whether given the sodium salt the step to the calcium salt can be considered inventive, or not. Upon examining one should start from the common general knowledge which the average

skilled person has. This notion should be understood in a continental European sense. Knowledge from general handbooks should be counted among this, as well as knowledge from review articles from leading magazines in the professional field.

4.9. Ranbaxy submitted the Review Article, "Pharmaceutical Salts", by Berge et al., published in Journal of Pharmaceutical Sciences (1977), p. 1 to p. 19 (Exhibit 5 of Ranbaxy, Annex 8). From this article the court derives the following:

> *p.1 Saltforming agents are often chosen empeirically. Of the many salts synthesized, the preferred form is selected by pharmaceutical chemists primarily on a practical basis: cost of raw materials, ease of crystallization, and percent yield. Other basic considerations include stability, hygroscopicity, and flowability of the resulting bulk drug.*
>
> *p. 5 The salt form is known to influence a number of physicochemical properties of the parent compound including dissolution rate, solubility, stability and hygroscopicity. These properties, in turn, affect the availability and formulation characteristics of the drug. Consequently, the pharmaceutical industry has systematically engaged in extensive preformulation studies of the physicochemical properties of each new drug entity to determine the most suitable form for drug formulation.*

In this article (p. 2, Table I) a review was also included of the relative use of commercially traded salts approved by the FDA for use in medicines. Data of 1974 teach that the three cations most used are sodium (61.97 %), potassium (10.82 %) and calcium (10.49 %). After that time calcium has overtaken potassium, thus the court concludes from the submitted Handbook of Pharmaceutical Salts of 2002. This handbook dates after the priority date, but confirms what was already a trend in 1974.

4.10. The court concludes that the research into the most suitable cation to get a pharmaceutically acceptable salt-form, is a permanent element in the development of medicinal products. The research is routine. The cations to be studied first include in any case sodium, potassium and calcium.

4.11. In this case this is the more so, because the closest prior art, US 893, also includes a pointer towards the calcium salt (col. 7, l. 7 et seq.) where it is stated that *"pharmaceutically acceptable metal salts" contemplates salts formed with the sodium, potassium, calcium magnesium, aluminium, iron and zinc ions*.

4.12. Thus the solution which claims 1 to 3 provide for the problem of finding a pharmaceutically acceptable salt-form for the most active trans-enantiomer, is so obvious that the patent, if meeting the novelty condition, is not inventive.

*Conclusion in the principal action*

4.13. Claims 1 to 3 of the patent should be considered invalid, because the invention incorporated in them is not new, at least these claims lack inventive step. The claim in the principal action will therefore be allowed on the understanding that the court will invalidate claims 1 to 3 of EP 281.

4.14. Being the party found to be in the wrong Warner-Lambert will be ordered to pay the costs of the proceedings.

*Conclusion in the cross-action*

4.15. Seen the invalidation, for the Netherlands, of claims 1 to 3 of the patent the claim in the cross-action of Warner-Lambert should be dismissed.

4.16. Being the party found to be in the wrong Warner-Lambert will be ordered to pay the costs of the proceedings.

**DECISION**

The court,

*in the principal action:*

invalidates, for the Netherlands, claims 1 to 3 of European Patent EP 0.409.281;

orders Warner-Lambert to pay the costs of the proceedings, assessed on the part of Ranbaxy at € 244 for disbursements and € 2,712 for fees of the the attorney-of-record;

declares this judgment in the principal action as far as the order to pay the costs is concerned enforceable notwithstanding appeal,

*in the cross-action:*

dismisses the claims;

orders Warner-Lambert to pay the costs of the proceedings, assessed on the part of Ranbaxy until this day at € 1,356 for fees of the attorney-of-record;

declares this judgment in the cross-action enforceable notwithstanding appeal.

This judgment was rendered by *mr*. Chr.A.J.F.M. Hensen, *mr*. G.R.B. van Peursem and *mr. drs.* L. Beijen and pronounced in public on 13 September 2006, in the presence of the clerk of the court.

(signature)