JUDGMENT

_____

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;
- the brief concerning exhibits 1 to 12 of Ranbaxy;
- the statement of reply in the principal action and claim in the cross-action, with exhibits 1 to 5;
- the statement of reply in the cross-action, with exhibits 13 to 20;
- the brief submitting exhibits 6 to 11 of Warner-Lambert;
- the brief submitting exhibits 21 to 37 of Ranbaxy.

At the session of 23 June 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:

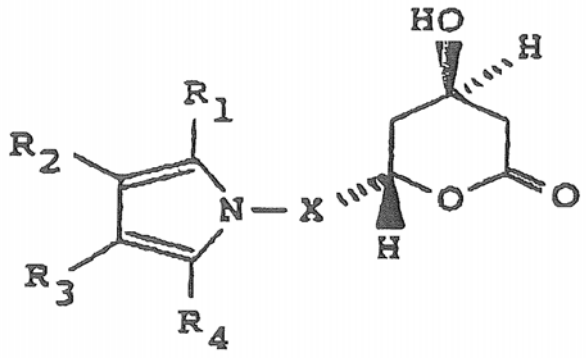
1. The following facts can be assumed:

1.1. Warner-Lambert is the proprietor of several patents which relate to the substance atorvastatin. One of these patents is European Patent 0 247 633, hereinafter EP 633. EP 633 expires on 28 May 2007. The priority date of EP 633 is 30 May 1986. Based on EP 633 a supplementary protection certificate has been issued having registration number 970034 for the medicinal product atorvastatin, hereinafter the SPC. Atorvastatin is the active ingredient in the medicine having the brand name Lipitor which is marketed worldwide by Pfizer (a company associated with Warner-Lambert). Atorvastatin is, like other statins, a cholesterol inhibitor. The SPC expires on 5 November 2011.

1.2. EP 633 bears the title Trans-6-[2-(3- or 4-carboxamid-substituted pyrrol-1-yl)-alkyl]-4-hydroxypyran-2-one inhibitors of cholesterol synthesis.

1.3. Claim 1 of EP 633 reads as follows:

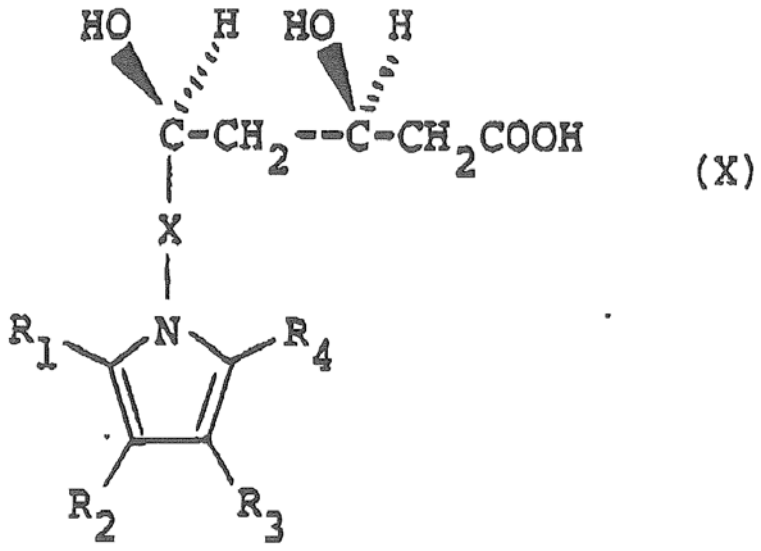
A compound of structural formula I,



(I)

wherein X is $-CH_2-$, $-CH_2CH_2-$, $-CH_2CH_2CH_2-$ or $-CH_2CH(CH_3)-$;
R_1 is 1-naphthyl; 2-naphthyl; cyclohexyl; norbornenyl; 2-, 3-, or 4-pyridinyl; phenyl, phenyl substituted with fluorine, chlorine, bromine, hydroxyl; trifluoromethyl; alkyl of from one to four carbon atoms, alkoxy of from one to four carbon atoms, or alkanoyloxy of from two to eight carbon atoms;
either of R_2 or R_3 is $-CONR_5R_6$
where R_5 and R_6 are independently hydrogen; alkyl of from one to six carbon atoms; 2-, 3-, or 4-pyridinyl; phenyl; phenyl substituted with fluorine, chlorine, bromine, cyano, trifluoromethyl, or carboalkoxy of from three to eight carbon atoms;

and the other of R_2 or R_3 is hydrogen; alkyl of from one to six carbon atoms; cyclopropyl; cyclobutyl, cyclopentyl, cyclohexyl; phenyl; or phenyl substituted with fluorine, chlorine, bromine, hydroxyl; trifluoromethyl; alkyl of from one to four carbon atoms, alkoxy of from one to four carbon atoms, or alkanoyloxy of from two to eight carbon atoms; R_4 is alkyl of from one to six carbon atoms; cyclopropyl; cyclobutyl; cyclopentyl; cyclohexyl; or trifluoromethyl;
or a hydroxy acid or pharmaceutically acceptable salts thereof, derived from the opening of the lactone ring of the compounds of structural formula I above, and having the formula X



where X, R1, R2, R3 and R4 are as defined above.

All sub-claims depend upon claim 1 and are not relevant to the examination.

1.4. In respect of the substance atorvastatin Warner-Lambert is also proprietor of European Patent EP 0 409 281, hereinafter EP 281. EP 281 bears the title, in English: R-(R*,R*)]-2-(4-flurophenyl)-ß,δ-dihydroxy-5-(1-methylethyl-3-phenyl-4[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid, its lactone form and salts thereof. The priority date of EP 281 is 21 July 1989.

1.5. During the prosecution for EP 281 Warner-Lambert gave its opinion in letters of 25 May 1994 and 20 June 1995, following questions of the Examiner, on the meaning of EP 633 (in the prosecution described as D1, the American counterpart of EP 633). Warner-Lambert wrote inter alia the following on 25 May 1994:

As pointed out by the Examining Division and as acknowledged by the applicant, document (D1) discloses certain trans-6-[(3- or 4-carboxamido)-substituted pyrrol-1-y1) alkyl]-4-hydroxypyran-2-ones and the ringopened hydroxy acids derived therefrom. It is also acknowledged that (D1) teaches that these trans-compounds, because of the asymmetric carbon centers, give rise to both the R-trans and the S-trans isomers (note column 3, lines 49 to 54, column 6, lines 56 to 58 and example 2).
However, (D1) at best only describes the trans-racemate containing the R-trans and the S-trans isomers in admixture.
Nothing is stated in (D1) about any possible difference of the optical isomers with respect to their activity or which isomer would be preferred, and there is no teaching whatsoever, how a person skilled in the art could make the pure optical isomers separately.

and in its letter of 20 June 1995:

Basically the structures drawn in (D1) do not establish that the compound represented is a sterochemically pure enantiomer. The teaching of (D1) just says that the two chiral centers have the same configuration, i.e. they could be (R,R*) as well as (S*,S*). (…) In other words, what is described in (D1) is the racemate of compounds, wherein both chiral centers have the same configura-tion. (…) In none of these formulae the R-form is described. (…) Applicants, therefore, again emphasize that nothing is stated in (D1) about any possible difference of the optical isomers with respect to their acti-vity or which isomer would be preferred, (…).*

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

1.7. 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 on 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 633 and the SPC. At the oral pleading Ranbaxy withdrew this claim.

2.2. In the case on the merits Ranbaxy claims a court declaration that EP 633 is not infringed by producing, using, marketing or reselling, leasing, delivering, or trading otherwise a medicine having atorvastatin as active ingredient, or by offering, importing it or keeping it in stock for any of those purposes; that the SPC be invalidated, 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 633, 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

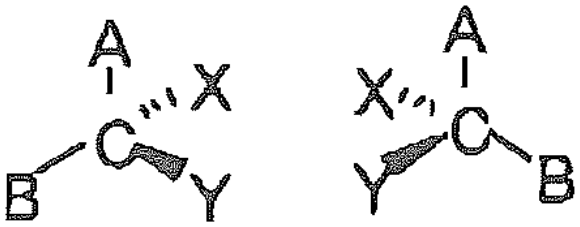
3.1. The patent relates inter alia to substances which meet the general structural formula X (reproduced above in 1.3). Within this general structure 7 variables are distinguished (the group R_2 or R_3 also has variables R_5 and R_6). In the substance atorvastatin X is $-CH_2CH_2-$, R_1 is phenyl which has been substituted by fluor, R_2 is phenyl, R_3 is $-CONR_5R_6$ in which R_5 is hydrogen and R_6 is phenyl and R_4 is alkyl with three carbon atoms.

3.2. Atorvastatin, therefore also the active ingredient which Ranbaxy wants to use in its medicine, thus meets – thinking away the stereochemical aspects to be discussed below – fully claim 1 of the patent.

3.3. However, Ranbaxy takes the position that the stereochemistry of atorvastatin implies that this substance does not infringe the patent. It is this aspect which must be examined in this case.

Stereochemistry

3.4. 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.



3.5. 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.

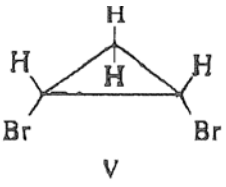
3.6. An asymmetric C-atom to which four different groups have been bonded is referred to as a chiral centre. Both configurations which are each other's mirror-image are called enantiomers. Enantiomers mainly have the same chemical and physical properties. Physically they can be distinguished by their 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).

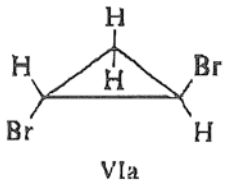
3.7. The biochemical properties of enantiomers are usually different. This fact is relevant to the development of medicines. In the body the desired action appears often to be linked to one of the enantiomers. The other enantiomer does not have such action or to a lesser degree or even has an undesirable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

3.8. 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.

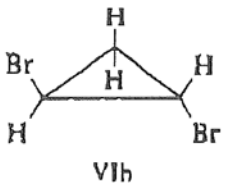
3.9. If the stereoisomers are not each other's mirror-image, then they are referred to as diastereomers. Diastereomers occur if there is more than one chiral centre. This can be illustrated on the basis of three possible three-dimensional configurations of 1,2-dibromecyclopropane:



V



VIa



VIb

3.10. 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.

3.11. 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.

3.12. 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

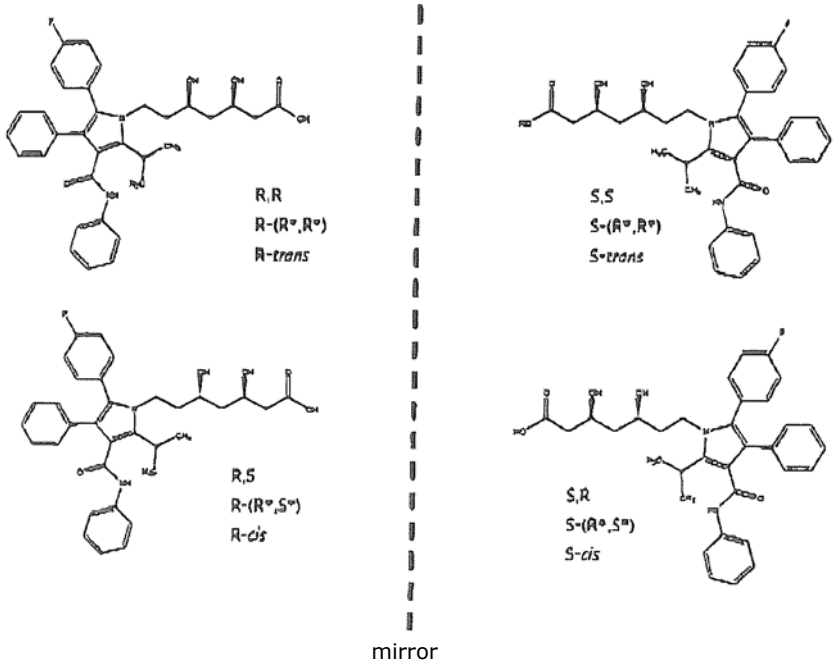
nomenclature one also uses the notions cis and trans discussed above. The R-trans enantiomer then is the absolute configuration which corresponds with the R,R-form.

The effect of atorvastatin

3.13 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 stereochemistry of atorvastatin

3.14. 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 dia-stereomers. 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 rotation and/or translation and are not mirror-images.



3.15. 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 represented at the top left in the chart reproduced above. 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.

Infringement

3.16. In essence Ranbaxy argues that the patent only describes and protects the racemate of R,R and S,S and therefore does not protect the optically pure R,R or S,S.

3.17. In the assessment one should take into account what is essential to the invention for which protection is invoked according to the average skilled person who studies the patent, or, to put it differently, what is the inventive thought lying behind the words of these claims. Decisive is Article 69 EPC and the protocol on interpretation connected thereto. One should examine what falls within the main claim in the light of the description in a manner which guarantees a fair scope of protection to the patentee and also safeguards a reasonable legal certainty for third parties.

3.18. In the view of the court the inventive thought of EP 633 is the combination of 7 variables to a given basic structure. Claim 1, a substance claim, specifies which values these variables (X and R_1 to R_6) must have to achieve the purpose – an improved anti-cholesterol medicine. The discovery that these substituents to the given basic structure result into an active medicine is the essence of the invention laid down in EP 633.

3.19. In principle therefore there is infringement when using a substance having the given basic structure with variables as claimed. Infringement occurs both when using a racemate and when using an optically pure enantiomer. The stereochemical aspects of the basic structure do not concern the inventive thought underlying the wording of the main claim. The question whether an enantiomer can be considered to be a separate substance in respect of its other enantiomer (its mirror-image), or its dia-stereomers, or in respect of the racemate, is not relevant within this context. After all, the point is whether the inventive thought is carried out in the substance, racemate or enantiomer.

3.20. This becomes different, as soon as specific embodiments are disclaimed, for instance in the form of a waiver of rights. In EP 633 this is the case, in the view of the court, in respect of all configurations in cis-form. The description says little about the stereochemistry of the molecule but does state that *the compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one-ring, and the other at the 6-position of the pyran-2-one ring where the alkyl-pyrrole group is attached. This asymmetry gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula I above*. (p. 4, l. 8-12). The disclaimer included in the last sentence of the quoted

part of the description is understandable, because these compositions – as diastereomer in respect of the trans-configurations – have different chemical and physical properties. That the cis-configurations would have a similar anti-cholesterol activity as a medicine is not a reasonable conclusion in that event. It is in admission between the parties that the patent does not relate to the cis-configurations. A confirmation thereof can be read in the title of the patent.

3.21. So the court has to examine whether there is also a disclaimer in respect of the R,R- and S,S-enantiomers (the trans-enantiomers).

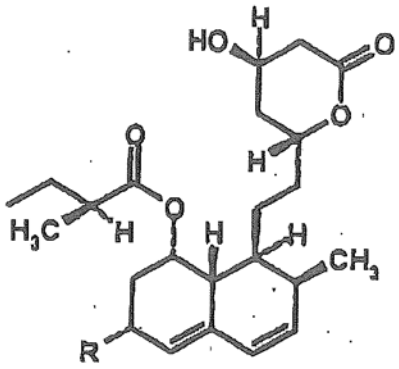
3.22. As a disclaimer one cannot consider the communications made on the part of Warner-Lambert in its letters (Exh. 10 Ranbaxy) of 25 May 1994 and 20 June 1995 to the European Patent Office. These were written during the prosecution of EP 281. EP 281 relates, see the title, to the R,R enantiomer of atorvastatin. In these letters Warner-Lambert gave an explanation of the document D1 which corresponds with US 4,681.893. This American patent is the counterpart of EP 633. In the letters concerned – let alone the question of whether they can be used at all when determining the scope of protection of another patent – regard the information content of EP 633. The issue was substantially whether the average skilled person would conclude from said patent (already) that only the R trans-enantiomer was active. "Basically" or "at best", so the answer is, EP 633 only **describes** ("disclosed" or "described") a racemate. This is understandable within the context of the questions raised by the Examiner. Thus in the view of the court no decision is given on a completely different matter: the question of the **scope of protection** of the main claim of EP 633. Waiver of rights is a legal act, and so under Dutch law a statement aimed at the will to waive rights is required, possibly to be construed on the basis of the criteria of Article 3:35 BW [Dutch Civil Code]. This is not the case, also having regard to the different contexts sketched (information for the skilled person vs. scope of protection). Having regard to its far-reaching effects, the conditions for waiver of rights must be strictly observed.

3.23. However, it *does* appear from EP 281 that the therapeutically active enantiomer is the R,R form. The racemate is considerably less active and the S,S enantiomer not at all. This knowledge from a later patent (priority date 21 July 1989) is not necessarily a reflection of the state of the science at the time of the priority date (30 May 1986) of EP 633.

3.24. At the time of EP 633 it was already known that enantiomers indeed have the same chemical and physical properties but nevertheless they can be active biologically, and therefore also as active ingredient in a medicine, to a different degree and in a different direction. This was discussed in detail by the (party-)expert Dr. R.F. Newton in his report for the benefit of the proceedings conducted in England in respect of EP 633 and EP 281 (submitted by Ranbaxy as Exhibit 12).

3.25. The court derives the following from Newton's report:

17. One of the most unfortunate and best known examples of this was the mil sedative and anti-emetic Thalidomide. The drug has an asymmetric centre bu was marketed as the racemate. The R-isomer is a non-mutagenic sedative whilst the S-isomer is mutagenic and caused widespread deformities amongs those children whose mothers took the drug during pregnancy (...). Although thi is a specific example, the principle was well understood by the skilled person a the 30 May 1986 priority date of the '633 Patent.
(...)
18. It is to be noted that even today, over 50% of useful drugs have a chira centre but only about 10% of these are marketed as single enantiomers. Fo many of the older drugs, the stereo-specificity of the metabolic and pharma cophoric effects has not been studied and are unknown. (...).
19. A typical drug might be approved as, for instance, 98.7% pure with no more than 0.7% of any single impurity. However, when a drug has a chiral centre and only one of the enantiomers is responsible for the required biological activity the inactive or less active enantiomer could be considered to be an impurity since it confers no biological benefit. In consequence, during the mid 1980s I was aware that the FDA was beginning to require information, not only in rela tion to racemates, but also on the constituent enantiomers, in order to evaluate the relative benefits (and practicability) of developing single enantiomers. At the time I was at Glaxo and became aware of these issues because they were rele vant to my involvement in the development of ZOFRAN and SEREVENT, which was going on during 1985 and 1986. I am sure that medicinal chemists at other pharmaceutical companies would also have been aware of these issues.
(...)
22. It was also generally accepted that within a series of structurally related biologically active molecules having the same mechanism of action, the absolute configuration of the more active enantiomer would be expected to be the same throughout the series. (...)
23. These general principles also apply to the 6-substituted 4-hydroxy pyran-2- ones that are the focus of this case.
24. As indicated above, the skilled person wishing to start a programme of work to discover or develop drugs for the treatment of, for instance, atherosclerosis and hypercholesterolemia, would first carry out a survey of the literature, or have one carried out on their behalf (which would certainly include in the con text of the '633 Patent the documents referred to in it). (...) This kind of knowl edge would be important to someone seeking to put the '633 Patent into prac tice.
25. From such a search, the skilled person would learn (if they did not know it already) that the importance of plasma levels of low-density lipoprotein ("LDL") in the epidemiology of atherosclerosis had been recognised well before 1986. Cholesterol in plasma is packaged in lipoprotein particles, most of it in LDL parti cles. The search would also reveal that the natural products compactin and mevinolin were known to inhibit HMG-CoA reductase, an enzyme on the biosyn thetic path to cholesterol, and were being successfully used in the clinic to treat familial hypercholesterolemia.
26. These molecules are optically active and their absolute configuration had been determined. For example EP 0 022 478, filed 12 June 1980 (see Annex 6) and cited in the '633 Patent, gives the absolute configuration of mevinolin and says on page 10, "The absolute configuration of the centres of asymmetry in these molecules has been determined from xray diffraction patterns." The de piction in Figure 3 below shows the absolute configuration of mevinolin and compactin. From this the skilled person would know that the 4-(R)-trans- iso mers of these compounds exhibit potent biological activity. They would expect the other isomers to have different biological activities and because compactin and mevinolin are very potent, they would consider it likely that the other iso mers would be less active.



Compactin R = H; Mevinolin R =CH_3
Figure 3

27. The literature search would also reveal that simpler synthetic analogues that retained biological activity had been made. For example see US 4,375,475 ("the '475 Patent"), filed 11 February 1981 (see Annex 7) and cited and discussed in the '633 Patent. The '475 Patent is significant because it identifies the 4-(R)-*trans*-enantiomers of this series of synthetic analogues as being highly active. (...) Some of the compounds of the '475 Patent are single enantiomers of trans racemates of compounds which are the subject of a previous Belgian patent. In column 3 at line 65 the '475 Patent says: "While the compounds of Formula I in which A is methyl are 4-R enantiomers of the trans- racemates of the compounds of the cited Belgian patent, **the latter prior art shows no recognition of the stereochemistry of these compounds, let alone the fact that an unexpectedly large improvement in the activity would result from the separation of the cis- and trans- racemates and the latter's resolution ... it has been found that the 4-R enantiomers of the trans- racemates corresponding to formula I specifically inhibit with high potency the activity of 3-hydroxy-3-methylglutaryl-coenzyme A reductase (HMG-CoA reductase), which is known to be the enzyme involved in the rate limiting step in the process of cholesterol biosynthesis.**" (Emphasis added).
28. The text that I have highlighted indicates that of the four isomers of the 6-substituted 4- hydroxy pyran-2-one ring system, it is the 4-(R)-trans- enantiomer which displays enhanced activity.
(...)
29. Thus at the time of the '633 Patent the skilled person who wanted to find a medicine to treat hypercholesterolemia would know that inhibition of HMG-CoA reductase was a viable biological mechanism. They would also know that compounds containing the 6-substituted 4-hydroxytetrahydropyran-2-one moiety exhibited this activity, and that of the four possible isomers, the 4-(R)-trans-compounds would be expected to be the most active.
30. Having learnt that the 4-(R)-trans-isomer of the 6-substituted 4-hydroxy pyranone moiety is the most active at inhibiting HMG-CoA reductase in several such molecules, the skilled person would expect this to be the most active isomer in any structurally related 6-substituted 4-hydroxy pyranonemolecules that they synthesised and which inhibited HMG-CoA reductase.

3.26. Thus the skilled person knew from US 475, mentioned in the description that the stereochemical form of the active substance in a medicine affects its effectiveness and furthermore that in the active substance of the present type in particular the R,R-form was active. This is further illustrated in the statement of Dr. Newton reproduced above. So for the medicine in question there was a serious indication that the most effective enantiomer would have the R,R-configuration. After all, the development concerned a medicine which was known to have to engage

to receptors of HMG-CoA reductase. Other substances having this effect were already known. Furthermore it was known of these substances that they always had the R,R-configuration. This implied that it was very likely that the substance to be newly developed would also have the R,R-form as its most effective form.

3.27. The finding above already makes it highly unlikely that Warner-Lambert would have disclaimed the R,R-form. Might Warner-Lambert not already have had the knowledge at the time of the priority that the R,R-molecule would in fact be the only embodiment of the inventive thought having the intended therapeutic effect, the court supposes in any case that Warner-Lambert was familiar at that time with the fact that the R,R-forms of the substances developed by it would have the highest potential.

3.28. The (skilled) third party who studies the patent would also have the knowledge as summarized in 3.26. Already for this reason this average skilled person would not assume that there is a disclaimer for the R,R-form, nor read this in the patent, the description and the claims.

3.29. Finally in the view of the court one cannot read anywhere in the description, claims or prosecution history of EP 633 an implicit or explicit disclaimer.

In the principal action

3.30. The examination above results in the principal action into the conclusion that the claim of Ranbaxy will be dismissed. Being the party found to be in the wrong Ranbaxy will be ordered to pay the costs of the proceedings.

In the cross-action

3.31. At the oral pleading Ranbaxy explicitly committed itself, upon being asked, to subject the effectuation of its intention to launch atorvastatin to the outcome of these proceedings in the principal action. Seen the outcome of the proceedings in the principal action which are negative for Ranbaxy, the court understands that Ranbaxy will not carry out its intention. In this circumstance there is no sufficient interest to be respected by law in the claimed infringement injunction. The claim in the cross-action will be dismissed. Warner-Lambert will be ordered to pay the costs.

4. The decision

The court,

in the principal action:

dismisses the claims;

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

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;

declares this judgment in the cross-action as far as the order to pay the costs is concerned 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)