COUR DE LA HAYE 12 SEPTEMBRE 1996
HOFFMANN-LA ROCHE c. ORGANON
B.E. 0.200.362
(Inédit)

GUIDE DE LECTURE

- EURO-INJONCTION **

Joindre au Dossier *"Euro-injonction"*, Dossiers Brevets 1996.I

I - LES FAITS

-	:	HOFFMANN-LA ROCHE (ci-après : HLR) est titulaire d'un brevet européen n.0.200.362 désignant entre autres la Hollande, l'Allemagne, l'Autriche, la Belgique, la France, l'Italie, le Royaume Uni, la Suède et la Suisse.
-	:	Les différentes filiales de la société ORGANON TEKNIKA (ci-après: ORGANON) accomplissent des actes suspects.
-	:	HLR assigne les différentes sociétés du groupe ORGANON en contrefaçon devant le Juge hollandais.
-	:	ORGANON forme une demande reconventionnelle en annulation du brevet.
- 14 décembre 1995	:	- Sur la demande reconventionnelle de ORGANON le Président de la Cour de La Haye . se déclare incompétent quant à l'annulation (demandée par ORGANON) des parties du brevet européen qui ont été enregistrées dans les autres pays (Belgique, Autriche, France, Allemagne, Italie, Angleterre, Suède, Suisse), . et déclare irrecevable la demande en annulation du brevet dans la mesure où il a été accordé pour les Pays-Bas. - Sur la demande principale de HLR, ordonne la cessation sur le territoire hollandais.
-	:	HLR fait appel.
- 12 septembre 1996	:	La Cour d'appel de La Haye confirme le jugement

II - LE DROIT

A - LE PROBLEME

1°) Prétentions des parties

a) Le demandeur en injonction (HLR)

demande au Juge du domicile de l'un des défendeurs de prononcer une injonction de cessation provisoire à l'encontre de tous les défendeurs sur leurs différents territoires nationaux d'intervention.

b) Le défendeur en inonction (ORGANON)

demande au Juge du domicile de l'un des défendeurs de refuser de prononcer une injonction de cessation provisoire à l'encontre de tous les défendeurs sur leurs différents territoires nationaux d'intervention.

2°) Enoncé du problème

Le Juge du domicile de l'un des défendeurs peut-il prononcer une injonction de cessation provisoire à l'encontre de tous les défendeurs sur leurs différents territoires nationaux d'intervention?

B - LA SOLUTION

1°) Enoncé de la solution

> *"Selon la Cour, la question de savoir si la Cour hollandaise est compétente pour l'ensemble des réclamations (donc dans chacun des pays) peut rester non débattue "may remain undiscussed".*
> *La Cour rappelle qu'il s'agit des premières démarches qui impliquent qu'il est essentiel de décider quelles mesures juridiques sont* ***suffisamment efficaces*** *dans le cas présent pour empêcher ou mettre fin à des actes illégaux.*
> *Pour atteindre ce but nous devons nous borner dans la présente affaire à imposer des injonctions sur ORGANON 1 et 2 (ceux dont le siège est en Hollande; après tout, cela aura pour effet que ORGANON (3 à 10) (les autres pays) ne pourront plus exercer des actes illégaux dans leur pays respectif".*

2°) Commentaire de la solution

- La Cour écarte le contentieux de l'annulation - qui ne doit pas relever du Président du Tribunal de La Haye - du brevet européen pour les différents Etats désignés sur les territoires desquels les filiales ORGANON accomplissent des actes suspects de contrefaçon.

- La Cour limite, pour des raisons d'opportunité, l'injonction d'interdiction provisoire à la seule société hollandaise, titulaire du brevet européen en tant qu'il désigne la Hollande.

(English translation)

-- In the name of the Queen --

The Court of Appeal in The Hague, judgment in preliminary proceedings of 12 September 1996, docket no. 96/277, in the case between:

F. Hoffmann-La Roche AG
with seat in Basel, Switzerland
appellants in the claim,
defendants in the counterclaim,
attorney-at-law: Mr P.A.M. Hendrick (Amsterdam),

against:

1. **Organon Teknika B.V.**, with seat in Boxtel, the Netherlands
2. **Organon Teknika Nederland B.V.**, with seat in Boxtel, the Netherlands
3. **Organon Teknika N.V.**, with seat in Turnhout, Belgium
4. **Organon GmbH**, with seat in Vienna, Austria
5. **Organon Teknika S.A.**, with seat in Fresnes, France
6. **Organon Teknika Medizinische Produkte GmbH**, with seat in Eppelheim, Germany
7. **Organon Teknika SA**, with seat in Rome, Italy
8. **Organon Teknika Ltd.**, with seat in Cambridge, England
9. **Organon Teknika AB**, with seat in Gothenburg, Sweden
10. **Organon Teknika AG**, with seat in Pfäffikon, Switzerland

defendants in the claim,
appellants in the counterclaim,
attorney-at-law: Mr W.A. Hoyng (Eindhoven).

The proceedings

1. In first instance Hoffman-La Roche - to be referred to hereinafter as HLR - claimed in preliminary proceedings:

"(i) to forbid the present respondents - hereinafter also referred to as Organon and Organon c.s. - each individually to be involved in any manner in activities which infringe directly or indirectly its European patent number 0.200,.362, not only in respect of the Netherlands but also in respect of direct or indirect infringements in other countries to which the present patent applies;

(ii) to order Organon c.s. each individually to provide a written account of all the buyers to whom they supplied, offered or sold products which fall within the extent of protection of the patent, not only in the Netherlands but also in the other countries for which the patent has been granted, while noting the dates and the quantities of the products;

(iii) to order Organon c.s. each individually to send the buyers a letter which informs that in the present proceedings it was found that specific kits infringe their patent and which asks the buyers to return the kits still available;

all this under penalty of astreintes[1].

2. By way of defence Organon c.s. pleaded - to put it briefly -:
- that the President is not competent to take cognizance of the claims against the Organon companies registered abroad;
- that there is no urgent interest;
- that there is no infringement;
- that the patent of HLR is invalid, at least claim 13 if the said claim has to be interpreted as pleaded by HLR;
- that should the claims be granted, the enforcement has to be subject to a security of NLG 500 million guilders.

In the cross-action Organon c.s. claimed:
(i) to invalidate the patent as a whole, or at least claim 13;
(ii) to order HLR not to take any provisional measure in respect of the alleged patent infringement caused by the performance of the so-called NASBA process, or the selling of the NASBA kits, in none of the countries for which its European patent has been granted, as far as it has not been decided in a procedure on the merits that the NASBA process, or the NASBA kits infringe the patent;
(iii) to order HLR not to inform in any manner potential buyers, or licensees of the PCR process and/or PCR kits and/or the NASBA process and/or the NASBA kits that the NASBA process and/or the NASBA kits infringe its patent;

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[1] sum of money to be paid if the principal order is not complied with

(iv) to order HLR, each time they inform that the PCR process or PCR kits are protected by patents, to inform at the same time that the Court in preliminary proceedings provisionally found that the patent, at least claim 13 is invalid;
(v) to order HLR to place an advertisement concerning the decision in the present case.

Furthermore by way of augmentation of the claim Organon c.s. claimed that HLR be ordered to pay the cost made by the consulted foreign experts, the Dutch patent agent and his patent division, estimated at a total sum of NLG 677,231.-.

3. By judgment of 14 December 1995 the President of the Court in The Hague dismissed the claims of HLR in the principal action. In the cross-action the President
- declared himself incompetent to take cognizance of Organon's claims to invalidate the parts of the European patent which have been registered in other countries;
- declared the claim of Organon to invalidate the patent inadmissible to the extent that it has been granted for the Netherlands;
- ordered HFL not to inform third parties that in their view the NASBA kits or the NASBA process fall within the extent of protection of their patent without informing each time that this is not the case in the provisional opinion of the President in preliminary proceedings and that an injunction was refused for that reason;
- ordered HLR to place a full-page advertisement in the first issue of Clinica concerning the result of the preliminary proceedings (upon allowance of their claims) under penalty of an astreinte;
- ordered HLR to pay an amount of NLG 35,000.-- by way of disbursement in respect of compensation of external expert fees charged in reasonableness;

4. HLR lodged an appeal from this judgment. By Statement of Grounds of Appeal they presented 23 grounds of appeal and moved for reversal of the judgment and allowance of their claims as yet. Furthermore they augmented their claim and claimed that Organon c.s. (upon allowance of their other claims) be ordered to place an advertisement in the magazine Clinica concerning the result of these proceedings, and to order Organon c.s. to pay a disbursement in respect of compensation of external expert fees charged in reasonableness.

5. By Statement of Reply Organon c.s. opposed the grounds of appeal. Presenting 15 grounds of appeal Organon c.s. lodged a cross-appeal moving for the reversal of the judgment rendered insofar in the principal action and for having the Court, adjudicating again, declare itself incompetent to take cognicanze of the claims against Organon 3 to 10, dismiss the claim against Organon 1 and 2, and, and in the event that the Court might find itself competent to take cognizance of the claims against Organon 3 to 10, to dismiss these claims. In the cross-action Organon c.s. want the judgment to be reversed

to the extent that only a disbursement of NLG 35,000.- was granted and that the claimed sum of NLG 677,231.- be allowed as yet.

By Statement of Reply in the cross-appeal HLR opposed the grounds of appeal of Organon c.s.

6. At the hearing of 11 June 1996 parties filed an official request to enter exhibits into the records, and next they had their stands pleaded by their counsels. Organon c.s. have augmented their claim with a disbursement concerning the fees of external experts. The counsels submitted their memoranda of oral pleading.

Examination of the appeal

in the initial appeal and the cross-appeal

7. Urgent Interest

7.1 Both in first instance and in the appeal Organon c.s. contested that HLR have an urgent interest in allowance of their claims.

7.2. It can hardly be denied after the results of the oppositions proceedings before the European Patent Office in Munich, which was to the advantage of HLR, that they have an urgent interest in putting an end to acts by which they believe their patent claims to be infringed as soon as possible.

7.3. Opposing this interest of HLR to have Organon ordered to immediately put an end to such activities, by means of a provisional measure in preliminary proceedings, there is the interest of Organon in having the need for such a drastic measure not examined and decided in preliminary proceedings but in ordinary proceedings. After all, the disputed issues can be examined and decided more thoroughly in ordinary proceedings. This interest grows as time passes between the moment that such activities start and the moment that the proprietor of the patent informs the alleged infringer by serving a default summons, a writ of summons or otherwise, that he finds such activities to infringe. After all, this passing of time increases the belief of the alleged infringer that his activities are allowed. It is obvious that the immediate ending of activities which the proprietor of the patent did not oppose for a long time, can be extremely harmful: investments made in the meantime may lose their value and 'loss of face' on the market is inevitable, with all the drawbacks involved.

7.4. The question arises of whether in the present case the interest of HLR has to give way to the one of Organon. The answer depends on the particulars of the case.

In that respect the Court takes the following into account.

- HLR does not contest that already since 1989 they should be familiar with the fact that Organon was dealing with the so-called NASBA process, at first as a licensee of the NASBA patents, later on as transferee of the said patents. HLR largely had the opportunity to form an opinion on the question of whether the NASBA process falls within the extent of protection of their patent.

- HLR does not contest either that they should know that already since May 1994 Organon sells kits which in the present proceedings HRL finds to infringe their patent rights.

- Not until the end of August 1995 did HLR inform Organon for the first time to object to the production and sale of NASBA kits, and next writs of summons were served in September 1995.

- Being a competitor of Organon HLR should know that - as Organon argued and HLR did not contest - the production and sale of kits such as the present ones usually require considerable investments and expenses, and that having to end activities is the more harmful the longer the time that they were able to develop the activities.

7.5. The Court believes that in the light of the particulars just mentioned, HLR should have informed Organon within some months after Organon put their kits on the market at least that in their view there was infringement, should they wish to prevent that their urgent interest had to give way to the interest of Organon in an examination of the issues of the dispute in ordinary proceedings. Although HLR was free to first wait for the decision in the opposition proceedings before taking any legal steps, they should have communicated this choice together with their view of the infringement to Organon. Since this has not been done, the urgent interest of HLR has less weight than the interest of Organon.

7.6. With this opinion the case has been decided as far as concerns the claims of HLR in the principal action. This also goes for the claims in the appeal filed by way of augmentation. Nevertheless the Court will discuss the other pleas of defence of Organon, to the extent that they concern the injunction claimed in the principal action, without being obliged to do so.

8. Suitability for preliminary proceedings

8.1. Furthermore Organon believes that the measures claimed should have been refused because the present case is too complicated and too extensive for preliminary proceedings.

8.2. Without any doubt the case is extensive. The volume of the documents of the case in first instance speaks for itself: the Writ of Summons includes 16 pages, the Statement of Claim 96 pages, the Statement of Reply in the princi-

pal action/Counterclaim 258 pages, the Statement of Reply in the Counterclaim 29 pages, and the Memoranda of Oral Pleading 38 and 53 pages respectively, while furthermore parties have submitted files including exhibits. (In the proceedings before this Court of Appeal over 500 pages were added - apart from the new exhibits.)

8.3. The case is also certainly complicated, both as far as concerns the technical and the legal issues. Apart from the Dutch defendants, eight defendants were summoned to appear before the Court from eight different jurisdictions. This makes it inevitable to answer questions of private international law, as well as to examine the infringement under the law of eight different countries. Considerable efforts are expected from the defendants to prepare and coordinate their defence, since they were given two months to do so. Also taking into account the considerable financial interest of the case - in first instance Organon mentioned a loss of over 200 million guilders - and the effects on employment upon allowance of the claims, the Court believes that the present case was not suitable to be examined in preliminary proceedings, notwithstanding the opportunity given to the parties after the Writ of Summons to put their position on paper before the hearing. There is too big a risk that the interests of the defendants will not be sufficiently safeguarded. And so in the view of this Court the President should have dismissed the claims of HLR, because within the framework of preliminary proceedings he could neither have acquired the understanding required for a justified decision, nor sufficiently oversee the consequences of the decision.

9. Jurisdiction

9.1. Ground of appeal VI of Organon in the cross-appeal involves that the President wrongfully found himself competent to take cognizance of the claims against Organon 3 to 10.

9.2. As to the facts, the Court first states the following. By reason of that alleged on the one hand and acknowledged or not (sufficiently) contested on the other hand, it has not been established that the individual defendants develop activities outside the countries in which they are registered. However, it has been established that the respondents 1 and 2 produce the kits under discussion in the present proceedings.

9.3. According to HLR the respondents each infringe in their country of origin the patent rights resulting from the European patent granted to HLR.

9.4. The Court believes that the question of whether the Dutch Court is competent to take cognizance of the claims against Organon 3 to 10 in the present proceedings, may remain undiscussed. These are preliminary proceedings. The nature of preliminary proceedings involves that it is essential to decide which legal measures are effective enough in the given case to prevent

or end (immanent) illegal acts. The claims of HLR against Organon 3 to 10 aim at putting an end to the alleged infringements made by these companies in their respective countries of registration. In order to achieve this goal we may confine ourselves in the present case to impose injunctions on Organon 1 and 2. After all, this will have the effect that Organon 3 to 10 can no longer perform any illegal acts - in the view of HLR - in the respective countries of registration. This, since the source of origins of the kits will be made dry. For this reason HLR does not have any interest in answering the question of whether the Dutch interim injunction Court is competent to take cognizance of the claims against Organon 3 to 10, or not.

9.5. This would be different if it was likely that an injunction imposed on Organon 1 and 2 would miss its target, because the production of the kits could be taken over from Organon 1 and/or 2 without any problem by one ore more of the Organon companies 3 to 10. In that case injunctions imposed on Organon 3 to 10 would certainly be useful. Although HLR stated that the transfer of activities by Organon 1 and 2 to one or more of the Organon companies 3 to 10 could take place, the Court does not find that it became likely that it concerns here a more than theoretical possibility, i.e. a real risk of this happening.

10. Infringement

10.1. In the discussion of the infringement the claims 1, 7 and 13 are key issues. In its most simple form, i.e. with omission of the measures for technical acts which are desirable but not necessary, and starting from the case that the original sample only contains one specific double-stranded nucleic acid sequence which has to be amplified and detected, claim 1 reads as follows in procedural language:

> *1. A process for detecting the presence or absence of... one specific double-stranded nucleic acid sequence in a sample... which process comprises first exponentially amplifying the specific sequence... by the following steps, and then detecting the thus amplified sequence:*
> *(a) separating the nucleic acid strands in the sample and treating the sample with a molar excess of a pair of oligonucleotide primers for... (said, Court) specific sequence being detected, one primer for each strand, under hybridizing conditions and in the presence of an inducing agent for polymerization and the different nucleotide triphosphates such that for each of said strands an extension product of the respective primer is synthesized which is complementary to the strand, wherein said primers are selected so that each is substantially complementary to one end of the sequence to be amplified on one of the strands such that the extension product synthesized from one primer, when it is separated from its complement, can serve as a template for synthesis of an extension product of the other primer of the pair;*

(b) *treating the sample resulting from (a) under denaturing conditions to separate the primer extension products from their templates;*

(c) *treating as in (a) the sample resulting from (b) with oligonucleotide primers such that a primer extension product is synthesized using each of the single strands produced in step (b) as template;... whereby exponential amplification of the nucleic acid sequence results thus permitting detection thereof:...*

As far as relevant at present claims 7 and 13 read as follows:

7. A process of any one of the claims 1-6, wherein a single-stranded nucleic acid sequence which it is desired to detect is... treated... to provide said starting double-stranded nucleic acid sequence...

13. A kit for the detection of... one specific nucleic acid sequence in a sample...

10.2. It should be noted that claim 1 covers any manner of detection of the nucleic acid sequence. Furthermore claim 7 means that a single-stranded nucleic acid sequence can also be detected in the sample, but that it has to be converted first into a double-stranded nucleic sequence, which will then serve as basic material for the process of claim 1. Finally it has to be pointed out that claim 13 has been phrased as an independent claim.

10.3. HLR argued (see the Memorandum of Oral Pleading of Mr Hendrick, page 10, in 9):

"The inventive thought can be described, taking into account the above, as the amplification of such sequence information in the mixture which is actually sought in order to make detection of such sequence information easier or possible. The only thing that will be amplified is that sought!"

10.4. This argument actually involves that the average skilled person who reads claim 1 in the light of the description and the drawings, will come to the conclusion that steps (a), (b) and (c) fo the amplification process can be interpreted in such manner that they can be left out of claim 1 for not being essential aspects of the patented invention; in other words, claim 1 could be enlarged into a process for the detection of the presence or absence of a specific double-stranded nucleic acid sequence, in which the said sequence in the sample is first amplified exponentially (in any manner) and in which next the thus amplified sequence is detected.

10.5. Now it will be examined whether the patent qualifies for such a large extent of protection.

10.6. According to the literal text of claim 1 which is clear as such, the patented process, thus the skilled person will understand, involves the use not of

any amplification, but of a very specific cyclic amplification process, in which a cycle consists of the following steps, summarized:
- starting with a double-stranded nucleic acid sequence;
- separating the double-stranded nucleic acid sequence in two individual strands (denaturation);
- hybridizing a first primer with (the target sequence of) one individual strand and of a second primer with (the target sequence of) the other strand (annealing);
- synthesis of a first extension product of the first primer and of a second extension product of the second primer with the target sequences as template in the presence of specific compounds for the extension products and a polymerization inducing means for the creation of two double-stranded nucleic acid sequences (hybrids) (chain extension);
after which steps each of both hybrids obtained go through another cycle of denaturation, annealing and chain extension to form four hybrids ... etc.

10.7 However it could be that upon thorough reading of the entire patent specification the skilled person finds clear indications in it that cyclic amplification methods other than the one referred to in claim 1 might also be used.

10.8 According to the introduction of the patent specification the invention relates to a process for the amplification and detection of existing nucleic acid sequences in a present test sample, in particular if these sequences are available in small amounts. It is found that there was little research carried out in the field of the amplification of a target sequence into quantities which allow simple detection with the available methods.

Next various methods to prepare nucleic acids are discussed which were known from the literature.

Thus several organic chemical syntheses of nucleic acids are discussed, but they have the disadvantage of not allowing in practice to prepare large quantities of nucleic acid.

There were also methods known on the basis of cloning, in which large quantities of nucleic acid can be prepared from small quantities of an already existing starting nucleic acid.

Next it is mentioned that the invention shows some similarity to these methods, but that by using the method according to the invention not all the sequences in the sample are amplified.

Then a publication by the group of Prof. H.G. Khorana in J. Mol. Biol., 56 (1971) 341-361 is referred to. In this article the authors discuss Kleppe et al:

> *"primer extension reactions using templates corresponding to portions of a tRNA gene, in which reactions the primers are used are complementary to substantial parts of corresponding templates and are extended therealong thereby to provide duplex DNAs. These template copying reactions, involving simple primer extension, are termed "repair replication" by the authors. The final paragraph of the article theorises that if duplex DNA denaturation is effected in the presence of appropriate primers, two*

structures consisting of a full length template strand complexed to a primer could be produced upon cooling, and repair replication achieved by adding DNA polymerase. The paragraph suggests that this process could be repeated."

10.9 It will immediately be obvious to the skilled person that the steps of the amplification mechanism according to claim 1 summarized above will already be known in principle from this article. In other words, the introduction of the specification gives the skilled person the strong impression that from the known amplification methods precisely such method has been chosen which already had been described in theory by Kleppe et al and that this method is therefore essential to the invention.

This impression is once more increased by the following passage page 4, lines 6-14, which briefly but clearly indicates that for the process according to the invention the cyclic amplification method as known from the said reference is used, which process has been described in more detail in claim 1.

On the next pages of the patent specification the preferential embodiments of the invention are discussed. Each time it includes the cyclic amplification with steps (a), (b) and (c) as described in claim 1 (cf. page 4, lines 20-34, page 5, lines 11-28, 40-58).

Furthermore on page 6 the relative European patent application 0.201.184 is referred to, which concerns processes for the amplification of nucleic acid sequences. The interested skilled person who reads this application will see that also in this application only cyclic amplification methods are described which include the said steps.

The following description of the figure (page 6-16) discusses in much detail a.o. which nucleic acids may be used as basic material, which primers, nucleotide triphosphates and enzymes are used as polymerization agents, and which reaction conditions must be respected, all this only within the framework of the aimed amplification according to claim 1, which amplification is explained once more in every detail on the basis of diagrams in the descriptive part page 7-13.

Finally the examples 1-13 follow. In all these examples as well the said amplification method with denaturation cycles, annealing and primer extension has been used (see page 17, lines 19-23; page 18, lines 43, 55; page 19, line 1; page 19, lines 54-57; page 20, lines 12-16; page 21, lines 33-40; page 22, lines 24-25, 35-39; page 23, lines 1-18, 42-49; page 24, lines 5, 14, 38-39; page 25, line 50; page 27, lines 3-4, and page 30, lines 8-12) excluding example 11 which is not relevant in that respect, because it relates to the detection of an amplified sequence with a specific probe.

10.10. By reason of the above it cannot be doubted that the average skilled person cannot come but to one conclusion after reading claim 1 in the light of the description and the drawings, i.e. that the cyclic amplification process with steps (a), (b) and (c) as stated in claim 1 is an essential aspect of the patented invention.

10.11. HLR also argued that the patent protects a "pioneering invention" and that for that reason the extent of protection of the patent must be defined (very) largely and this in the manner indicated by Mr Hendrick in his Memorandum of Oral Pleading (see above).

Organon denies that it concerns a pioneer invention, *"because it appears to be very hard to see a still patentable invention in the work of Mullis taking into account the state of the art (Kleppe). This is not only shown from the reaction of the examiner when the publication by Kleppe in 1971 (...) was pointed out to him, but also from the fact that the Opposition Division did not find the original claim of EP 201184 which described the PCR amplification patentable"* (see SofR, page 196 et seq.).

10.12. We may concede to Organon that the road towards the grant of the patent has been a difficult one. According to the grant file submitted by them even the intervention of a Nobel prize winner in the person of Professor Sir Aaron Klug was needed to convince the granting body of the inventive step of the process in question. However, it cannot be denied that the embodiment of the patented process which is founded on dsDNA as double-stranded nucleic acid and which is known at present as the PCR (Polymerase Chain Reaction) method is considered to be extremely pioneering in professional circles, and being one of the inventors Dr Kary B. Mullis was awarded the Nobel Chemistry Prize for that. And so the Court believes that the patented PCR method provided a considerable degree of innovation. The present case can be characterized as a "minor" invention with a "high degree" of innovation as a result. It is sometimes assumed that a small invention should be given a small extent of protection, while a large degree of innovation should result into a larger extent of protection. The Court believes that the said concepts as such are too abstract for the average (technically) skilled person who wishes to predict with some certainty the extent of protection of a patent, and therefore unworkable, in particular if these concepts point in the opposite direction, as in the present case. As to the extent of protection the criterion for the skilled person should be the content of the claims read (with ordinary know-how) in the light of the description and the drawings (art. 69 EPC). Since the skilled person does not find the slightest indication in the entire patent specification that other cyclic amplification methods may also be used for the process - on the contrary, the patent specification shows that precisely the choice of the specific amplification method according to claim 1 only allows from the nearest state of the art to amplify only the sought sequence in a sample and next simply detect it - it is considered that in the present case the extent of protection is no larger than defined above.

10.13. In support of their allegation that the inventor also had other amplification methods in mind HLR presented two more arguments (see SofC, page 76-77):

In the first place they referred to claim 3 which mentions reverse transcriptase. Reverse transcriptase is mentioned in claim 3 and in the descrip-

tion in a listing of enzymes, which may be used as polymerization inducing agents for the synthesis of the primer extension products (see page 8, line 54 - page 9, line 4). And so reverse transcriptase, the enzyme and also polymerization activity of which had been described long before the priority date of the patent (see exh. 18 of Mr Hoyng, the statement of Prof. P. Borst, page 1), does not indicate in this listing another cyclic amplification mechanism.

In the second place HLR referred to the examples 9B and 9D. In example 9B primers are used having an extension of 26 nucleotides composed of T7 promotor in an amplification with nine cycles including denaturation, annealing and chain extension according to claim 1 (see example 9A) in which within two hours the relatively pure 101 bp fragment of the plasmid pBR322 is obtained as amplification product (a similar process has been noted in example 9D). Next T7 (RNA) polymerase is added to the amplification product (the 101 bp fragment), which enzyme identifies the built-in T7 promotor and then initiates the transcription of single-stranded RNA. So this shows that the transcription process, which had also been part of the state of the art for a long time (exh. 18, statement by Prof. B. Borst, page 2), has not been included in the cyclic amplification according to claim 1, but only serves to transcribe the (DNA) amplification product (once) into RNA.

These arguments do not involve either that the skilled person will understand that other cyclic amplification methods were meant in the patent, because the said measures are mentioned in the patent in their quality as was already known long before from the state of the art.

10.14. Organon is the proprietor of the European patent 0.329.822 originally granted on 8 June 1994 to Cangene Corporation. The said patent relates to a process for the amplification of a specific nucleic acid sequence. Organon c.s. market test kits under the names NASBA HIV-1 RNA QT kit and Qualitative HIV-1 RNA NASBA kit (SofR, page 33). The use of these kits provides a process for the detection of the presence or absence of a specific nucleic acid sequence, in which process on the basis of this sequence a cyclic amplification is carried out according to the European patent 0.329.822 and in which next the thus amplified sequence is detected.

10.15. HLR alleged (see the Memorandum of Oral Pleading of Mr Hendrick, page 48 et seq.) that this process infringes claim 1 of their patent (as this Memorandum of Oral Pleading also shows infringement of the combination of claims 1 and 7 is actually meant).

10.16. The instructions of the test kit NASBA HIV-1 RNA QT includes a figure which both parties use as basis for the defence of their respective stands. This figure shows that the cyclic amplification according to the NASBA kits starts with a single-stranded nucleic acid sequence (ssRNA), which sequence has been obtained in a preliminary stage from the basic material (target RNA), an also single-stranded nucleic acid sequence. The cyclic amplification of the process

according to claim 1 of the patent of HLR starts with a double-stranded nucleic acid sequence. Although according to claim 7 a single-stranded nucleic acid sequence (such as ssRNA) can be taken as basis, this should first be converted in a preliminary stage (in a manner known as such) into a double-stranded nucleic acid sequence (DNA/DNA hybrid, in short dsDNA) with which next the cyclic stage can be entered.

Merely for this difference in preliminary stage there cannot be any literal infringement. As to the technical substance the process carried out with the kits is therefore not inferior, but at the same level as the process according to claim 1 of the patent such as the said claim has been interpreted above on the basis of the description and the drawings.

10.17. Now we come to the question of whether this process at the same level can be considered a process which is equivalent to the patented process, i.e. includes measures which in fact operate in the same manner to obtain the same result.

10.18. The cyclic stage of the NASBA method as reproduced in the figure of the instructions include the following steps (described as much as possible in the terms of claim 1 of the HLR patent):
- starting with a single-stranded nucleic acid sequence (ssRNA);
- hybridizing a first primer to the single-stranded nucleic acid sequence as target sequence (ssRNA) (annealing);
- synthesis of a first extension product (eDNA) of the primer having the single-stranded nucleic acid sequence as template (ssRNA template), in which a double-stranded nucleic acid sequence (RNA/DNA hybrid) is created (chain extension);
- separating the extension product (cDNA) and the template (RNA), whereat the template is destroyed (the RNA strand is hydrolysed);
- hybridizing a second primer with a promoter to the first extension product (cDNA) (annealing);
- synthesis of a second extension product (DNA) having the first extension product as template (cDNA template), whereat a double-stranded nucleic acid sequence is created including the promoter (DNA/DNA hybrid);
- synthesis of single-stranded nucleic acid sequences (ssRNAs) in a number considerably higher than two with the second extension product as a template (DNA template) (transcription),
after which steps each of the single-stranded nucleic acid sequences (ssRNA transcripts) go through a subsequent cycle.

10.19. Comparison of the cyclic stage of the NASBA process and the one according to the patent as reproduced above in 10.6 provides a large number of differences: the starting material of the cycle differs by reason of the difference in preliminary stage, the number of steps in the cycle amounts to six instead of three, the order of the steps of separating, annealing and chain extension differs and also the performance of the step of separating has been modified. As

to the latter point it is pointed out that the separation trap according to the NASBA cycle, in which the template (RNA strand) is destroyed, does not meet the essential condition of the separation step according to the cycle of the process of the HLR patent, i.e. that this step results into two individual strands (ssDNA), which both have to remain intact as template in order to effect the aimed doubling in the cycle of the double-stranded basic material. So one cannot sustain that the cyclic amplification according to the NASBA process leads to an amplification product to be detected in the same manner as the one according to the process of the patent. Since the said essential condition of the separation step according to the cycle of the patented process is not met, one cannot sustain either that NASBA only adds the transcription to the process according to claims 1 and 7 (see the Memorandum of Oral Pleading Mr Hendrick, page 62 et seq.).

10.20. Furthermore it is pointed out that even if the cyclic amplification process according to NASBA should have to be considered an equivalent embodiment of the amplification process of the HLR patent, the NASBA process does not fall within the extent of protection of the patent. After all, the NASBA process is found to be new and inventive in respect of the process according to the present patent 0.200.362 (and also in respect of the one according to patent 0.201.184), as shown by the European patent 0.329.822 granted to the NASBA process, which refers to both patents as being state of the art. The legal certainty would suffer to an unacceptable degree, if it be allowed to consider that equivalent amplification methods which became available after the patent application thanks to inventive efforts, to fall within the extent of protection of the patent, while the inventor himself did not realize that other cyclic amplification methods than the only one mentioned in the patent specification, could be used in the patented process.

10.21. HLR also founded their claim on patent claim 13. Claim 13 concerns an independently phrased (not referring to the process claims 1-12) claim which aims at a kit for the detection of a specific nucleic acid sequence in a sample.

10.22. Parties disagree on the question of which extent of protection should be attributed to claim 13. Organon c.s. believe that claim 13 only protects kits which are intended for the performance of the patented process, while HLR believes that claim 13, seen its independent nature, provides protection to each kit which meets the characteristics stated in the claim, regardless whether such a kit is suitable and/or intended for the performance according to the patent, or not.

10.23. Claim 13 has also to be interpreted in conformity with art. 69 EPC and the corresponding protocol.

10.24. The only passage in the description of the patent (page 4, line 45, page 5, line 31) which mentions the kit, merely states that the kit involves another

subsequent embodiment of the invention, and next claim 13 is repeated word by word; the description does not discuss at all any problem raised in respect of known kits and any characteristics of the kit in question which might solve that problem.

This makes it immediately clear to the average skilled person, assisted by his patent agent, that he is faced with a claim "to complete the protection". In the practice of patent granting it is not exceptional that, in this particular field, apart from process claims applicants present also claims to the patent granting body which aim at a kit for the performance of the intended process and its variants in order to acquire the protection they see necessary.

In that case the kit claim is phrased in such manner that it only mentions the characteristics required for the performance of the process. So the kit as such lacks an inventive step because the skilled person will immediately understand which characteristics have to be available in the kit to make it suitable and intended for the performance of the process. Nevertheless such kit claims are considered allowable by the patent granting body, because the kit is seen as a facet or embodiment of the invention which lies in providing the new process; thus the kit claim also meets the condition of the inventive step.

In such a case in which the kit claim derives its right to exist from the process claims, it goes without saying that it is incorrect to fully disconnect the kit claim from the process claims. Seeing that the entire patent specification claim 13 has to be interpreted in such manner that the extent of protection does not go beyond kits which are suitable and intended for the performance of the patented process, even if it has been phrased as an independent claim.

The above implies that, even should it have to be assumed that the NASBA kits are suitable for the performance of the process according to the patent of HLR, which is contested by Organon, these kits do still not fall within the extent of protection of claim 13, because it has been established that they are not intended for the application of the process.

11. Invalidity

Seen the provisional judgment that there was no infringement, the Court will not discuss the question of whether the patent of HLR is liable to be invalidated. This matter has been raised by Organon alternatively, i.e. in the event that infringement would be assumed.

12. Other matters in the initial appeal

12.1. Ground of Appeal XIX according to which juridical ground 53 of the judgment in the cross-action of the President is said not to be sufficiently complete and decisive, can be left undiscussed. Even if the ground of appeal would be correct, this would not have any effect on any decision of the President.

12.2. Ground of Appeal XX concerns grounds on which the injunction imposed in the cross-action on HLR not to inform third parties that in their view the NASBA kits or the NASBA method fall within the extent of protection of their patent, without adding each time that this is not the case in the provision opinion of the President in preliminary proceedings and that an injunction was therefore refused in these proceedings.

12.3. This ground of appeal holds good. It has indeed not become sufficiently likely that HLR informed third parties in that manner. The judgment will therefore be reversed to the extent that it concerns the said injunction and the related astreinte. For the rest, the Court believes that if HLR would communicate their opinion on the infringement by Organon c.s. to third parties, the decency requires that they also inform that the provisional opinion of the judge is contrary and that the injunction claim has been dismissed. This does not prejudice the freedom of speech.

12.4. Ground of Appeal XXI concerns the grounds of the President on which the order imposed on HLR to place an advertisement in the cross-action has been founded.

12.5. This Ground of Appeal holds good. In the opinion of the Court it has not become sufficiently likely that HLR stirred up the market to such an extent that a drastic measure such as placing an advertisement be justified.

12.6. Ground of Appeal XXII relates to the grounds on which the decision to order HLR to pay a disbursement of the fees of external experts, has been founded.

12.7. The Court believes that there is no room for allowance of the claimed disbursement, since an urgent interest has not even been established. To that extent the judgment cannot be upheld.

12.8. Ground of Appeal XXIII does not have any independent meaning and does not require any discussion.

12.9. The Court will order HLR to pay the cost of the initial appeal being the party found to be at fault for the largest part.

13. Furthermore in the cross-appeal

13.1. The grounds of appeal do not require any separate discussion anymore. A large number of grounds of appeal concern facts found to be established on forehand by the President (Ground of Appeal I to V) and grounds of the President (Grounds of Appeal VII to XIV) which did not result into decisions to which Organon c.s. disagree. Ground of Appeal VI concerns grounds of the President in respect of jurisdiction. The Court discussed that in 9. Ground of

Appeal VI also concerns the question of the urgent interest; this has already been answered in 7. The ground concerning the opinion on the expert fees has been answered above in 12.6 and 12.7. The Court adds to this not to consider these fees as fees in the sense of art. 56 Netherlands Code of Civil Legal Procedure. Taking into account the above the grounds of appeal cannot result into reversal of the judgment on appeal.

13.2. The cost of the cross-appeal will be compensated by the Court as stated below, since the parties were both found to be at fault.

Decision:

The Court of Appeal:

in the initial and the cross-appeal:

- upholds the judgment of the President, to the extent that it has been rendered in the principal action;

- dismisses that claimed by HLR by way of augmentation of claim before the Court of Appeal;

in the initial appeal:

- reverses the judgment, to the extent that it has been rendered in the cross-action, but exclusively as far as

- HLR has been forbidden under penalty of an astreinte to inform third parties that in their view the NASBA kits or the NASBA method fall within the extent of protection of their patent, without mentioning each time that this is not the case in the provisional opinion of the President in preliminary proceedings and that an injunction has been refused for that reason;
  - HLR has been ordered under penalty of an astreinte to place an advertisement in the magazine Clinica;
  - HLR has been ordered to pay a disbursement in respect of refund of external expert fees;

and adjudicating again to that extent:

- dismisses the claims of Organon c.s. (including that claimed by way of augmentation of the claim);

- orders HLR to pay the cost of the initial appeal, estimated until the present decision on the part of Organon c.s. at NLG 20,000.-;

in the cross-appeal:

- dismisses the appeal;

- compensates the cost of the cross-appeal in such manner that each party will bear its own cost.

This judgment has been rendered by Brinkhof, Fasseur-van Santen and Grootoonk, and was pronounced at the public session of 12 September 1996, in the presence of the clerk of the Court.