date of judgment: 14 December 1995
cause list number: KG 95/940

The President of the District Court in The Hague.

Judgment in interim injunction proceedings in the case having cause list number 95/940 of:

the company under foreign law
F. HOFFMANN-LA ROCHE AG,
having its registered office in Basel, Switzerland,
plaintiff in the principal action,
defendant in the cross-action,
procurator: H.C. Grootveld,
attorney-at-law: P.A.M. Hendrick in Amsterdam,

versus:

1. the company under Netherlands law ORGANON TEKNIKA B.V.,
having its registered office in Boxtel,
2. the company under Netherlands law ORGANON TEKNIKA NEDERLAND B.V.,
having its registered office in Boxtel,
3. the company under foreign law ORGANON TEKNIKA N.V.,
having its registered office in Turnhout, Belgium,
4. the company under foreign law ORGANON GMBH,
having its registered office in Vienna, Austria,
5. the company under foreign law ORGANON TEKNIKA S.A., having its registered office in Fresnes, France,
6. the company under foreign law ORGANON TEKNIKA MEDIZINISCHE PRODUKTIE GMBH,
having its registered office in Eppelheim, Federal Republic of Germany,
7. the company under foreign law ORGANON TEKNIKA SPA,
having its registered office in Rome, Italy,
8. the company under foreign law ORGANON TEKNIKA LTD.,
having its registered office in Cambridge, United Kingdom,
9. the company under foreign law ORGANON TEKNIKA AB,
having its registered office in Göteborg, Sweden,
10. the company under foreign law ORGANON TEKNIKA AG,
having its registered office in Pfäffikon, Switzerland,
defendants in the principal action,
plaintiffs in the cross-action,
procurator: W. Taekema,
attorney-at-law: W.A. Hoyng in Eindhoven.

Course of the proceedings.

Plaintiff in the principal action (hereinafter: Hoffmann-La Roche) had defendants in the principal action summoned to appear at the session of the President in interim injunction proceedings of 4 October 1995. All the defendants appeared, the defendants in 3 to 10, however, exclusively to contest jurisdiction of the President.

The counsel of Hoffman-La Roche submitted a written explanation of the claims, including exhibits. Next the hearing of the case was held over in consultation with the parties to the time fixed to that end before, i.e. 7 December 1995 at 2:00 pm.
On 8 November 1995 the counsel of defendants in the principal action (hereinafter also: Teknika) sent a written statement of their points of view including exhibits to the court and filed a counterclaim on that occasion.
Next the counsel of Hoffmann-La Roche was given the opportunity to respond to that in writing, which opportunity he took and he submitted two additional exhibits consisting of legal opinions.
On the occasion of the hearing on 7 December 1995 parties had their stands pleaded by their counsels, assisted in that by the respective patent agents of parties. The memoranda of oral pleading are included in the file of the case.

<u>As to the law in the principal action and cross-action.</u>

<u>Concise summary of the decision and the division of the judgment.</u>

By reason of the following considerations the President comes to the conclusion that he is competent to take cognizance of the claims, but that the claim against defendants in the principal action should be dismissed.
The counterclaim is allowed to the extent that defendant in the cross-action is forbidden to inform that the NASBA kits of plaintiff in the cross-action infringe the present patent, without adding that for the time being it was judged otherwise in interim injunction proceedings. Moreover defendant in the principal action is ordered to publish a rectification advertisement and has to pay an advance.
For the rest the counterclaim is also dismissed.

The large amount of exhibits submitted and arguments advanced by both parties requires a detailed discussion.

For clarity's sake its organization is as follows:
Facts assumed
Mutual claims
Applicable law in the Netherlands?
Competence of the President in the principal action
Under which law should be examined whether interim injunction proceedings can be instituted, or not?
Urgent interest?
Infringement?
Competence of the President in cross-action
Invalidation in interim injunction proceedings?
Injunction of provisional measures?
Announcements by Hoffmann-La Roche unlawful?
Rectification advertisement?
Cost.

Facts assumed.

1. In the present proceedings the following will be assumed:

1.1. The problem which the present patent relates to is of microbiological nature. In particular it concerns the detection of DNA or RNA sequences which occur only in a very small amount in samples to be examined. The said detection is carried out in principle by adding a short, labelled, nucleic acid sequence to the sample to be examined: the so-called probe. The said probe has been constructed in such manner that it is complementary to part of the sequence to be found. If the sequence to be found is included in the sample, the probe will attach itself to it by reason of its complementarity (hybridize). Next it is examined whether the sample contains compounds of the probe with other sequences. If so, then it has been proven that the sequence to be found was included in the sample and it can be quantified, if desired.

1.2. The problem is that the sequences concerned may occur in a sample in such a small amount that they are not or hardly distinguishable from background noise upon using the previous detection methods.
This problem was solved by first amplifying the sequences concerned, at least sequences which are complementary to them, exponentially before starting the detection. After such an exponential amplification of the sequence concerned detection is possible without having the detection signal drown out by the background noise.

1.3. Furthermore it is important that parties distinguish (at least) two processes for such exponential amplification of nucleic acid sequences, which two processes are referred to by parties as PCR (Polymerase Chain Reaction) and NASBA (Nucleic Acid Sequence-Based Amplification) respectively.

1.4. Next it is reminded that two different processes involving nucleic acids take place in the cell in vivo:

1. In the first place there is duplication (replication) of the DNA within the framework of the division of the cell.

2. In the second place there is reading (transcription) of the DNA for the sake of the creation of protein. This process takes place precisely during the 'normal' life of the cell and not in the stage of cell division.

During the process of DNA replication first both strands which compose the double-stranded DNA are separated. Next a complementary DNA strand is constructed on each strand

by the enzyme DNA polymerase using loose nucleotides available in the cell. After this process there are two identical double-stranded copies of the DNA one of which will end up in each new cell upon the actual cell division. Each copy consists of one strand of 'old' DNA and one newly formed strand. The nucleic acid created in this process is DNA exclusively, which has been constructed from deoxyribonucleotides.

During the process of DNA transcription separation of both DNA strands only takes place very locally and temporary. A partial copy is made of the temporarily and locally separated DNA strand by the enzyme RNA polymerase in the form of RNA. To that end the RNA polymerase needs a so-called promoter: a piece of double-stranded DNA with a specific base sequence. This promoter itself will not be transcribed; the transcription starts immediately after the promoter sequence. After this temporary and local unlinking the DNA combines into a double helix. The created single-stranded RNA ('messenger RNA') moves from the nucleus to ribosomes in the cytoplasm and is 'read' there within the framework of protein synthesis. Thereby no new nucleic acid is produced but amino acids are linked up into protein molecules, this in the sequence as directed by the messenger RNA. The DNA which remained in the nucleus has not been increased or modified. The nucleic acid created in this process is not DNA but RNA, which is composed of ribonucleotides (and so not of deoxyribonucleotides).

1.5. Schematically replication and transcription were reproduced in the statement of reply as follows:

Replication.

Transcription.

1.6. The Polymerase Chain Reaction (hereinafter: PCR) involves - reproduced in a concise manner - that a double-stranded nucleic acid is denaturated, i.e. divided into two strands.
Next a large amount must be provided of two different so-called primers; rather short pieces of nucleic acid which are complementary to the 3' end of both loose strands. The said primers will attach themselves to the said 3' end of the strands by reason of their complementarity. Furthermore one must provide an enzyme (DNA polymerase) which sees to extension of the primers at their 3' end (whereat the template must be transcribed in the direction 3' -> 5') by attaching the right loose nucleotides (which are also provided). The 'old' strand (to which the primer attached itself) serves as a template in that.
When both loose 'old' strands have been duplicated in that manner and thus become two double strands, the

process can be repeated: the (new) double-stranded molecules are denaturated again and next the thus created loose strands are made again into double-stranded molecules using primers, DNA polymerase and loose nucleotides. Thus the number of the aimed nucleic acid molecules is doubled in each step; the number of the other nucleic acid molecules remains the same because there are no primers available which might start their replication.
Should one aim at multiplication of a single-stranded nucleic acid, such as RNA, then by using the enzyme reverse transcriptase a DNA strand is provided which is complementary to the RNA concerned (cDNA) and can hybridize to it into a double-stranded molecule, which the aforementioned process can be applied to. In the PCR process DNA is created exclusively, just like in replication in vivo.
Applied to an RNA strand (for instance: ^{5}A-C-G-U-A-C)[1] the PCR process produces a multiple of the same ^{5}A-C-G-U-A-C RNA molecules and an equally large number of ^{5}G-T-A-C-G-T cDNA molecules complementary to that, to which they will be hybridized into double-stranded molecules.
In each 'round' of the reaction (which will be repeated several times) the number of aimed molecules is multiplied by a factor 2.

1.7. The Nucleic Acid Sequence-Based Amplification (hereinafter: NASBA) involves - also reproduced in a concise form and without taking away anything from the detailed description in the patent claim quoted in 1.15 - that the starting point is one single-stranded nucleic acid instead of a double-stranded molecule. This method consists of the following steps:
I. The single RNA strand is first provided with a complementary DNA strand and so after hybridization a double-stranded molecule comes about, consisting of one RNA strand and one cDNA strand.
In this are used the enzyme reverse transcriptase and a primer which is complementary to the 3'-end of the wanted RNA strand. So this is the same step as used in the PCR method (cf. page 6 line 23 to 28) if one whishes to multiply a single-stranded nucleic acid like RNA.[2]
II. Next the RNA part - i.e. the originally present strand - is destroyed by enzymeatic hydrolysis. To that

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[1] Double-stranded DNA consists of the base pairs Adenine-Thymine and Guanine-Cytosine (abbreviated as A-T and G-C respectively) whereas RNA consists of the bases Adenine, Uracil, Guanine and Cytosine (abbreviated as A, U, G and C respectively).

[2] As shown from the exhibits 12 (manual Maniatis a.o. 1982) and 18 (statement by Prof. P. Borst) of Teknika and as not being contested either this step as such was part of the state of the art.

end the enzyme ribonuclease H[3] is added. The said enzyme leaves the cDNA strand intact. So for each originally present RNA strand there is (only) one cDNA strand left.
III. A second primer (which is complementary to the 3' end of this strand) attaches itself to the cDNA strand, the said primer being provided with several additional bases which constitute the complement to a promoter sequence.
IV. By means of DNA polymerase and using the said second primer and the cDNA strand as a template a complementary DNA strand is synthesized. This hybridizes to the cDNA strand and thus creates a double-stranded cDNA/DNA molecule provided with a functional promoter.
V. This (double-stranded) DNA molecule provided with a promoter is now taken as basis for a transcription:
VI. In that the DNA strand can be 'read' and 'translated' into newly created RNA strands many times by means of the enzyme RNA polymerase.
VII. The said RNA strands are complementary to the original RNA strand and so they have the same polarity as the (complementary) cDNA strand in steps I and II. And so primer 2 can seize upon the said RNA strands in its turn: the process repeats itself as from step III.
So in the NASBA process both DNA and RNA molecules are created.

1.8. Applied to an RNA strand (eg.: ^{5}A-C-G-U-A-C) the NASBA method produces a large amount of <u>complementary</u> (single-stranded) RNA molecules (^{5}G-U-A-C-G-U) while the originally present RNA strand is no longer present. Apart from that there will be double strand DNA molecules, which served as 'primer' for the enzyme RNA polymerase. It concerns double-stranded molecules which will no longer hybridize just like that.

In every 'round' of the reaction, which will be repeated many times, the number of wanted molecules increases by a factor 10 to 12.

1.9. Reproduced schematically the NASBA process looks as follows:

1.10. Hoffman-La Roche is the proprietor of the European patent 200 362 B1, which was granted on an application dated 27 March 1986 on 20 January 1993 for a "Process for amplifying detecting, and/or cloning nucleic acid sequences". Priority was claimed as from 28 March 1985, 25 October 1985 and 7 February 1986.

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[3] A ribonuclease which decomposes specific RNA which is part of RNA/DNA hybrids but leaves DNA and 'loose' RNA intact.

1.11. The patent was granted for Austria, Belgium, Switzerland, Germany, France, United Kingdom, Italy, Liechtenstein, Luxemburg, the Netherlands and Sweden.

1.12. The patent includes 12 process claims (claims 1 to 12) and one product claim (claim 13).
The relevant claims here are the claims 1, 7 and 13 of the patent and they read in the authentic English text as follows:

"I. A process for detecting the presence or absence of at least one specific double-stranded nucleic acid sequence in a sample or distinguishing between two different double-stranded nucleic acid sequences in said sample, which process comprises first exponentially amplifying the specific sequence or sequences (if present) by the following steps, and then detecting the thus-amplified sequence or sequences (if present):
(a) separating the nucleic acid strands in the sample and treating the sample with a molar excess of a pair of oligonucleotide primers for each different 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 nucleoside thriphosphates 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 a template; and, if desired,
(d) repeating steps (b) and (c) at least once; whereby exponential amplification of the nucleic acid sequence or sequences, if present, results thus permitting detection thereof; and, if desired,
(e) adding to the product of step (c) or (d) a labelled oligonucleotide probe capable of hybridizing to said sequence to be detected: and
(f) determining whether said hybridization has occurred.

(...)

7. A process of any one of Claims 1-6, wherein a single-stranded nucleic acid sequence which it is desired to detect is first treated under hybridizing conditions with a primer, inducing agent for polymerization and the

different nucleoside triphosphates, to form a complementary strand thereto thereby to provide said starting double-stranded nucleic acid sequence and to permit detection of said single-stranded sequence.

(...)

13. A kit for the detection of at least one specific nucleic acid sequence in a sample, which kit comprises, in packaged form, a multicontainer unit having:
(a) each of two oligonucleotide primers for each different sequence to be detected, wherein
(i) if the specific nucleic acid sequence to be detected is single-stranded one primer is substantially complementary to one end of the strand so that an extension product of said one primer formed under hybridizing conditions and in the presence of an inducing agent for polymerization and the different nucleoside triphosphates is substantially complementary to one end of said extension product and can be used under hybridizing conditions and in the presence of an inducing agent for polymerization and the different nucleoside triphosphates to synthesize another extension product employing said extension product of said one primer as a template thereby providing a nucleic acid consisting of two strands; or
(ii) if the specific nucleic acid sequence to be detected is double-stranded the primers are such that each is substantially complementary to one end of one of the strands and an extension product synthesized from each primer using its complement strand as a template under hybridizing conditions and in the presence of an inducing agent for polymerization and the different nucleoside triphosphates, when separated from its complement, can serve as a template for synthesis of an extension product of the other primer under hybridizing conditions and in the presence of an inducing agent for polymerization and the different nucleoside triphosphates;
(b) an agent for polymerization;
(c) each of the different nucleoside triphosphates;
(d) an oligonucleotide probe capable of hybridizing to said sequence if it is present in said sample; and
(e) means for detecting hybrids of said probe and said sequence."

1.13. An opposition was filed against the grant of the patent. The Opposition Division of the European Patent Office in Munich maintained the patent in unaltered form by its decision of 16 March 1995. The term of appeal from the said decision of the Opposition Division has not yet passed. In view of the future appeal proceedings Teknika

filed a notice of intervention which claims revocation of the patent.

1.14. All the Teknika parties are involved in the manufacturing and/or assembly of, trade in and marketing of and/or distribution of detection kits which are put into commerce under the names "NASBA HIV-1 RNA QT" or "HIV-1 NASBA QL". The said kits (to be referred to hereinafter as: the NASBA kits) serve to detect nucleic acid sequences originating from the HIV-1 virus. They do this by using the method referred to above for the amplification and detection of specific RNA strands, called the NASBA process by parties. Teknika is the proprietor of a European patent granted for this process no. 329.822 B1, on 8 June 1994 originally granted to Cangene Corporation for a "Nucleic acid amplification process".

1.15. Claim 1 of the said patent describes the NASBA process patented by that as follows:
"a process for the amplification of a specific nucleic acid sequence, at a relatively constant temperature and without serial addition of reagents, comprising the steps of:

(A) providing a single reaction medium containing reagents comprising
(i) a first oligonucleotide primer,
(ii) a second oligonucleotide primer comprising an antisense sequence of a promoter recognized by an RNA polymerase,
(iii) a DNA-directed RNA polymerase that recognizes said promoter,
(iv) an RNA-directed DNA polymerase,
(v) a DNA-directed DNA polymerase,
(vi) a ribonuclease that hydrolizes RNA of an RNA-DNA hybrid without hydrolizing single- or double-stranded RNA or DNA, and
(vii) ribonucleoside and deoxyribonucleoside triphosphates;
then

(B) providing in said reaction medium RNA comprising an RNA first template which comprises said specific nucleic acid sequence or a sequence complementary to said specific nucleic acid sequence, under conditions such that a cycle ensues wherein
(i) said first oligonucleotide primer hybridizes to said RNA first template,
(ii) said RNA-directed DNA polymerase uses said RNA first template to synthesize a DNA second template by extension of said first oligonucleotide primer and thereby forms an RNA-DNA hybrid intermediate,
(iii) said ribonuclase hydrolizes RNA which comprises said RNA-DNA hybrid intermediate,

(iv) said second oligonucleotide primer hybridizes to said DNA second template,
(v) said DNA-directed DNA polymerase uses said second oligonucleotide primer as template to synthesize a functional promoter recognized by said RNA polymerase by extension of said DNA second template; and
(vi) said DNA-directed RNA polymerase recognizes said functional promoter and transcribes said DNA second template, thereby providing copies of said RNA first template;
and therafter
(C) maintaining said conditions for a time sufficient to achieve a desired amplification of said specific nucleic acid sequence."

1.16. Publications on the NASBA process did not appear but after publication of the patent of Hoffmann-La Roche.

1.17. Late October/early November 1995 Organon Teknika Limited, Organon Teknika S.A. and Organon Teknika Medizinische Produkte GmbH instituted in England, France and Germany respectively procedures on the merits against Hoffman-La Roche aiming at, reproduced in a concise form, obtaining a declaratory judgment stating that the NASBA kits do not infringe the patent of Hoffmann-La Roche. About the same time invalidation proceedings were instituted in France concerning the patent.

Mutual claims

2. Hoffman-La Roche claims - reproduced in a concise form - an injunction to all the Teknika parties not to be involved in acts which infringe its said European patent, this in all the countries for which it was granted, and under penalty of an astreinte, and including other subsidiary claims.

3. It founds the said claims on the allegation that the NASBA kits fall within the scope of protection of its patent - and in particular within claim 13 - and so Teknika infringes the said patent.

4. Teknika pleads a defence while stating reasons. It claims in the cross-action (reproduced in a concise form):
- invalidation of the European patent 0200362 for all the countries for which it was granted,
- un injunction to Hoffmann-La Roche not to take any provisional measure in the countries for which the patent was granted in respect of the alleged infringement of the patent by the NASBA process or as the case may be the NASBA kits as long as it has not been decided in a procedure on the merits in the country concerned that the said kits infringe,

- an injunction to Hoffmann-La Roche not to inform potential buyers or licensees that the NASBA process or the NASBA kits infringe the patent,
- an order to Hoffmann-La Roche to inform each time that it informs that the PCR process[4] or PCR kits are protected by patents, at the same time that the patent was provisionally judged invalid in interim injunction proceedings,
- an order to Hoffmann-La Roche to publish a rectification advertisement,
- all this under penalty of astreintes,
- and finally payment of the expense made by it to a total amount of NLG 677,231.--.

Hoffmann-La Roche pleads a defence against the said claims by stating reasons.

Examination.

Applicable law in the Netherlands.

5. Officially it is established first that this concerns a European patent the grant of which was published before 1 April 1995, and so the Rijksoctrooiwet 1910 fully applies as far as the Netherlands are concerned, this under the provisions of article 103 Rijksoctrooiwet 1995.

Furthermore in the principal action:

6. The stands of parties on both sides require that the following questions be answered:

I. Is the President competent to take cognizance of the claims filed against foreign defendants?
II. Under which law should it be examined whether a provisional measure in interim injunction proceedings can be given?
III. Does plaintiff have an urgent interest in its claims?
IV. If so, do the NASBA kits fall within the scope of protection of the patent?
V. If so, should the claims which result into acts outside the Netherlands be allowed also, even if an injunction cannot be obtained by way of provisional measure in the other country?
VI. If question IV is answered in the affirmative: Is there a serious not negligible chance that the patent, or at least claim 13, will be revoked or invalidated?

to I: Competence of the President.

7. It has to be stated first that the President is competent to take cognizance of the claims against the defendants registered in the Netherlands. Taking this into account the

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[4] i.e. a process using the so-called Polymerase Chain Reaction, see above in 1.5.

President is also competent to take cognizance of the claims against the other defendants, this under the provisions of article 6 in 1 EEX, and art. 6 in 1 EVEX respectively, at least art. 126-7 Netherlands Code of Civil Procedure.

8. Teknika challenged this while referring to the decree of the Court of Justice of the European Union dated 27 September 1988, NJ 1990, 425 (JCS) in the case Kalfelis/Schröder. In its view there is no question of a proper administration of justice requiring simultaneous trial and hearing - as demanded in the said decree - in order to avoid that incompatible decisions are made in the case of individual trial.
In this respect Teknika argued that there is no question of any incompatible decisions since the infringement of which Hoffman-La Roche accuses defendants in 3 to 10 concerns patents other (i.e. a Belgian, Austrian, French, German, Italian, British, Swedish and Swiss patents) than the Dutch patent, which defendants in 1 and 2 are said to infringe.

9. This argumentation is dismissed.
It concerns a European patent here and this has to be interpreted in the same manner in all the member countries in conformity with article 69 of the EPC and the related protocol. So it would certainly be contrary to that if infringement was established in one member country and not in the other one. Even if Teknika might be right by stating that formally it concerns individual patents, then this would still not alter the fact that there be substantially contrary judgments.
Moreover - as has been indisputably established - all the defendants in the present case are part of the same group, which emphasizes the existing correlation between these cases even more.

10. Teknika also argued that a Dutch judgment in interim injunction proceedings can never be contrary to a foreign judgment in a procedure on the merits since after all the interim injunction proceedings result into a provisional measure, whereas the judgment in the procedure on the merits establishes the legal relationship between parties.
This argument is not subscribed to either for the time being. Although there is of course a difference as referred to above between interim injunction proceedings and a judgment in a procedure on the merits - and for that reason one cannot sustain that both procedures concern "the same subject-matter" as referred to in art. 21 EEX (cf. in that respect also juridical ground 24 below) - it does not imply that there could not be any contrary decisions. After all, both decisions include a judgment in respect of the same matter in dispute.

11. Teknika also wished to found the lack of sufficient correlation between the claims against the various defendants on the argument that in respect of the patent infringement in foreign countries foreign law should be applied.

According to Teknika there are in that case "Ansprüche aus unterschiedlichen Rechten (..)" which are "(...) darüber hinaus voneinander völlig unabhängig". As is judged for the time being the mere circumstance that different claims should not all be judged under the same law, does not have to hinder the conclusion that the decisions concerning these claims on the contrary show a correlation and might be contrary to each other. Anyway, nobody would sustain that claims included in a European patent might be "völlig unabhängig" of each other in the various countries for which it has been granted.

12. In respect of the competence of the President under art. 6 in 1 of the EEX one might judge otherwise - cf. also juridical ground 9 of the decree Kalfelis / Schröder - if the claim against some of the defendants had been filed with the sole aim to draw one of the other defendants away from the judge of the country where it has been registered. This did not appear at all in the present case.

13. Since the President is competent by virtue of the provisions of the conventions and laws referred to above it can be left out of the discussion whether apart from that there is competence under the provisions of art. 5 and art. 24 EEX/EVEX respectively or not, just like the question of whether any competence exclusively founded on the said articles would have the same scope as the competence which - as in the case of article 6 paragraph 1 EEX/EVEX - has been founded in principle on the place of registration of the defendant(s).

14. Furthermore Teknika argued that art. 16 paragraph 4 EEX obstructs the competence of the President. In these interim injunction proceedings it challenged the validity of the patent. However, the judgment on that point is reserved, as Teknika (rightfully) states, to the foreign judges - in any case to the extent that it concerns the foreign parts of the patent. However, the claims in the principal action, says Teknika, cannot be judged as long as it is not known whether the patent will be maintained in the foreign countries. Teknika draws the conclusion from this that the present proceedings - where the validity of the patent is challenged - are proceedings as referred to in art. 16 paragraph 4 EEX and so the President should officially declare himself incompetent.

15. It is said on forehand that this argumentation of Teknika seems hardly consistent with the counterclaim it filed - for it asks the President to invalidate the patent for all the countries for which it has been granted.
Apart from that the argumentation does not hold water either. These interim injunction proceedings aim - in the principal action - at maintaining a patent by way of a provisional measure. This is not at all a claim "in respect of the registration or the validity of patents" as referred to in art. 16-4 EEX. The fact that in the event of established

infringement one must make, within the framework of a balancing of interests, an assessment of the likeliness of the patent being maintained, has nothing to do with that.

16. The circumstance that a provisional judgment in interim injunction proceedings may lead to such drastic measures that a procedure on the merits becomes useless, as pleaded by Teknika, if correct, cannot result into a different stand. The question of whether in interim injunction proceedings specific measures have to be ordered or not, is an individual one and has nothing to do with the question of whether the President is competent to take cognizance of a claim under, e.g., article 6 in 1 of the EEX.

17. The allegation of Teknika, that also for urgent measures Hoffmann-La Roche has to address the judge who is competent to examine the invalidity, is rejected now that it is found for the time being that such allegation does not find any support neither in the Netherlands Code of Civil Procedure, nor in the EEX, nor in the EVEX.

18. Furthermore upon discussing the question of competence Teknika pointed out that art. 24 EEX/EVEX assigns the competence to take provisional and safekeeping measures to the judge of the country where such measures have to be enforced. From this Teknika concludes - as the President understands - (page 45/47 statement of reply) that only the local judge is competent to issue provisional measures since he is best capable to judge circumstances by reason whereof the claimed measures have to be allowed or refused.
To the extent that Teknika intended to take that stand, it is dismissed. After all, it is ignored that the competence to take provisional measures referred to by Teknika (among other things shown by the use of the word "even" in the text of article 24 EEX/EVEX -Treaty of Lugano) is clearly intended as a complementary competence and not as an exclusive one.

19. Teknika also referred to (analogous application of) art. 17 paragraph 2 of the Protocol on Disputes of the European Patent Convention which restricts the competence of the national judges to infringing acts within the territory of their state.
However, this reference does not hold for the mere reason that such restriction will not apply also according to the text of the said provision in the Protocol on Disputes in the event that the national judge is competent to take cognizance of a claim against specific defendants by virtue of the provisions in article 6 in 1 EEX.

20. For that same reason the reference of Teknika to the decree of the European Court of Justice in the case Shevill / Presse Alliance dated 7 March 1995 no. C-68/93 must fail. After all, this decree also discusses only the competence under art. 5 in 3 EEX and not the competence under the provisions of art. 6 in 1 EEX, which - like the principal rule

of art. 2 EEX - has been founded on the place of residence of (one of) the defendant(s).
Although we may concede to Teknika that the said decree might be understood to mean that exceptions to the principal rule - the competence of the forum rei - must be interpreted in a restrictive manner, this cannot result in the present case to assuming that the President is not competent. After all, a competence founded on article 6 in 1 EEX/EVEX definitely involve the forum rei, anyway in respect of at least one[5] of the defendants.
For the time being there do not seem to be any compulsive reasons to interpret the article of the treaty in a more restricted manner than in conformity with its wording and purport neither in such a case.
On the contrary: if article 6 in 1 EEX is interpreted and applied in such a restricted manner as Teknika pleads, it would loose almost all its meaning in cases concerning industrial property (seen its rights that often have only a territorial effect). An interpretation which deprives a provision of a large part of its effect, should not be too readily assumed to be right.

21. The suggestion of Teknika that the President should ask the European Court of Justice in Luxemburg for a preliminary ruling concerning the interpretation of article 6 in 1 EEX must fail by reason of the provisions of article 2 of the Protocol on Interpretation of the EEX. After all, this article prevents the judge in first instance from raising such questions.

22. Furthermore Teknika argued that in the present case art. 21 EEX would obstruct the competence of the President, seen the circumstance that in various contracting states (Germany, France and the United Kingdom) meanwhile claims have been filed which concern the same subject-matter and so the President should declare himself incompetent under art. 21-2 EEX.

23. This argumentation should fail for the mere reason that the foreign proceedings were not instituted but after the present proceedings and that the obligation to postpone included in art. 21 EEX only applies to the judge of the court before which the case was brought later.

24. Moreover this argumentation is dismissed in principle since it is judged that there are no claims which concern "the same subject-matter" as referred to in art. 21 EEX, which wording should be interpreted subject to autonomy of the treaty. (Cf. also Kropholler, Europäisches Zivilprozesrecht, 3. Auflage, 1991, page 234).

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[5] in the present case even two

Article 21 EEX intends to prevent the situation that art. 27 paragraph 3 EEX be invoked. In the present case there is no risk of that.
After all, the proceedings instituted in Germany, France and the United Kingdom are procedures on the merits, whereas this case concerns a provisional measure by way of interim injunction proceedings. However, a Dutch judgment in interim injunction proceedings can never be "incompatible" (in the sense which should be given to art. 27 EEX) with a foreign judgment in a procedure on the merits since art. 292 Neth.Code of Civil Procedure states that the provisional decision does not prejudice the case in chief. To the extent that this should be examined under Netherlands law, it cannot be understood that such provision would only relate to provisional measures with effect within the Netherlands.

25. We may concede to Teknika that thus a difference occurs between the notion "incompatible decisions" as understood in the decree Kalfelis/Schröder (cf. below) and the notion "incompatible decisions" as referred to in art. 27 paragraph 3 EEX (read in correlation with art. 21 EEX). For the time being this is considered likely seen the different rationales: article 6 in 1 is a provision which intends to create an additional forum, whereas art. 27 paragraph 3 EEX includes a ground for refusal of the recognition of decisions at the recognition whereof the entire treaty precisely aims.

26. Neither do the rules of fair trial include that the President should desist from taking a decision because there are already procedures on the merits instituted in other countries. Such procedures on the merits were after all instituted by Teknika and this after the service of the summons in the present interim injunction proceedings. Assuming that the claiming party may choose sometimes from various fora, it would not be appropriate to allow the defendant to deprive him/her of such choice, and this even with retroactive effect, by instituting yet another procedure before a different forum. (forum selection)

27. So we must conclude that the appeal to incompetence made by the defendants in 3 to 10 is dismissed.

28. Apart from the question of competence, there is, as considered above, the question of whether an injunction should be pronounced for all the defendants or an injunction to be pronounced should concern all the designated countries, or not. Such questions will have to be examined individually, as far as necessary.

to II: Under which law should the possibility of a provisional in interim injunction proceedings be examined?

29. Furthermore, under the heading "Applicable Law" Teknika argued that the question of whether a provisional measure in interim injunction proceedings is possible or not, should be

considered a question of substantial law - to which the lex causae applies - and not a question of procedural law - to which the lex fori applies.

30. This argument seems to be founded on a confusion of the question of which procedural rules have to be applied, the question of what may be claimed substantially (e.g. an injunction or other sanctions in substantial sense) and the question of which sanctions may be imposed in order to guarantee the enforcement of the judgment (sanctions in a more narrow sense).

31. For the time being it is considered as follows in this respect:
The first question has to be answered - as Teknika itself also states - in conformity with the lex fori. This concerns - in the present case - the question whether interim injunction proceedings can be instituted against a given defendant on the ground of a given allegation. This question must be answered here under Netherlands law and this, for the present case, in the affirmative. After all the President is competent, as considered above, to take cognizance of the case and Hoffmann-La Roche has an urgent interest in its claim, as will be explained below.
The second question (what may be claimed substantially) has indeed to be answered under the lex causae - as is judged for the time being and in any case for cases which fall under art. 2 paragraph 2 EPC - in this case the law of the (individual) relevant market.
The third question (which sanctions in a more narrow sense may be imposed) falls in its turn under the procedural law and so it has to be answered on the basis of the lex fori.
To put it differently: the question of whether an injunction may be imposed or not should be answered subject to the lex causae, the question of whether this may also be done in interim injunction proceedings and whether an astreinte can be attached to that should be answered subject to Netherlands law, for this is the lex fori.

32. We may concede to Teknika that thus differences may arise or remain between various competitors since some of them cannot be involved in interim injunction proceedings and others on the contrary can be involved.
However, on the other hand total equality of procedural terms will appear not or not too soon within reach of the various countries and so total equality within the (European) market will remain, in that respect anyway, an utopia for the time being.
And so the inequality referred to in the first paragraph cannot be a reason not to pronounce an injunction in interim injunction proceedings against such defendants in whose respect such competence does exist. Also in that case (i.e. in case of refusal of such an injunction) total equality of all the competitors on the European market will not be achieved because in that case - in the view of Teknika - the

effectivity of the protection of the proprietor of the patent would depend on the procedural possibilities in the country of registration of the alleged infringer.

to III: Urgent interest?

33. Teknika argued that Hoffman-La Roche does not have any urgent interest in the claimed provisional measure, since the challenged kits are on the market as from May 1994. Furthermore Hoffmann-La Roche must be aware since 1989 of the common fact that Teknika was the exclusive licensee of the NASBA patents (which it acquired meanwhile). Hoffmann-La Roche never served any warning and/or awareness notices to Teknika, but all of a sudden served a writ of summons as late as September 1995. So it left more than a year pass unused.

34. Hoffmann-La Roche on the contrary argued that it first waited for the results of the opposition proceedings and next, after the decision was pronounced in the opposition proceedings on 16 March 1995, examined the activities of Teknika in the various designated countries. After it reached the conclusion that Teknika infringed, its counsel sent a letter of warning to all the defendants on 29 August 1995. When these letters did not give any result, it decided to take legal action in interim injunction proceedings, for which it applied for a date on 7 September 1995.

35. In that respect the following was considered.
As the Court of Appeal in The Hague decided by decree of 3 February 1994 (cause list number 93/960 Kirin Amgen / Boehringer Mannheim) the proprietor of the patent who waits for the decision in the opposition proceedings and takes steps against infringement soon after dismissal of the opposition, will keep an urgent interest regardless of the service of a summons to desist from infringement or awareness notice in an earlier stage.
Furthermore within this framework it is considered that the term within which the proprietor of the patent will have to take steps should not exceed a period of about six months without any particular reason in the view of the President. Such termijn is also applied elsewhere in Europe.
Taking this into account it is hard to see that there would be no urgent interest for Hoffmann-La Roche since the application for interim injunction proceedings is dated 7 September 1995 and so it started to take steps within six months after the decision of the Opposition Division dated 16 March 1995.
Whether this happened out of the blue or not, is not relevant to the question of an urgent interest.
Neither is it relevant that Teknika was not party to the opposition proceedings in first instance. The proprietor of the patent is allowed to wait for the results of opposition proceedings in order to get insight into the chances of maintenance of his patent before taking expensive legal steps. For the time being it seems to be unimportant who filed the opposition.

36. And so the claims of Hoffmann-La Roche can be admitted in interim injunction proceedings.

to III: infringement?

37. It is stated first that the scope of the protection of a European patent under article 69 of the European Patent Convention is defined by the content of the claims whereat the specification and the drawings serve to explain the said claims. Such explanation has to be made according to the protocol to the said article of the convention in such manner that both a fair protection is offered to the applicant and a reasonable degree of legal certainty to third parties. The essential point in that is the manner in which the person skilled in the art will understand the patent specification. Upon reading it such skilled person will bear in mind the problem which the patent aims to solve and in which manner this is handled.

38. The first question is whether the NASBA kits fall within the litteral text of claim 13 of the patent, which mentions several subfeatures. This will be discussed in imitation of parties for the subsequent subfeatures:

38.1. The NASBA kits concern a "kit for the detection of at least one specific nucleic acid sequence in a sample" since it is a kit by which it is aimed to show the presence of viral RNA in a serum sample.

38.2. For the time being it is judged that the said kit also includes "a multicontainer unit". It is shown by the instructions of the NASBA kits submitted by Hoffmann-La Roche that the various reagents are packaged in several 'vials', 'tubes' and 'bottles'. To the extent that Teknika wished to argue that there is no question of 'units' since the various elements were not packaged together in the same boxes, the argument is dismissed. The elements intended for amplification and the ones intended for detection are offered jointly and under one name as shown by the exhibits submitted by Hoffmann-La Roche. Whether they are packaged in the same box or not, does not seem to be relevant under patent law; functionally the various elements belong together and most certainly do form 'units', whereat each unit includes several 'containers'.

38.3. Even if the argument of Teknika that seen the history of the grant the patent must be understood to mean that there has to be an individual container for each individual reagent, might be correct, then putting it on the market in a different packaging would still have to be considered to be a total equivalent. It does not appear anywhere that it has any effect on the patented invention, nor that the proprietor of the patent

wished to renounce his protection for the said forms of packaging.

38.4. Teknika contested that the NASBA kits provide "an agent for polymerization". The article "a" should in its view be interpreted "in the light of the specification" as one agent for polymerization "exclusively".
It states that the NASBA kits do not include "a" agent for polymerization but two of such agents, combined with a ribonuclease which precisely decomposes the result of polymerization. To the extent that this argument which is not developed any further is intended seriously, it is dismissed: in the provisional view of the President it cannot be derived from the specification that "a" should be understood to mean "one exclusively". After all, it would have been obvious to include in the text "only a" or even "only one". That there is in any case at least one agent for polymerization present in the NASBA kits seems to be clear since according to the submitted instructions both reverse transcriptase and RNA polymerase are present.

38.5. It was also challenged that the NASBA kits contain "the different nucleoside triphosphates". However this is also wrong. We may concede to Teknika that its kits do not only contain deoxyribonucleotides (intended for the structure of DNA molecules) but also ribonucleotides, intended for the construction of RNA molecules. However the presence of ribonucleotides does not mean that the various deoxyribonucleotides cannot be present as well. With the latter presence the subfeature concerned is met, since it cannot be understood from it that only the various deoxyribonucleotides may/must be present.

38.6. The subfeature that there must be a primer which is "substantially complementary" on one end of the wanted strand, is also met. This is the primer which is referred to as "Primer 1" in the figure reproduced in 1.9.

38.7. Furthermore claim 13 also requires an"other primer", complementary to the extension product of the first primer (the strand which in its turn is complementary to the wanted strand). This 'other primer' is also present in the NASBA kits. After all, by means thereof and with the first extension product as a template, the strand with the promoter sequence is composed. In the figure reproduced in 1.9 this primer is referred to as 'Primer 2'.

38.8. The subfeature that by means of the said 'other primer' and by means of the extension product of the first primer 'a nucleic acid consisting of two strands' is provided, is also met. Using de cDNA strand as a template the functional promoter (described in the step above in juridical ground 1.7 in IV) is created. This

will remain hybridized to the cDNA strand, as has to be assumed, and so there is creation of a double-stranded nucleic acid molecule.

38.9. However the subfeature referred to in claim 13 in (d): "an oligonucleotide probe capable of hybridizing to said sequence (...)" is not met.
The words "said sequence" cannot be understood in the specification but to mean the "one specific nucleic acid sequence in a sample" as referred to in the head of claim 1 and also of claim 13. So it concerns a probe which can hybridize to the sequence to be detected.
Such a probe is not present in the NASBA kits.
Although the said kits include a probe, this probe does not hybridize to the wanted sequence but to a sequence which is precisely its reverse. To the extent that the sample contains a sequence with the same order of bases[6] and the same polarity as the original RNA sequence, it is a DNA sequence which is part of the double-stranded 'primers'. However, the probe will not be able to hybridize to that just like that, since there are no free bases available, whereas moreover the said DNA sequence is not the specific (in this case RNA) sequence to be detected.

39. And so the conclusion must be that the NASBA kits do not meet the letter of claim 13 of the patent.
However this will not necessarily mean that they cannot fall within the scope of protection of the said claim. After all it is conceivable that there may be equivalence under patent law.

40. Upon answering the question of whether the NASBA kits may nevertheless fall within the scope of protection of the patent it has to be taken into account that claim 13 is not an independent one but one of the embodiments of the invention disclosed and claimed by the patent (see also page 4 line 45 of the patent specification and cf. also art. 82 EPC).
To put it differently: the kits of claim 13 are only the kits by which the invention can be applied, as Teknika rightfully argued.

41. Contrary to what is argued by Hoffmann-La Roche it is assumed for the time being that the said invention consisted of the (application of) the Polymerase Chain Reaction.
Although the phrasing of the patent specification is so broad that to the letter it is not restricted to the Polymerase Chain Reaction, the specification hardly mentions anywhere the use of the transcription mechanism but almost exclusively mentions the replication mechanism. The invention aims to achieve amplification of the aimed strand by repeatedly applying the replication mechanism and this by duplicating it

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[6] of course on the understanding that instead of U(racil) there is A(denine) each time.

over and over again. The only place where transcription is mentioned is found at the end of example 9C of the patent specification. There (page 23 line 56 to page 24 line 4) it is mentioned that a primer may be used which has been provided with the sequence for the T7 promoter, which promoter, says the patent specification, "can be used to initiate RNA transcription. T7 polymerase may be added to the 101-bp fragment to produce single-stranded RNA."
However it is not mentioned here that transcription is used for the amplification of the wanted sequence. On the contrary: the said 101bp sequence is precisely the product of the amplification by means of the polymerase chain reaction, as shown by lines 48/49 in conjunction with lines 32/47 of page 23.

42. The skilled person who reads the patent will understand from it that the aim is to protect the PCR process:

- Claim 1 of the patent is almost a 'portrait' of the polymerase chain reaction.
- The polymerase chain reaction is mentioned in so many words on page 6 line 19 of the patent specification.
- On page 8 line 7 it is explicitly stated that it "is necessary to separate the strands of the nucleic acid", which is not necessary upon transcription.
- On page 9 line 5-8 it is once more explained: "The newly synthesized strand and its complementary nucleic acid strand form a double-stranded molecule which is used in the succeeding steps of the process. In the next step, the strands of the double-stranded molecule are separated using any of the procedures described about to provide single-stranded molecules."
- Furthermore it is said again on page 9 lines 13 and 14: "(...) half of the extension product will consist of the specific nucleic acid sequence bounded by the two primers."
  This also seems to lead to the conclusion that it was intended to use the replication mechanism and not the transcription mechanism.
- The same thing appears again clearly from the detailed description on the pages 10 to 12 of the patent specification.
- Moreover the skilled person will be aware that the NASBA process had not yet been published at the time of the application or the grant of the patent, and so in that respect it is neither likely that the applicant intended to obtain protection for the said process.

43. It is admitted that for the NASBA kits not the Polymerase Chain Reaction is used but the NASBA process as patented in the patent referred to in 1.15 and as summarized above in 1.7. So it has to be examined whether the NASBA process can be considered equivalent to the PCR process under patent law. In other words: whether the NASBA process achieves essentially the same result in essentially the same manner and with essentially the same means.

44. The mere circumstance that a patent was also granted for the NASBA process does not have to mean as such that the said NASBA process could not fall within the scope of protection of the patent of Hoffmann-La Roche: for it is conceivable that there might be question of a dependent patent.

45. In favour of assuming equivalence is the following:
- by means of polymerase and using a single-stranded nucleic acid in the NASBA process also a strand complementary to that is produced which may hybridize to the strand used as a template. (See above, juridical ground 1.7 step IV.)
- Moreover it can be stated that this does not happen once: in each cycle of the process a double-stranded molecule is created again which serves as 'primer' for the transcription process.
- Finally it should be taken into account that apparently the PCR process (let alone whether it was new in the sense of patent law on the date of priority, or not) was a pioneering invention, which was considered worthy of a Nobel prize. It must have been hard for the applicant to foresee all the consequences of such an invention upon phrasing his claims. Should he be given a fair protection, then this has to be taken into account in the interpretation of the claims.

46. The following goes against assuming equivalence:
- In the NASBA process not the wanted (RNA) strand is used as a template for the duplication but a (cDNA) copy produced from it.
- Although a double-stranded molecule is created several times, this is not done consecutively: between both geneses of double-stranded molecules there is always a stage of transcription in which a rather large amount of complementary RNA copies is created. So the question can be raised whether there is a "polymerase chain reaction".
- Between two creations of double-stranded molecules there is no denaturation (in the sense of: separation of both strands), but the RNA half of the molecule is hydrolized.
- In the NASBA process the final product is not a large amount of copies of the wanted strand but a large amount of molecules which are complementary to the wanted strand, which is destroyed itself.
- The double-stranded molecule in the NASBA process is not the aimed final product (if necessary after repeating the process) but is only used in its (biological) function of primer.
- Furthermore the NASBA process was granted for an individual patent. So anyway the Application Division of the EPO considered this process inventive in respect of the patent of Hoffmann-La Roche, for this is mentioned among the state of the art. One can hardly sustain that a process which was considered inventive is "essentially" the same as a process already known. (Cf. also Singer,

EPÜ Art 69 Rdn 3 page 21 and Benkard, Patentgesetz §14 Rdn 122.)

- Last but not least: third parties are entitled to a reasonable sense of legal security. This might be jeapordized if the scope of protection of a patent would be extented to include a process which is not disclosed by the patent and was not even known at the time of its grant.

47. Summarizing it is judged for the time being that there is question of an essentially different process and so equivalence cannot be assumed. A fair protection of the proprietor of the patent does not seem to require the assumption of equivalence either, and a reasonable sense of legal securitiy of third parties seems to oppose this.
So we must conclude that the NASBA kits are not considered infringing under Netherlands law. It has not become likely that under the law of one of the other designated countries it should be judged otherwise.
So at present the questions in V and in VI do not have to be discussed.

48. In the principal action Hoffmann-La Roche has to be found to be at fault and ordered to pay the cost.

Furthermore in the cross-action:

49. The President is competent to take cognizance of the counterclaims by virtue of the provisions in article 6 in 4 of the EEX/EVEX, or as the case may be by virtue of the provisions of article 250 Netherlands Code of Civil Procedure.

50. The counterclaim can be divided, after its augmentation, into the following parts:

1. A claim to invalidate the patent for all the countries for which it was granted.

2. An order to Hoffmann-La Roche not to take any provisional measure in any of the countries for which the patent was granted in respect of alleged patent infringement by (using) the NASBA kits as long as it has not been decided (for the country concerned) in a procedure on the merits that the NASBA process or the NASBA kits infringe said patent.

3. An order to Hoffmann-La Roche not to inform in any way the potential buyers or licensees of the PCR process and/or PCR kits and/or the NASBA process or the NASBA kits that the NASBA process and/or the NASBA kits infringe the patent.

4. An order to Hoffmann-La Roche to inform each time that it informs that the PCR process or the PCR kits

are protected by patents, at the same time that the President in interim injunction proceedings took the provisional stand that the patent is invalid, alternatively that the kit claim is invalid.

5. An order to Hoffman-La Roche to publish in the first next issue of Clinica a full-page advertisement with the content - reproduced in a concise form - that Hoffman-La Roche instituted interim injunction proceedings in order to obtain an injunction not to use the NASBA kits in all the designated countries but that the claim was dismissed and that the President took the provisional stand that the patent is invalid.

6. All this under penalty of astreintes and whil ordering Hoffmann-La Roche to pay the cost, including the expense of extrajudicial expert advice.

51. In that respect the following is considered:

to 1: Invalidation?

52. Let alone the fact that the Dutch judge under the provisions of art. 16 paragraph 4 EEX or EVEX is not competent to take cognizance of the said claim in respect of patents which were not registered in the Netherlands, the said claim should also fail because there is no opportunity in interim injunction proceedings to establish legal relationships between parties. Neither is there any room for a 'constitutive' judgment in the form of an invalidation of a patent. In respect of this part of the claim the President will declare himself incompetent to the extent that it concerns the elements of the European patent which were not registered in the Netherlands and declare Teknika inadmissible for the rest concerning this part of its claim.

53. To the extent that Teknika intended to claim that the President give his opinion on the validity of the patent, it is stated that there is no room for that in the present interim injunction proceedings.
If there had been question of patent infringement then it would have been examined - before proceeding to impose an injunction - whether there was a serious not negligible chance of revocation or invalidation, but this is not the case here. Teknika wants a pseudo 'declaratory judgment'. However this goes beyond the limits of interim injunction proceedings, even supposing that Teknika might have an urgent interest in that.

to 2: Injunction not to take provisional measures?

54. As such it is understandable that the Teknika parties, some of which were involved in proceedings before the Dutch court against their will, wish to see a measure taken in

exchange which prevents them to have to go to yet another court for the same case.

55. The question of whether Hoffmann-La Roche may proceed to provisional (legal) measures in any other country must always be answered on the basis of the foreign law concerned: apparently Teknika considers the taking of such foreign legal steps to be a (threatening) unlawful act by Hoffmann-La Roche. Both the question of whether an act should be considered unlawful and the question of whether an injunction can be imposed against that, have to be answered under the lex loci delicti.
Teknika did not make it plausible in any manner that Hoffmann-La Roche should be forbidden to claim provisional measures under the legal systems concerned.
Moreover one should be extremely careful in raising barriers to the access to the (foreign) judge. Not only because this may easily become contrary to decency under international law, but also because this seems to be at odds with art. 6 paragraph 1 of the European Treaty on Human Rights since such an injunction would involve obstructing the access to the judge.

56. And so the wish of Teknika cannot be met and this part of the counterclaim will have to be dismissed also.

to 3 and 4: Announcements by Hoffmann-La Roche unlawful?

57. In our provisional view Hoffmann-La Roche cannot be forbidden to inform that its kits are protected by the challenged European patent, for such an announcement is not at all contrary to the facts.

58. On the other hand under rules of Netherlands law Hoffmann-La Roche is not free just like that to inform third parties that in its view the NASBA kits or the NASBA process fall within the scope of protection of its patent. To keep this within the limits of decency and care in the course of trade Hoffmann-La Roche will have to inform also that in the provisional view of the President this is not the case and that for that reason an interim injunction was refused.
In that sense the injunction claimed will be imposed.

59. It was not alleged nor did it appear that this question should be judged otherwise under foreign law. The injunction to be imposed can therefore apply to all the designated countries.

to 5: Rectification advertisement?

60. Teknika founds this part of its claim on the allegation that Hoffmann-La Roche informs potential buyers/licensees of Teknika that the NASBA kits infringe the patent of Hoffmann-La Roche and that an injunction is claimed concerning the said kits for all the designated countries in interim injunction

proceedings. Teknika finds this unlawful and points out that Hoffmann-La Roche thus obtains an unjustified advantage in competition, also in the event that the claimed injunction be dismissed in interim injunction proceedings. The said unjustified advantage lies according to Teknika in that Hoffmann-La Roche causes unrest on the market whereat its potential buyers/licensees will be put off doing business with it concerning the NASBA kits.

61. In support of its allegations Teknika submitted a written statement by M. Siccum. Moreover it alleges without being contested that a potential licensee renounced to enter into a license agreement at the very last moment (while the date of signing of the agreement had already been fixed).

62. Against this Hoffmann-La Roche stated only very generally and not before the reply at the hearing that it never meant to cause uncertainty or unrest on the market.

63. This plea of defence of Hoffmann-La Roche is not only considered to be insufficiently reasoned but also insufficiently credible.
As it appeared on the occasion of the hearing Hoffmann-La Roche made any normal consultation almost impossible. When Teknika received a letter from the counsel of Hoffmann-La Roche stating that the NASBA kits infringed, Teknika invited Hoffmann-La Roche to a meeting on that subject. On the part of Hoffmann-La Roche the only reaction was the application for a date for the present interim injunction proceedings, and then Teknika obviously did no longer see any basis for consultation.
This behaviour of Hoffmann-La Roche makes us suspect for the time being that Hoffmann-La Roche was more interested in these interim injunction proceedings than in athorough review of the mutual arguments. Such an attitude is more in line with the allegations of Teknika than with the ones of Hoffmann-La Roche.
Anyway all this gives no reason to let the interests of Hoffmann-La Roche play an important part in the balancing of the interests of parties: since Hoffmann-La Roche made consultation in fact impossible the risk should be for its account if it appears that it misjudged the answer to the question of infringement by the NASBA kits.

64. Now that it became plausible that Hoffmann-La Roche created unrest on the market by ventilating patent pretensions to an extent which is considered inappropriate for the time being and that decent competition requires that it should not gain any unjustified advantage from that, the claim to publish a rectification advertisement can be allowed.
After all, it has not been contested that such an advertisement is a reasonable means to remove the unrest caused among potential buyers.

However, the claimed text will be altered since the claim to invalidate the patent, or to pronounce a provisional judgment on such invalidity, is dismissed.

to 6: Astreinte?

66. On the occasion of the hearing Teknika claimed compensation of expense made by it, partly consisting of the expense of national and foreign lawyers and patent agents consulted by it and partly consisting of expense of its own patent department. According to its estimate the first mentioned expense amount to NLG 256,231.-- and the latter to NLG 420,000.-- and so it claims a total sum of NLG 677,231.--.

67. For the time being it is judged that this claim must be considered to be an augmentation of the claim - which was not contested as such. Since this augmentation of the claim was not substantiated with proof on the one hand and obviously was only generally contested (could be contested) on the other hand, the President does not find any grounds for allowance of the amounts claimed.

68. However, taken into account the advices submitted as exhibits by Teknika, the President believes that the said expense, at least part thereof, were made in reasonableness and so in principle qualify for compensation insofar. Since it did not become clear why the proof concerning the said expense had not been submitted already with the statement of reply in the principal action/counterclaim (and so there is at present no support of this claim of expense) such lack of proof should remain in principle on account and at risk of Teknika.

69. Taking this into account the President will allow ex aequo et bono and by way of advance an amount of NLG 35,000.-- for expense made for external experts.

70. Seeing that in the cross-action both parties were mutually found to be at fault the cost of the proceedings in cross-action will be counterbalanced.

Decision:

The President, adjudicating in interim injunction proceedings:

in the principal action:

- dismisses the claims;

- orders Hoffmann-La Roche to pay the cost of the proceedings, estimated insofar on the part of Teknika at NLG 330.-- for disbursements and at NLG 15,000.-- for fees of its procurator;

in the cross-action:

- declares himself incompetent to take cognizance of the claims of invalidation of the parts of the European patent 200.362 B1 registered in other countries;

- declares the claim of Teknika to invalidate this patent inadmissible to the extent that it is granted for the Netherlands;

- orders Hoffman-La Roche not to inform third parties that in its view the NASBA kits or the NASBA process fall within the scope of protection of its patent without informing each time that this is not the case in the provisional view of the President in interim injunction proceedings and that an injunction was refused for that reason;

- orders Hoffmann-La Roche to pay the Teknika parties jointly an astreinte of NLG 25,000.-- for each breach of the said order;

- orders Hoffmann-La Roche to insert a full-page advertisement in the first issue of Clinica after the service of the present judgment in which this will be feasible in reasonableness, with exclusively the following text:

> "Dear Reader,
>
> The President of the District Court of the Hague, Netherlands, has ordered us to inform you as follows.
>
> We have started preliminary injuntion proceedings before said President asking among others to order Organon Teknika to stop the sale of its NASBA kits for amplification and detection of HIV RNA in Austria, Belgium, Switzerland, Germany, France, United Kingdom, Italy, Liechtenstein, Luxemburg, Sweden and the Netherlands.
>
> The President has REFUSED to issue such order because according to the preliminary opinion of the President ORGANON TEKNIKA'S KITS "NASBA HIV-1 RNA QT" AND "HIV-1 NASBA QL" DO NOT INFRINGE OUR EUROPEAN PATENT 200 362 B1.
>
> Hoffmann-La Roche."

while determining that the underlined words will be printed either bold or in red.

- orders Hoffmann-La Roche in the event of not or not timely compliance with the said order to pay an astreinte of NLG 100,000.-- for each issue of Clinica in which the said advertisement is not inserted;

- orders Hoffmann-La Roche to pay the joint Teknika parties an amount of NLG 35,000.-- by way of disbursement in respect of compensation of expert fees made in reasonableness;

- declares the judgment in the cross-action insofar provisionally enforceable;

- refuses the other provisions claimed;

- counterbalances the cost of the proceedings in the cross-action, on the understanding that each party bears its own cost.

Thus rendered by J.H.P.J. Willems and pronounced at the public session of 14 December 1995, in the presence of the clerk of the court.

(signature) (signature)

certified true copy
the Clerk of the District Court 14/12/95
(signature)