(Translation from the Dutch)

IN THE NAME OF THE QUEEN

Judgment : 3 February 1994
Roll number : 93/1272
Roll number first instance: 93/535

The Court of Appeal of the Hague, Chamber IVA, has reached the following decision in the case of

APPLIED RESEARCH SYSTEM ARS HOLDING N.V.,
established in Willemstad, Curacao, Dutch Antilles,
appellant, defendant in the conditional incidental appeal,
procureur: G.M.H. Hoogvliet LL.M.,
barristers: Ch. Gielen LL.M. and R.E. Ebbink LL.M. of Amsterdam.

versus

1. ORGANON INTERNATIONAL B.V.,
established in Oss, the Netherlands;

2. Diosynth,
established in Oss, the Netherlands;

3. Organon België B.V.,
established in Brussels, Belgium;

4. Organon GmbH,
established in München-Oberschliessheim, Germany;

5. Organon S.A.,
established in Saint-Denis, France;

6. Organon GmbH,
established in Vienna, Austria;

7. Organon Laboratories Limited,
established in Cambridge, United Kingdom;

8. Organon A.B.,
established in Västra Frölunda, Sweden;

9. Organon A.G.,
established in Pfaffikon SZ, Freienbach, Switzerland;

respondents, appellants in the conditional incidental appeal,
procureur: J.L.R.A. Huydecoper LL.M.

The proceedings

1. In the first instance ARS has claimed, in brief, from the Organon companies, under penalty of fines being imposed:

(i) that an infringement of European patent be prohibited, number 211894, in Belgium, France, Liechtenstein, Luxembourg, the Netherlands, Austria, the United Kingdom, Switzerland and Sweden, including in part, the application of the patented working methods and manufacture, use, supply and/or storage of patented product within the scope of clinical trials aimed at obtaining a product registration as a medicine in the countries concerned for the pharmaceutical preparations they use;

(ii) that a list of names and addresses of the hospitals, laboratories and other research centres where the clinical trials are held shall be made available to the counsel acting on behalf of ARS;

(iii) that the stock of recFSH and Org 3249 be destroyed, or at least be given to ARS, or to the Dutch Technical Research Institute (T.N.O.);

(iv) that - should the claim for the destruction of the product be granted - counsel for ARS be informed as to the place, date and time and the way in which said destruction has taken place.

2. In a ruling given on 6 July 1993, the President of the Court of The Hague refused to grant the provisions requested.

3. ARS has appealed against this ruling. In its statement of appeal it scheduled 9 complaints against the ruling and concluded with a request to have the ruling quashed and its claims awarded.

The memorandum in reply submitted by the Organon companies in their defence requested that the ruling be upheld. By submitting a complaint they instituted a conditional, incidental appeal with the conclusion that the ruling be upheld.

The memorandum in reply in the incidental appeal submitted by ARS disputed the complaint and concluded that the Organon companies in the incidental appeal be disallowed and the disputed consideration of the Judge be upheld.

4. Parties had their opinions heard in court at the session of 25 November 1993, pleaded by counsel. Counsel have appended their Pleading Notes together with the Exhibits belonging thereto to the documents of the proceedings.

Assessment of the Appeal

5. The Court assumes the following facts:

- ARS is the holder of the European patent number 211 894 the title of which reads: FSH. This abbreviation stands for "Follicle Stimulating Hormone". The patent was granted for Austria, Belgium, Switzerland, Germany, France, the United Kingdom, Liechtenstein, Luxembourg, the Netherlands and Sweden, on the understanding that for Austria, separate conclusions are formulated which contain divergences in respect of the conclusions granted for the remaining states. The priority date is 30 January 1985. The application which led to the patent was published on 4 March 1987. The publication of the granting of the patent took place on 24 March 1993.

- According to the description, the patent concerns the application of recombinant DNA techniques for the production of a human follicle stimulating hormone which is a hetero-polymeric protein hormone, and the beta sub-unit thereof.

- Diosynth has manufactured FSH, using recombinant DNA technology, hereinafter also called rFSH, of which the pharmaceutical preparation is known to the respondents as Org 32489. The DNA used by Diosynth codes for the beta sub-unit of this hormone.

- Respondent sub 1 and respondents 3 to 9 inclusive conduct clinical trials in connection with this FSH manufactured by Diosynth.

6. ARS states that the basis of its claims is that the manufacture of Org 32489 and the use thereof for clinical trials form infringements of the rights accruing to it in the countries for which the patent was granted arising out of its European patent.

Chance of revocation and nullity?

7. The President rejected the claims submitted by ARS. The Court has, inter due, judged that for an injunction against an infringement of rights there are no grounds because "a reasonable, at least not insignificant chance is present that the patent shall fail to survive the instituted nullity proceedings and the opposition proceedings to be instituted".

8. According to complaint VI and the notes on this, ARS has two objections to this assessment.
The first objection is that the President made use of an incorrect criterion. According to ARS, the President ought to have assumed the validity of the patent unless this would have been unreasonable.

The latter is the case if the party alleged to have infringed the rights of ARS proves that the examiner of the European Patent Office (EPO) failed to take into account "pertinent literature" or apparently made an error. In its opinion, such a judicial ruling should be "marginal". Where inventiveness is at stake, according to ARS, the claims ought to be refused "only if there is a convincing absence of the level of invention".

The second objection made by ARS is that if the assumption is made of the correctness of the criterion used by the President, then the President has judged that there is a reasonable, or at least not insignificant chance that the patent shall not survive the nullity and/or opposition proceedings in question.

9. In a number of rulings this Court has, in recent years, proceeded from the assumption that in preliminary relief proceedings there is, in principle no place for granting an injunction to infringement patent rights, if there is a (serious,) not negligible chance that the patent will be revoked or cancelled. The Court presently sees no reason for distancing itself from this assumption.

10. The Organon companies are of the opinion that such a chance exists. According to them, the patent held by ARS was granted incorrectly because the descriptions contained therein and the material did not meet the demands of novelty as set forth in Article 54 of the European Patent Convention (EPC), nor the demands of inventiveness as set forth in Article 56 EPC either on the date of submission or on the priority date - to which according to the Organon companies no claim may be made ARS has disputed these issues.

11. In the light of the complaint, the following questions arise:

a. Have the Organon companies made it plausible to assume that a serious, not negligible chance exists that the patent will be revoked or cancelled when novelty and level of inventiveness are assessed on the basis of the state of the art as this had been attained prior to the priority date; being 30 January 1985?

b. If the answer to question a is negative, have the Organon companies made it plausible to assume that such a chance exists if the assessment includes the so-called Beck abstract? Of course, answering this question is only of use if the Beck abstract is to be included among that which is the state of the art. Whether or not this is the case shall thus first need to be determined.

c. If the answer to question b is negative, is it plausible to assume that ARS may not make a claim to priority and that the Organon companies have made it

plausible to assume that the aforementioned chance does exist when an assessment is made of the novelty and level of inventiveness which assumes the state of the art for these techniques prior to the application date of the patent; being 30 January 1986?

re question a

12. The Court shall focus special attention on inventiveness and novelty:

inventiveness

13. The Organon companies take the point of view that the core of the problem with DNA recombinant technology lies in identifying and isolating the gene required. It may be assumed that they assume that the core of ARS' patent lies in identifying and isolating the DNA fragment which codes the beta sub-unit of FSH. ARS and the examiner of the European Patent Office take this view. In contrast to ARS and the European Patent Office, the Organon companies do not consider this to be inventive.

14. As a point of departure for their discourse, the Organon companies use the ruling given by the Opposition Department concerning the European patent number 148.605 of Kirin-Amgen, which ruling was given on 20 January 1993. In this ruling, among others, the question was dealt with as to whether or not, prior to the priority date of the patent in question, being 13 December 1983, the cloning and expression of a DNA sequence which codes for the protein erythropoletin (EPO) may be deemed to be the result of activities conducted by an inventor or inventors.

15. In the light of the assessment of the inventiveness issue, the Opposition Division posed two questions. The first read:

> would the skilled person (team) have reasonably expected that cloning and expressing of DNA sequence encoding EPO could provide a product biologically and immunologically equivalent to the natural product?

The Opposition Division stated that

> "a reasonable expectation of success" should not be confused with "the hope to succeed". Of course, at the priority date the skilled person hoped that recombinant DNA techniques could allow the provision of sufficient amounts of EPO (long-felt want). However, "a reasonable expectation of success" in the above context implies the prediction of a positive conclusion of a research endeavour within acceptable time limits on the basis of the progress

in the art.

Thereafter the Opposition Division considered:

> The Opposition Division does not agree with the statement made in P179 that "by late 1983 the art of cloning genes had progressed to the point that established procedures were known for screening DNA libraries with oligonucleotide probes based on amino acid sequences of a known protein to isolate a DNA sequence encoding the protein, and for transforming a host cell line with the isolated DNA in a manner that the transformed cell could express the protein" and that, therefore, "in December 1983 it was no longer inventive to simply clone and express a gene". The Opposition Division rather shares the view of Maniatis et al ... that "although molecular cloning seems straightforward on paper, it is more difficult to put into practice."
>
> With respect to EPO, in particular hEPO, there were generally recognised problems and uncertainties (rarity of the protein, difficulty of isolation, limited structural information available, lack of precise information on cell types producing it, impurity and heterogeneity of target cell populations, lack of any information about the EPO gene etc.

After which it concluded:

> The fact that the skilled person could at the priority date conceive a generalized approach for identifying, cloning and expressing an EPO gene on paper does not necessarily mean that he had a "reasonable expectation of success". In fact, he could not have had as he was entering into an unexplored area of a rather unpredictable technical field.

The second question read:

> could the skilled man attain such a result simply by following a series of early steps?

The Opposition Division answered this question in the negative.

16. According to the Organon companies, there are at least three aspects which may be indicated in which the material of ARS' patent differs substantially from those contained in the aforementioned ruling given by the Opposition Division.

(i) The structure of FSH was, with the exception of a small number of errors, known. FSH was available in large quantities for research. People also knew which cells in the human body produce FSH, namely pituitary

gland cells. Pituitary gland cell tissue was available for research.

(ii) Prior to 30 January 1985 publications about research conducted appeared in which reports were given as to successfully obtaining rFSH and about other and hence closely related human (and animal) fertility hormones. A skilled person could therefore assume with certainty that research conducted along the lines indicated in these early publications, would lead to success.

(iii) Between 13 December 1983 and 30 January 1985, the technique of screening using 'long' probes was generally known and had become customary.

17. Given these points of difference, the Organon companies are of the opinion that the patent held by ARS lacks inventiveness, or at least, that it cannot be denied that the chance that the patent shall be revoked is greater than negligible.

18. Are the differences so major that a serious, more than negligible chance exists that in opposition a ruling shall be given that identifying and isolating the DNA fragment which encodes for the beta sub-unit of FSH is not inventive, in contrast to identifying and isolating the DNA fragment which codes for EPO?

19. The following comments are made by the Court in connection with the differences put forward by Organon.

re (i):

It has been determined that the information about the amino acid sequence of the beta sub-unit of FSH was incomplete prior to the priority date and that it contained errors. The correct amino acid sequence was only made public in the application which led to ARS being granted the patent. It is true that the beta sub-unit of FSH was found in the pituitary gland cells but the Organon companies do not dispute that pituitary gland tissue is not widely available and degenerates rapidly, while the amount of the hormone which is found in pituitary gland tissue is small.

re (ii):

There are no publications - besides the Beck abstract to be discussed below - which have been entered into the proceedings which show that human rFSH has been successfully obtained. Neither have publications been entered into the proceedings which announce the DNA fragment encoding the beta sub-unit of FSH having been found in mammals related to mankind in terms of evolution.

re (iii):

Of course, the techniques used did improve during

the period in question. But, that the solution for the problem of identifying and isolating the DNA fragment being searched for became in fact simpler has not been made plausible.

20. In connection with answering the question posed in consideration 11 under a, the Court bears the following in mind:

a. Prior to the priority date it was theoretically possible to tread different paths in looking for the DNA fragment which codes for the beta sub-unit of FSH. That not all paths appear to lead to the desired goal has been put forward and not disputed by ARS. Furthermore, it appears from the remark made by Keene et al, who in 1989 wrote about successfully isolating the gene which codes for the beta sub-unit of FSH: "Our initial efforts to isolate the hFSH ß gene by screening this library with a bovine FSH ß cDNA probe were unsuccessful."

b. In 1988, the Jameson group published on a successful isolation of the DNA fragment which encodes for the beta sub-unit of human FSH.

c. In 1989, the Keene group published on a successful cloning of this gene.

d. In 1990, the Van Wezenbeek group published on a successful cloning of this gene.

21. On the grounds of that set forth in 19 and 20 the Court considers it likely that the Opposition Division shall consider and conclude in the same manner to its ruling in the case concerning patent number 148.605, fragments of which are cited in consideration 15 above. Given the considerations of the Opposition Division in the case concerning patent number 148.605, the Opposition Division, partly in the light of the circumstance that theoretically open roads in practice turn out to be cul-de-sacs, shall, it is expected, give greater weight to the remark made in the re-printed first edition in 1984 of the Maniatis Manual, which reads:

"Although molecular cloning seems straightforward on paper, it is more difficult to put into practice. Most protocols involve a large number of individual steps and a problem with any one of them can lead the experimenter into difficulty." and shall similarly do so to the remark made by Keene et al who reported in 1989 on the successful isolation of the human FSH ß gene and its cloning, which reads: "The study of FSH has been hindered by the lack of comparable systems." than it will do to the declarations submitted by the Organon companies which were made by Professor Goldbach and Dr. Hoijmakers and by Professor Schoenmakers, all of which date from 1993. The more time goes by since the relevant moment, the more

difficult it becomes to assess inventiveness, especially when, like in this case, technology has, in the meantime, also developed further.

novelty

22. The Organon companies state that the material of the patent held by ARS collides with the contents of older patent applications submitted by ARS itself, particularly with application WO 85/01958.

23. This application was submitted on 31 October 1984 and published on 9 May 1985. This application is hence, pursuant to article 54, section 3, juncto article 158, section 1 European Patent Treaty, part of the so-called fictitious state of the art. Given the core of the patent held by ARS lies in identifying and isolating the DNA fragment which codes for the beta sub-unit of FSH, and given this core - as the Organon companies also do not dispute - is not published in application WO 85/01958, it may not be deemed plausible that the patent held by ARS shall be revoked or cancelled due to a lack of novelty. The Court does not consider whether or not other aspects of the patent, particularly that set forth in conclusion 1, are new.

24. On the grounds of the foregoing the Court answers the questions formulated above in consideration 11 negatively.

re question b:

25. Given the point of view taken by ARS that in these proceedings it does not dispute that the Beck abstract was accessible prior to the priority date, this shall be assumed.

26. ARS contends that the publication of the Beck abstract may not be included in the state of the art because in the first place it is the result of apparent abuse in relation to Dr. Beck and in the second place because it took place during the time period set forth in Article 55, section 1 EPC.

27. In the provisional opinion of the Court, the publication ought to be deemed the result of evident abuse. In the words of the Appeals Chamber of the European Patent Office (1 June 1985, Official Journal EPO, 1987, p. 465) this is the case "if it emerged clearly and unquestionably that a third party had not been authorised to communicate to other persons the information received." For the time being, the Court considers this plausible on the grounds of the following passages in the letter dated 15 June 1993 from Dr. Beck to Mr. Ebbink:

"I herewith confirm that we as scientists at Integrated Genetics Inc. were very well made aware of the dangers of pre-publication by our patent agent...Since intellectual property like patents are the major asset of a young biotechnology company, it was a company rule that abstracts and papers had to be screened by the patent agent and that patent applications had to be filed before release of the publications.

...

With regard to the above case of human FSH (Poster presentation at the fifth annual congress for recombinant DNA research in San Francisco, February 3-6, 1985 and publication of the related abstracts: "Cloning and expression of DNAs coding for follicle stimulating hormone" by Beck A., V. Velluci and K. Curry in DNA 4/1.1985), I asked the editor of "DNA", Dr. W. Miller of San Francisco, when the "DNA" containing the Conference materials would be published. He assured me that this particular issue of DNA would not be available before the first day of the San Francisco Conference; February 3, 1985. Relying on his assurance, I made sure that the patent application was filed before this date; it was in fact filed on January 30, 1985."

28. With this, the answer is not yet forthcoming. When Article 55, section 1 EPC is taken literally, then it must be determined that the publication did not take place within six months prior to the submission of the European patent application; publication after all took place within those six months preceding the priority date.

Article 89 EPC determines that the right of precedence means that the priority date is deemed to be the date of submission for the European patent application for the application of, among others, Article 54, section 2 EPC. It would then seem logical, in the light of that set forth in Article 55 EPC, to explain the protection afforded to the applicant - Article 55, section 1 EPC, that should a right of precedence exist, then the period of six months shall be calculated from the priority date.

29. This explanation appears, doctrinally, to be disputed. There is barely any case law. The Swiss Federal Court has ruled that Article 55, section 1 EPC ought, on this point, to be taken literally (19 August 1991, GRUR Int. 1992, p. 293). Furthermore, there is a decision from the Opposition Division of the European Patent Office in which consideration is given to "the balance of arguments and the balance of convenience indicate that the priority date is the relevant date" (8 July 1991, EPOR 1992, p. 79). Given that considered above in 28, the Court agrees with the view held by the Opposition Division.

30. From the foregoing it follows that the Beck abstract, apart from in connection with Switzerland, should be excluded and that question b, apart from in connection with Switzerland, does not need to be answered.

31. Partly in connection with Switzerland, and for the remaining countries moreover, the Court considers the following.

Even if the Beck abstract was to be included in the relevant state of the art, there would still not be a serious, not negligible chance that the patent held by ARS shall be revoked or cancelled.

The Beck abstract discloses the fact that the DNA fragment which encodes for the beta sub-unit of human FSH had been identified and isolated. Furthermore, this abstract discloses the fact that the DNA fragment can be isolated from a genome collection with the aid of a 45-mer probe, and that the knowledge that had been acquired about the amino acid sequence had contained errors.

This did not disclose that which contains the core of the patented invention: the DNA sequence of the DNA fragment which encodes for the beta sub-unit of human FSH. The amino acid sequence of this unit could not be directly and unambiguously derived by the average skilled person and neither (implicitly) could this be read because the information for this is too unclear and incomplete. Hence real information about the probes used is lacking.

That knowledge of the Beck abstract would mean "a reasonable expectation of success" implying "the prediction of a positive conclusion of a research endeavour within acceptable time limits on the basis of the progress of the art" is not considered plausible, bearing in mind on the one hand that in the Beck abstract an indication is made that the amino acid sequence contained errors but not where these errors were, and on the other hand that in connection with the probes various theoretical possibilities remain open which in practice do not all appear to lead to the desired result.

These matters are demonstrated by the fact that both Jameson et al as well as Keene who did have access to the Beck abstract, only succeeded in 1988 and 1989 respectively, and only then with the assistance of the inventors of the invention protected by the patent held by ARS - in identifying and isolating the gene in question. It may not be said that the average skilled person at the beginning of 1985 with the assistance of knowledge about the Beck abstract was 'routinely' able to choose the right probes and construct them.

<u>answer to question b</u>

32. Solely in connection with Switzerland is the Beck abstract included among the state of the art. In spite of

this, it has not been deemed plausible, as in connection with other States is superfluously considered, that a serious, not insignificant chance exists that the patent shall be revoked or cancelled.

re c:

33. Question c is really two questions. The second question only needs to be answered if the point of view taken by the Organon companies that an appeal has incorrectly been made to priority is correct. This point of view taken by the Organon companies is rooted in the statement that the American patent application number 695.647 on which the priority of ARS' patent is based, contains the same subject-matter as the older American patent application number 548.228 which in turn established the priority of the application set forth above in WO 85/01958.

34. This statement has not been made plausible. ARS submitted the American patent application number 695.647. For the assessment of the statement made by the Organon companies the Court is of the opinion that it may make a comparison between the application WO 85/01958 on the one hand and the just cited American patent application on the other. The Court determines that the core of the invention embodied in the American application: identifying and isolating the DNA fragment which encodes for the beta sub-unit of FSH, was not published in WO 95/01958. From this it follows that the point of view taken by the Organon companies can not be shared. The Court does in that event not arrive at an answer to the second question under c.

conclusion in connection with complaint VI

35. From the foregoing it follows that complaint VI is sustained in part: the Organon companies have not made it plausible that a serious, not insignificant chance exists that the core of the patent held by ARS shall be revoked or cancelled.

Authorisation for continued use?

36. This does not mean that the ruling should be quashed. That depends, among other things, on the answer to the question whether the defence made by the Organon companies as to them being at liberty to continue using rFSH manufactured prior to the publication of the patent being granted - partly - has been justly honoured. Complaints II, III, IV and V concern this.

37. In connection with the Netherlands, the matter concerns the explanation of Article 30, section 4, second full sentence of the Dutch Patent Act. This Act determines that products manufactured prior to that time

may be, or may remain in use at the service of that company. Is there use at the service of that company if, as in this case, rFSH is made available to hospitals and research centres for clinical trials? The Court answers this question negatively. The stipulation contains an exception to Article 30, section 1 Dutch Patent Act, where the sole right of the holder of the patent is described. The nature thereof dictates it should be applied narrowly. Making rFSH available to third parties may not be deemed to be use at the service of that company even if this does take place under the condition that the Organon companies are to be informed as to the experiences gained with rFSH.

38. In connection with other countries, it can be derived from the declarations submitted by ARS, and which were not disputed by the Organon companies (Exhibits 99 up to and including 104 of ARS) that no comparable regulation with Article 30, section 1 second full sentence of the Dutch Patent Act exists in Belgium, Germany, the United Kingdom, France, Sweden and Switzerland. As to the situation in Liechtenstein, Luxembourg and Austria, information is lacking. As far as these countries are concerned: Even if a regulation should apply there the contents which are materially the same as in Article 30, section 4, second full sentence of the Dutch Patent Act - the Organon companies dispute that such a regulation does not exist - this would not benefit the Organon companies given that set forth in consideration 37.

39. That set forth in considerations 37 and 38 arises from the fact that complaints II, III - besides the no longer important question as to whether ARS has been able to disprove the factual basis of the defence put forward by the Organon companies -, IV and V are upheld.

Research exemption

40. Whether the ruling can be upheld also depends on the answer to the question as to whether the defence put forward by the Organon companies succeeds in that they should be allowed to appeal to the so-called research exemption. The President has not honoured this defence. The Organon companies have not abandoned this defence in appeal as also appears in part from the sole complaint in the conditional incidental appeal.

41. ARS has submitted a report from Professor Dukes. At the request of counsel for ARS, advice was provided in connection with the actions of the Organon companies concerning the clinical trials or in connection with rFSH. In this report Dukes writes on the basis of a study of material, some of which came from Organon itself, that the research conducted by Organon may be deemed to be 'an exceptionally large and costly research programme' in

which no less than 19 researchers are deployed in 10 European countries. He further writes having understood that the number has grown to at least 30 research centres. He concluded that the research 'was primarily meant to form a basis for the international registration and commercial promotion of the product.'

42. The Organon companies have not contradicted Dukes statements as to the size of the research programme. They state that trials of the new substance are still at the forefront. Their clinical trials are aimed at establishing whether or not the inventions can be put to practical use and whether or not the inventions can be further developed.

43. Given that the Organon companies have not made it sufficiently plausible that it is necessary for the research they state they conduct take place on the scale as described by Dukes, the Court hence assumes that the clinical trials conducted by the Organon companies are to a considerable extent intended to attain the registration of the medicine they have developed.

44. In connection with the Netherlands, the Supreme Court considered in its ruling of 11 December 1992 (NJ 1993, 735) under 3.3.3. that Article 30, section 3 of the Dutch Patent Act - the stipulation on the research exemption in the Dutch Patent Act - is a "stipulation which is to be interpreted restrictively" "pursuant to which actions "serving research purposes of that which is patented" which in principle lead to an infringement of patent rights, are permissible if and inasmuch this is justified by the goal of the research. That is solely the case if the person or persons conducting the research alleges and when necessary proves that his research is solely of a purely scientific nature or that it is solely aimed at fulfilling a purpose as set forth in the patent law, such as further developing technology." Under 3.3.2. the Supreme Court had mentioned examples of such a goal: "investigating whether the invention can be put into practice or be developed further."

45. The Court is of the opinion that the research conducted by the Organon companies in the Netherlands, based on declarations submitted by the Organon companies from Dr. Fauser and Dr. Coelingh Bennink, primarily seems to concern the <u>application</u> of that which is patented, therefore research <u>with</u> that which is patented, and hence does not meet the criterion of the Supreme Court in order to fall under the scope of the research exemption.

46. Considering that the stipulation on the research exemption in the Dutch Patent Act is in conformity with the stipulation in the Community Patent Convention, and furthermore, that the States which are signatories to that Convention have promised to amend their national

legislation to conform with this Convention, it may be assumed that the national laws of those States contain stipulations like Article 30, section 3 of the Dutch Patent Act and that the actions of the Organon companies in these States shall therefore also not fall within the scope of the research exemption. This is confirmed by the declarations submitted by ARS made by lawyers in Germany, the United Kingdom and France as well as in the ruling of the Dusseldorf Landgericht given on 26 May 1993 and the Dusseldorf Oberlandesgericht ruling of 9 July 1992. From letters submitted by ARS from lawyers from Sweden and Switzerland it may be derived that the clinical trials of the Organon companies in these countries may also not be conducted without the permission of the holder of the patent. That the legal regulations in Liechtenstein, Luxembourg and Austria deviate in detail from this, is not obvious given the international character of the patent law and the harmonisation and unification of patent laws in Europe nor was this put forward by the Organon companies.

Considering the interests at stake

47. Furthermore, the Organon companies have put forward that a weighing up of the interests of the parties should lead to the requested prohibition of the infringements being denied.

48. It needs to be firmly stated that a holder of a patent, when his rights are infringed, certainly has an interest in having such an infringement halted. Only in exceptional cases an injunction shall be refrained from.

49. Are the interests of the Organon companies so great that the interest of ARS with an injunction must be relegated?

50. The interests which the Organon companies state they have are irrevocably tied to their expectation that the patent held by ARS shall be revoked: They put forward that they shall experience a backlog of many years if a prohibition is granted and the patent is then revoked after many years.

51. In the foregoing an assessment is made that the Court does not share the expectation held by the Organon companies. Should it share this opinion then it would not consider the claim against the infringement admissible.

52. The Organon companies have furthermore put forward that they will sustain considerable but difficult to determine tangible and intangible damage if a prohibition is granted and the patent is revoked many years later.

53. If the patent held by ARS is indeed revoked, then of course the Organon companies will sustain damage. This in

itself does not form grounds for refraining from granting an injunction against the infringement. In any case, that ground is lacking given the fact that ARS has offered to provide security.

Conclusion

54. From the foregoing it follows that the first instance ruling cannot be upheld. The injunction requested against the infringement of the European patent is admissible in the Netherlands. The injunction against the infringement of this patent in the other countries for which it is applicable is also admissible. That such an injunction in those States may not be attained using provisional measures does not detract from this as it may be assumed that the actions of the Organon companies form infringements in those States of the rights retained by ARS and that - in any case in a full legal action - could be prohibited. The Court shall require ARS to provide security when granting the prohibition with the stipulation that this obligation shall terminate when the Opposition Division of the European Patent Office arrives at the assessment that the core of the patent held by ARS as described in conclusion 6 for Austria and conclusion 5 for the other States in question, is not revoked.

55. In connection with the claim as described in consideration 1 under (ii), the Court is of the opinion that this is admissible inasmuch as it concerns the Netherlands. This concerns a suitable measure deployed to check the prohibition of the infringement. The Court has not been informed as to the question concerning whether or not this measure is admissible in the other States and considers that in preliminary relief proceedings it is not bound to investigate this matter officially. For the other States this measure shall therefore be denied.

56. That claimed as described in consideration 1 under (iii) shall be denied by the Court because the interest of ARS in this measure in addition to the prohibition granted has not be made clear. The result of this is that for granting that claimed as described in consideration 1 under (iv) there is no place.

57. As the parties which are, for the most part, found to be in the wrong, the Organon companies shall be required to pay the costs of the proceedings in the first instance as well as the costs of the appeal.

58. All this leads to the following decision.

Decision

The Court of Appeal in the incidental appeal:

1. confirms the judgment in first instance;

in the principal appeal:

2. annuls the judgment in first instance;

and in doing de novo justice:

3. forbids each of the defendants, after thirty days following service of this judgment, from directly or indirectly infringing European patent no. 211894 in Belgium, Germany, France, Liechtenstein, Luxembourg, the Netherlands, Austria, the UK, Switzerland and Sweden, which also includes application of the patented process and manufacture, use, delivery and/or keeping in stock of the patented product in the course of clinical trials directed at obtaining a product registration as a pharmaceutical product in the countries concerned of a pharmaceutical preparation to be marketed by Organon c.s.;

4. orders each of the defendants, within ten days after service of this judgment, to deliver to ARS's lawyers for purposes of control a complete list of names and addresses of hospitals, laboratories, and other research centres where the clinical trials referred to in provision 3 are performed in the Netherlands.

5. orders each of the defendants to pay an immediately due and payable penal sum of Dfl. 100,000 to ARS for each time the relevant defendant breaches one or more of the provisions of 3 and 4 of this holding and for each day that one or more of the defendant(s) concerned does not duly perform one or more of the provisions of 3 and 4 of this holding;

6. declares this judgment to be enforceable notwithstanding appeal under the condition that ARS puts up security in favour of Organon c.s. by way of a bank guarantee in the amount of Dfl. 5,000,000, on the understanding that this duty to put up security shall end in the event the Opposition Division of the European Patent Office reaches the decision that the core of ARS' patent as described in claim 6 for Austria and claim 5 for the other designated states, will not be revoked;

7. denies what was claimed further or differently;

8. orders Organon c.s. to pay the costs incurred in first instance and in the principal and incidental appeal, up to this decision on the side of ARS estimated at Dfl. 20,000.

This judgment is rendered by Messrs. Brinkhof, Hamaker, and Ir. Grootoonk, and was pronounced at the public court session of 3 February 1994, in the presence of the court clerk.

(Signature) (Signature)