

IN THE NAME OF THE QUEEN!

Docket number: KG 96/127  
date of judgment: March 25, 1996

The President of the District Court of The Hague

Judgment in the interim injunction proceedings in the case with docket number KG 96/126 of:

**AMERSHAM INTERNATIONAL plc.**, a corporation incorporated under foreign law, established in Amersham, Buckinghamshire, United Kingdom, plaintiff,  
attorney of record: C.J.J.C. van Nispen, LL.M.

versus:

1. **ICN Pharmaceuticals Holland B.V.**, a close corporation established in Zoetermeer,
2. **ICN Biomedicals B.V.**, a close corporation established in Amsterdam,
3. **ICN Pharmaceuticals Inc.**, a corporation incorporated under foreign law, established in Costa Mesa, California, United States of America,
4. **ICN Biomedicals Inc.**, a corporation incorporated under foreign law, established in Costa Mesa, California, United States of America,
5. **Labor-Partner Laborbedarf Handelsges. mbH**, a corporation incorporated under foreign law, established in-Vienna, Austria,
6. **ICN Pharmaceuticals NV**, a corporation incorporated under foreign law, established in Asse-Relegem, Belgium,
7. **ICN Biomedicals NV**, a corporation incorporated under foreign law, also trading under the name **ICN Biomedicals Benelux**, established in Asse-Relegem, Belgium,
8. **Dr. Rudolf Streuli AG Zürich**, a corporation incorporated under foreign law, established in Zürich, Switzerland,
9. **Life Science Danmark ApS**, a corporation incorporated under foreign law, established in Fredensborg, Denmark,
10. **ICN Pharmaceuticals GmbH**, a corporation incorporated under foreign law, established in Meckenheim, Federal Republic of Germany,
11. **ICN Biomedicals GmbH**, a corporation incorporated under foreign law, established in Meckenheim, Federal Republic of Germany,
12. **ICN Hubber S.A.**, a corporation incorporated under foreign law, established in Barcelona, Spain,
13. **ICN Ibérica S.A.**, a corporation incorporated under foreign law, established in Barcelona, Spain,
14. **ICN Pharmaceuticals France**, a corporation incorporated under foreign law, established in Orsay Cedex, France,
15. **ICN Biomedicals France S.A.R.L.**, a corporation incorporated under foreign law, established in Orsay Cedex, France,
16. **ICN Pharmaceuticals Ltd.**, a corporation incorporated under foreign law, established in Thame, Oxfordshire, United Kingdom,

17. **ICN Biomedicals Ltd.**, a corporation incorporated under foreign law, established in Thame, Oxfordshire, United Kingdom,

18. **ICN Pharmaceuticals S.r.L.**, a corporation incorporated under foreign law, established in Opera, Italy,

19. **ICN Biomedicals S.r.L.**, a corporation incorporated under foreign law, established in Opera, Italy, and

20. **Chemicon AB**, a corporation incorporated under foreign law, established in Skärholmen, Sweden,

defendants

attorney of record: R. Laret, LL.M.

attorney: R.E. Ebbink, LL.M., in Amsterdam

### Course of the proceedings

Plaintiff, hereinafter also referred to as: Amersham, summoned defendants before the Court in interim injunction proceedings of February 14, 1996.

All defendants (jointly hereinafter also, in singular: ICN), appeared in Court. The defendants nos 3 to and including 9, 11, 13 to and including 17, 19 and 20, however, solely to dispute the competence of the Court.

Mr. van Nispen submitted a statement of complaint in writing, together with exhibits. The proceedings were then stayed until the date and time previously set thereto: March 20, 1996 at 09.30 hrs. On February 28, 1996, Mr. Ebbink sent in a statement of answer in writing, together with exhibits.

Next, Mr. van Nispen submitted additional exhibits, as did Mr. Ebbink.

The withdrawal of interim injunction proceedings with respect to the same patent which were before court simultaneously, led the parties to submit a number of exhibits that had only been submitted in these parallel proceedings. Both parties had their standpoint explained by their attorneys during the session of March 20, 1996. Amersham by its attorney of record, ICN by its attorney. Counsel for both parties were assisted by the parties' patent attorneys. The documents of the case include submitted written summaries of the arguments.

### Grounds for the judgment

#### **In the original complaint and in counterclaim**

1. In these proceedings the following premises shall be accepted.

1.1 Amersham is holder of European patent 594 837 B1, which it was officially granted with priority as from April 30, 1992, on its application of April 27, 1993, for 'radiolabelled compound formulations.'

1.2 The patent was granted for Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, the United Kingdom, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, The Netherlands,

Portugal and Sweden. However, Amersham relinquished protection of its patent in the countries Luxembourg, Greece, Monaco and Portugal.

1.3 In the original English text, the claims which are deemed of importance for the matter in hand read as follows:

*'2. A composition comprising a solution of a colourless organic compound labelled with a  $\beta$ -emitting radionuclide and a dye, said composition contained in a closed vessel adapted for storage and shipment.*

*5. A composition as claimed in claim 2, further comprising a stabiliser.*

*8. A composition as claimed in any one of the claims 1 to 7, wherein the radiolabel is selected from 37-P, 35-S, 33-P, 3-H and 14-C.'*

1.4 Under the brand name 'Redivue', Amersham brings preparations on the market which are protected by the patent.

Under the brand name 'Isoblué', ICN brings preparations on the market which fall within the scope of protection of Amersham's patent as granted.

1.5 E.I. Du Pont de Nemours and Company of Wilmington, Delaware, USA, filed an opposition to Amersham's patent, at the European Patent Office in Munich on February 28, 1996. This opposition, however, was subsequently withdrawn.

2. On the grounds of its exclusive right as patentee, Amersham claims - in summary - a ban on ICN to infringe the patent in all countries in which the patent has validity, and that ICN be ordered to recall all infringing preparations which are supplied and to destroy the returned preparations and to supply Amersham with a list of purchasers of infringing preparations, stating the date and the quantity of each transaction, all this under pain of payment of penalties.
3. ICN sets up a motivated defense.
4. *Ex officio* it is considered first of all that a European patent is involved which the granting was published after April 1, 1995, so that the Patent Act of 1995 applies.
5. The dispute between the parties furthermore requires the following questions to be answered:
  - A) Is the Court competent to take cognizance of the claims against all the defendants?

- B) If so, does the Court have jurisdiction to issue injunctions which have effect outside The Netherlands?
- C) Do all defendants infringe Amersham's patent?
- D) Can it be said that Amersham abuses a dominant position in the sense of article 86 of the EC-treaty?
- E) Can it be said that there is a serious possibility which should not be ignored, that the patent shall be revoked, or, as the case may be, declared invalid?
- F) Are all parts of the summons allowable everywhere?
- G) May the penalty payments claimed be deemed excessive?
- H) Does an injunction have to be accompanied by the providing of a security by Amersham?

**ad A: competence of the Court.**

6. It must be put first that the Court is competent to take cognizance of the claims against the defendants established in The Netherlands. Taking this into consideration, the Court is also competent to take cognizance of claims against the other defendants, on the grounds of the provisions of article 6, sub 1 EEX and article 6 sub 1 EVEX respectively, or at any rate article 126-7 of the Dutch Code of Civil Procedure.

7. ICN disputed this, referring to the ruling of the Court of Justice of the European Union dated September 27, 1988, NJ 1990, 425 (JCS), in the case of *Kalfelis v. Schröder*. In the opinion of ICN it cannot be said here that - as dictated by this ruling - a proper administration of justice requires simultaneous processing and adjudication, in order to avoid inconsistent judgments from being passed, in the event of separate adjudication. In this respect, ICN argued that there cannot be judgments which may be inconsistent, because the infringements of which Amersham accuses the defendants nos 3 to 20 concern different patents from the Dutch one, which the Dutch defendants allegedly infringe. (These concern, after all, an Austrian, Belgian, Swiss, Danish, German, Spanish, French, British, Italian and Swedish patent respectively.)

8. This argument is rejected  
What is concerned here is a European patent which has to be interpreted in the same way in all designated countries, pursuant to article 69 of the European Patent Convention (EPC) and the protocol forming part thereof. A situation whereby in one designated country infringement would be deemed to take place but not in another country, would definitely be in conflict therewith. Even if ICN's claim is correct that from a formal point of view there may be

said to be separate patents, this would not alter the fact of materially conflicting judgments.

Moreover - which because it is not contested is accepted as fact - all defendant in question save four belong to the same corporation, which underlines the relationship which exists between these matters.

9. It should not be forgotten that in the grounds for judgment nos. 11 and 12 of its ruling in the case of *Kalfelis v. Schröder*, the Court of Justice clearly made a connection between the required relationship to be set when applying article 6 paragraph 1 EEX on the one hand, and the concept of relationship as formulated in article 22 EEX on the other. The reason why this is important is that concerning the concept of relationship of article 22 EEX (which may therefore also be applied with article 6 paragraph 12 of the EEX) the Court of Justice, in its ruling of December 6, 1994 C-406/92, NJ 1995/659 Tetry, considered that this concept should be interpreted independent from the treaty, and it goes on to say (ground for judgment no. 53):

'In order to ensure a proper administration of justice, this interpretation should be broad and encompass all incidents which may contain the risk of conflicting judgments, even if these judgments may be enforced individually and do the legal consequences thereof not exclude one and another.'

The Tetry-case concerned different owners, who had cargo shipped by the same ship and under the same conditions under separate (though identical) agreements. Now that sufficient relationship was accepted in that case, it is difficult to see why in the present claims, which concern alleged infringements of separate though identical European patents, there is insufficient relationship to justify an appeal to article 6 paragraph 1 EEX.

10. Concerning the competence of the Court on the grounds of the provisions of article 6 under 1 of the EEX, a different view may be taken - cf. also ground for judgment no. 9 of the ruling in *Kalfelis/Schröder* - if the claim against some of the defendants was lodged with the sole object to pull these defendants away from the court in the country in which they have their place or residence. In the present case there is no proof for that whatsoever.

11. Now that it is established that the Court is competent by virtue of the provisions of the conventions and laws referred to above, it may be left unanswered whether there is also competence by virtue of the provisions of article 5 and 24 of EEX/EVEX respectively, as well as the question whether competence which would solely be based on these articles would have the same scope as the competence which - as is the case in article 6 paragraph 1 EEX/EVEX - is based in principle on the place of residence of the defendant(s).

12. For this reason, the appeal ICN makes to the ruling of the European Court of Justice in the case of *Shevill v. Presse Alliance* of March 7, 1995, no. C-68/93 has to fail as well.

In this ruling<sup>1</sup>, after all, only the competence by virtue of art. 5 under 3 EEX is being dealt with, and not the competence pursuant to the provisions of article 6 under 1 EEX, which - just as the principal rule of article 2 EEX - is based on the place of residence of (one of) the defendant(s).

Though it may be admitted to ICN that from this ruling it may be inferred that exceptions to the principal rule - the competence of the *forum rei* - should be restrictively interpreted, this may not lead in the present matter to presume the incompetence of the Court. After all, in the case of competence based on article 6 under 1 EEX/EVEX, there may actually be said to be a *forum rei*, at any rate with respect to at least one<sup>2</sup> of the defendants.

For now there do not appear to be any compelling grounds to interpret the article of the convention more restrictively in a case like this than would correspond with its phrasing and meaning.

On the contrary: If article 6 under 1 EEX would be interpreted and applied a restrictively as ICN proposes, it would deprive virtually all meaning thereof in cases of industrial property (of which the rights often only have territorial scope). An interpretation which to a large extent deprives a provision from its intended effect, should not be accepted as correct too hastily.

13. Pursuant to the provisions of article 6 paragraph 1 EEX, the Court is therefore competent to take cognizance of the claims against the defendants 7, and 9 to and including 19.

Pursuant to the corresponding article from the EVEX (Lugano Treaty) competence is, *mutatis mutandis*, due to the Court with respect of the defendants 8 and 20.

Finally, with respect to the other defendants (3, 4 and 5), the Court is competent by virtue of the provisions of art. 126-7 Code of Civil Procedure.

14. It must therefore be concluded that the appeal to incompetence by the defendants 3 to and including 20 is rejected.

15. ICN had it further argued that the Court would in any case have to declare itself incompetent with respect to the defendants 19 and 20. According to ICN, these defendants, Italian and Swedish respectively, received the writ of summons (as a consequence of a mix up of the two writs by the process server when sending them out) in Swedish and Italian respectively, language they do not understand.

16. This argument has to be rejected as well. First of all, such omission could only have effect on the validity of the summons; it is not clear how this could influence the competence of the Court. Now that both defendants apparently have not been damaged in their defense - which has been conducted centrally for all the defendants - any mistakes in the summons have been undone by

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<sup>1</sup> Aside from the question whether the decision in this case may also be applicable for concerning alleged infringements of patents, or a ban thereof.

<sup>2</sup> And in this case even two.

their appearance in Court, so that this matter need not be investigated further.

17. Apart from the question regarding competence, there is the question, as considered, whether a ban has to be pronounced against all defendants, or whether a ban to be pronounced has to extend to all designated countries.

**ad B: does the Court have jurisdiction to issue injunctions that have effect outside The Netherlands?**

18. The principal rule - formulated in article 296, book 3 of the Dutch Civil Code, and in the ruling of the High Court dated November 24, 1989 (NJ 1992, 404, 'Lincoln v. Interlas') is that, unless the law, the nature of the obligation, or a legal act provides differently, he who is under an obligation towards a third person to give, to do or to refrain from doing something, shall be ordered by the Court to do so, if so claimed by the party entitled.

In general, so says the ruling, there is no reason to assume that there is no ground for such a judgment when it concerns an obligation - which may also be an obligation under foreign law - which has to be complied with outside The Netherlands.

19. ICN complains, or so the Court understands, that the High Court has not further theoretically supported its standpoint on this subject.

For now it would seem that for a correct application of Netherlands law such theoretical foundation is not required. The rule as given in the ruling is clear: Under Netherlands law, the Dutch Court assigns to the plaintiff what the plaintiff is entitled to (if necessary pursuant to foreign law). There does not seem to be proper grounds to differentiate thereby between those incidents wherein a defendant is obliged to a positive performance - which he may then be ordered to perform - or to refrain from doing something - which he may also be ordered to do. In other words: why should the Court be able to order a foreign defendant to do - or not do - something and not be able to forbid him to do something?

Whatever the case may be: the principal rule as given by the High Court is clear and must be applied by a lower Court.

**ad C: do all defendants infringe the patent?**

20. ICN's counsel argued that the defendants 10, 12 and 18 ceased to exist as per last year, or at least under the given names.

21. This defense, which is in no other way substantiated, must be disregarded, now that the names of these defendants appear on the advertising brochure submitted by Amersham as exhibit 13 as well as on the back of the ICN catalogue which Amersham showed at the session.

22. Furthermore, ICN argued that the chemicals under attack are manufactured in the United States by defendant no. 4. This defendant supplies them FOB to defendant no 5, to defendant no. 7, to defendant no. 8 and to defendant no. 17. Defendant no. 7 moreover acts as European warehouse and

reseller and supplies FOB to the defendants 2, 9, 11, 15, 19 and 20 and sometimes also to defendant no 17.

The 'pharmaceutical' defendants (nos 1, 3, 6, 13, 14, 16 and 18) are not involved in any alleged infringing activities whatsoever, according to ICN. The defendant no. 3 does offer in Europe, but exclusively for sale and shipment to the United States. Already in America the property rights and risk pass to the buyer.

The remaining distributors only operate in the country in which they are established, with the exception perhaps of the Belgian defendant no.7.

23. ICN had it argued that at any rate the defendants which have 'pharmaceutical' in their name, are not involved in bringing the Isoblu preparations on the market.

24. This assertion has to be rejected as well: now that their names - even pre-eminently - appear on the previously mentioned advertising brochure, these defendants are at any rate guilty of offering the isoblu preparations in the countries in which the folder is distributed.

It is not contradicted that this takes place in all designated countries.

25. ICN furthermore argued that solely offering is not something which is only reserved for the patentee, if this offering is not actually followed by a sale in a country in which the patent has validity. This defense, however, is rejected:

- For The Netherlands applies that offering in The Netherlands is temporarily judged to fall under the exclusive right of the patentee, as formulated in article 53, paragraph 1a of the Patent Act 1995, if this offering takes place, among others, for the professional use of the offered product.

- Pursuant to the provisions of §9 Patentgesetz, offering a patented product falls under the exclusive right of the patentee in Germany as well. Also under German law is offering by means of advertisements or catalogues distributed in Germany temporarily judged to constitute an infringement of the patent. (Cf. Benkard, Patentgesetz, 1993, §9, margin no. 11 and 12 and the case law mentioned therein.)

- For France applies that art. L 613-3 of the Code de la Propriété Intellectuelle under a) also mentions 'l'offre' as belonging to the exclusive exploitation rights of the patentee. Distributing a catalogue in France may under French law be judged to be an infringement: cf. Mathély, Le Nouveau Droit Français des Brevets d'Invention (1991), page 429, as well as Chavanne and Burst, Droit de la Propriété Industrielle, 1993, margin number 415 and the case law mentioned therein.

- Where the United Kingdom is concerned, section 60(1) of the Patent Act 1977 designates as an infringement of a patent he who 'makes, disposes of offers to dispose of, uses or imports the product...' Cf. also Cornish, Intellectual Property (1989), no. 6-009.

That the sole offering would not be an infringement of the patent in the other designated countries should, in view of the above and in view of the fact that



offering is also mentioned in article 25 of the Community patent convention, not be deemed likely and neither has it been made plausible by ICN.

**ad D** has Amersham abused its dominant position in the sense of article 86 EC Treaty?

26. This ICN assertion already has to fail on the fact that Amersham's statement that it is prepared to grant a license to every candidate who desires one, went uncontested. It has already granted such license to a third large player (apart from the parties) on the market of radioactive labelled nucleotides and aminoacids: Du Pont de Nemours.

Aside from whether it may be deemed to be obligated to grant such license, it may, in view of this willingness, at least not be maintained that Amersham abused its dominant position (if it has one).

**ad E** can it be said that there is a serious possibility which should not be ignored, that the patent shall be revoked, or be declared invalid?

27. ICN argued that the patent must be revoked, because:

- i) There may be said to have been an unauthorized widening of the subject of the patent;
- ii) the description is insufficiently clear in order to allow a person skilled in the art to repeat the patent;
- iii) the basic claims, 2 and 5 in particular, are not new, or
- iv) are not inventive.

28. The Court is of the opinion that there are grounds to investigate all this in first instance for claim 2, because this claim has the widest scope. Should it appear very likely that claim 2 shall be held up, claim 5 shall not have to be investigated anymore in these proceedings. On the other hand, it is an established fact between the parties that should claim 2 go under, claim 5 shall be to no avail to Amersham.

**29 ad i): unauthorized widening of claim 2?**

29.1 According to ICN, unauthorized widening of claim 2 allegedly has taken place because it includes the words '*contained in a closed vessel adapted for storage and shipment*', which did not occur in the claim of the original application.

29.2 For now this is not viewed as an unauthorized widening in the sense of article 123-2 EPC. Unlike as asserted by ICN, this addition does not constitute an extra, inventive stage, but only a demarcation of the state of the art. This state of the art, after all, already included the mixing of  $\beta$ -labelled preparations with a dye shortly before use. Amersham wanted to set its invention apart from this, in which that dye is already added by the manufacturer of the  $\beta$ -labelled preparation, after which the preparation may be shipped and stored in liquid form. A foundation for this marking off could be found in the original application, which, after

all, states on page 2, lines 4 and further: *'It would be a significant advantage, both to the shipper and to the customer, if the radiolabelled nucleotides could be supplied at ambient temperature and stored in unfrozen form'* and in the lines 30 and further: *'The invention is mainly concerned with radiolabelled organic compounds which are supplied, shipped and stored in solution...'*

**30. ad ii: claim 2 not repeatable?**

30.1 ICN is of the opinion that claim 2 is not repeatable because not every dye shall meet the requirements and the patent - or so does the Court interpret the assertion - does not indicate which dyes are and which dyes are not suitable.

30.2 This same objection was initially also made by the Examiner of the European Patent Office (EPO) during the granting procedure (cf. missive of June 3, 1994, page 3 ad (a3). In a letter dated August 18, 1994 Amersham's patent attorney replied that he would not deem it fair to restrict the scope of protection - in accordance with the Examiner's proposition - to the dyes mentioned in the application. He continues: *'Clearly described in the Examples are ways in which dyes can be tested for their efficacy in the compositions according to the invention. Thus, the specification not only tells the reader certain dyes that will work, but also, it contains instructions which would enable a person skilled in the art to determine whether or not any other specific dye is suitable. The experimentation necessary is not unduly lengthy or complicated'*. The Examiner resigned himself to this standpoint and ICN has not indicated why this would have been unjustified. This defense is therefore disregarded.

**31. ad iii: claim 2 not new?**

31.1 By means of a report of one of its patent attorneys, ICN has drawn the attention to the following publications, in which mention has already been made of a colourless solution of a substance which emits  $\beta$ -particles (hereinafter referred to as  $\beta$ -emitter) together with a dye in a closed vessel:

- a) Chem Abstract 111:934636
- b) an ICN catalogue (page 45)

31.2 Neither of these publications is deemed damaging to the novelty claim by the Court:

- a) because, as the patent attorney himself remarks as well, no mention is made therein of a closed vessel
- and
- b) because in this catalogue reference is made of a red ink with 14-C, which liquid cannot be said to be a 'colourless organic compound'. Nowhere in the publication does it appear that this ink is made from such colourless solution.

31.3 During the session ICN appealed to grounds for invalidity as contained in the opposition document as submitted by E.I. Du Pont de Nemours, which it produced.

Concerning the novelty of claim 2 these are the following publications:

- c) Abraham, G.E. (1974) Acta Endocrinologica,
- d) Abraham, G.E. et al. (1977) Handbook of Radioimmunoassay
- e) Maxam, A.M. & Gilbert, W. (1977) proc. nat. Acad. Sci. U.S.A.
- f) NEN Catalogue 1976, page 121,
- g) The Ferritin RIA kit instruction manual, 1982,
- h) The PAP RIA kit instruction manual, 1990,
- i) Williams et al. BioTechniques, Vol. 4, No. 2, pp. 138-147, 1986,
- j) The 1991 Amersham catalogue.

31.4 For now, c), d), and e) are not deemed damaging to the novelty claim, because in these publications reference is made only to the adding of dye just before using the labelled substances.

31.5 Publication i) can not be damaging to the novelty claim, if only because reference is made therein of freeze-dried preparations, and therefore not of what a person skilled in the art shall understand to be 'a solution' as referred to in claim 2.

31.6 The publications f), g) and h) refer to dyed preparations which are radioactively labelled with 125-I. ICN deems these publications damaging to the novelty claim because in its opinion, 125-I is a  $\beta$ -emitter. In this respect, ICN refers to publication d (page 5), a PCT application of Amersham WO 9426413 (page 7, ll. 18-20) as well as to a letter from the granting file from the Examiner, dated June 3, 1994 (page 1). Amersham has disputed that 125-I is a  $\beta$ -emitter, and in order to corroborate this, has produced a Table of Isotopes of Lederer and Shirley, in which no mention is made that the 125-I emits  $\beta$ -particles, as well as some pages from 'Radioactive isotopes' of Whitehouse and Putman, in which it may be read that Auger-electrons, which apparently are emitted by 125-I, shall not readily be mistaken for  $\beta$ -particles, because they contain a lower energy.

31.7 It may be admitted to ICN that in publication d) it is stated:

*'A second class of  $\gamma$ -emitters that also emit  $\beta$ -particles and are used in RIA consists of 125-I, 131-I and 60.Co.'*

Furthermore it may be admitted to ICN that in the PCT application of Amersham, no. WO 94/26413 it is stated on page 7, ll 18-20:

*'Ideally, the isotope of the radiolabel should have a relatively low energy beta-emission, for example tritium, or iodine-125 auger electrons,' and that in the said letter the Examiner writes: '... with beta-emitting 35-S, 3-H, 32-P, 33-P, 14-C, 125-I or 131-I...'*

131.8 The publications enlisted by the parties are not unambiguous. The point, however, is not so much what may be found in this or that

publication, but what the average person skilled in the art who tests the patent understands a  $\beta$ -emitter to be, in the context of the patent.

As a person skilled in the art should, for the time being, be regarded the organo-chemical engineer who is professionally involved in research, whereby use is made of radioactive labelled molecules.

On the basis of the publications produced by Amersham, it does not seem unlikely that 125-I (whatever the pertinence may be of the question whether there are also particles emitted which may be labelled  $\beta$ -particles) shall be used by a person skilled in the art in its capacity of  $\gamma$ -emitter and that consequently, a person skilled in the art would, normally speaking, not include under the general term ' $\beta$ -emitter' 125-I.

31.9 In view, however, of the uncertainty which does exist in this respect and also in view of the far-reaching nature of the provisions claimed by Amersham, the Court needs expert advice before deciding on this matter. Therefore, the Court shall ask the Bureau voor de Industriële Eigendom to advise, as laid down in article 87 Patent Act 1995.

### 32. ad iv: may claim 2 be deemed inventive?

32.1 According to Amersham, the inventiveness of the invention lies in the fact that at the time of the priority date, persons skilled in the art were prejudiced against adding a dye to solutions marked with  $\beta$ -emitters, other than just before the application. Persons skilled in the art were said to fear that with  $\beta$ -emitters, unlike  $\gamma$ -emitters, the dyes would disintegrate as a consequence of the radiation they underwent and that these disintegration products would lead to undesired effects in laboratory tests.

For this reason, before the priority date nobody dared adding the dyes already prior to the shipment.

32.2 ICN contested the existence of this prejudice.

32.3 Taking into account the fact that it was known to add a dye to radioactive labelled reagents and also that it was part of the state of the art to dye  $\beta$ -labelled reagents thus immediately before applying these reagents, it does, for now, not seem inventive to dye  $\beta$ -labelled reagents - whether or not equipped with stabilising substances which were already known at the time - already in the plant, if there was no prejudice as referred to. It shall therefore have to be investigated whether such prejudice existed on the priority date.

32.4 In this respect, Amersham produced a statement by professor P.N. Goodfellow of the University of Cambridge (UK), in which it is stated that he believes that there was 'considerable prejudice' against the adding of dyes to 'radiolabelled products' before storage. This statement, however, does not distinguish between the type of radioactive marking ( $\beta$  or  $\gamma$ ), and moreover, it is not signed.

Furthermore, Amersham produced a statement by professor E.M. Southern of the University of Oxford (UK), who writes that to him it would not have been obvious to add dyes to  $\beta$ -emitting nucleotides and that he would have been 'very hesitant' to do so. Although this statement certainly does not lack importance, the Court - again also in view of the far-reaching nature of the provisions claimed - deems it insufficient to accept the existence of a prejudice as previously mentioned solely on this basis.

32.5 Therefore, the Court shall request the Bureau's advise as laid down in article 87 Patent Act 1995, on this subject as well.

33. Concerning the other matters in dispute between the parties, the Court shall, if necessary, consider these at a later date.

34. For process-economical reasons, interim appeals against this judgment shall be excluded.

### Decision

The Court, delivering judgment in interim injunction proceedings:

- requests the Bureau voor Industriële Eigendom to give advice, as laid down in article 87 Patent Act 1995, on the following questions:
  - I. At the priority date of BO 594 837 B1 (April 30, 1992), did a person skilled in the art in the sense of ground for judgment 31.8 understand (a) ' $\beta$ -emitting radionuclide(s)' as mentioned in the patent also to be the substance 125-I?
  - II At the said priority date, was the aforementioned person skilled in the art prejudiced against adding - before shipment and storage - dyes to 'organic compound(s) labelled with a  $\beta$ -emitting radionuclide'?
  - III What would you like to add further which you deem important in order to reach a decision in this dispute?
- rules that the Bureau shall give the parties the opportunity to ask questions and make remarks and that it shall report these in its advice.
- understands that the court clerk shall send a copy of this judgment to the Bureau and that the attorneys of record of the parties shall send copies of the other documents of the proceedings to the Bureau;
- rules that the proceedings shall be continued after the advice of the Bureau has been received, on a date and hour to be determined in consultation with the parties, unless both parties prefer to claim a decision on the documents and/or to confine themselves to a reaction in writing;

- rules that appeal against this judgment shall only be possible together with an appeal against the final judgment
- defers any further decision.

Thus rendered by J.H.P.J. Willems and pronounced in open court on March 25, 1996, in the presence of the judge's clerk.

[signed]