BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [X] To Chairmen and Members
(C) [ ] To Chairmen
(D) [ ] No distribution

D E C I S I O N
of 30 April 2003

Case Number: T 0590/98 - 3.3.2

Application Number: 90914225.9

Publication Number: 0441953

IPC: A61K 51/00

Language of the proceedings: EN

Title of invention:
New cores for technetium radiopharmaceuticals

Patentee:
Amersham plc

Opponent:
The Du Pont Merck Pharmaceutical Company

Headword:
"Radiopharmaceuticals/AMERSHAM PLC"

Relevant legal provisions:
EPC Art. 54(3), 84, 99, 100, 104, 105, 107, 108, 123(2), (3)
EPC R. 57a, 64

Keyword:
"Admissibility of appeal (yes): no evidence of transfer of business"
"Main request: disclaimer not acceptable under Articles 84 and 123(2) EPC; no reason to suspend the proceedings until decision of the Enlarged Board of Appeal in cases G 0001/03 and G 0002/03"
"Auxiliary requests 1 to 4: not admissible as *reformatio in peius*"
"Apportionment of costs (no)"

Decisions cited:
G 0004/88, G 0009/92, G 0004/93, G 0001/99, T 0004/80, T 0434/92, T 0653/92, T 0659/92, T 0426/94, T 0298/97, T 0451/99, T 0507/99, T 724/99

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0590/98 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 30 April 2003

Appellant: (Opponent)
The Du Pont Merck Pharmaceutical Company
974 Centre Road
Wilmington, DE 19805 (US)

Representative:
von Kreisler, Alek, Dipl.-Chem.
Patentanwälte
von Kreisler-Selting-Werner
Postfach 10 22 41
D-50462 Köln (DE)

Respondent: (Proprietor of the patent)
Amersham plc
Amersham Place
Little Chalfont
Buckinghamshire HP7 9 NA (GB)

Representative:
Gaunt, Robert John
Stevens, Hewlett & Perkins
Halton House
20/23 Holborn
London EC1N 2JD (GB)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 16 April 1998 concerning maintenance of European patent No. 0 441 953 in amended form.**

Composition of the Board:

Chairman: J. Riolo
Members: G. F. E. Rampold
C. Rennie-Smith

Summary of Facts and Submissions

I. The respondent is proprietor of European patent No. 0 441 953 ("the Patent") which was granted on the basis of European patent application No. 90 914 225.9. with 10 claims as follows:

"1. A complex of technetium (^{99}Tc or ^{99m}Tc) which contains a moiety Tc=NR, Tc-N=NY or Tc(-N=NY)$_2$, and a ligand which confers biological target-seeking properties on the complex, wherein
R represents an aryl group, a substituted or unsubstituted alkyl group, or the grouping -NR^{1}R^2;
Y represents an aryl group or a substituted or unsubstituted alkyl group; and
R^1 and R^2 are hydrogen, aryl groups or substituted or unsubstituted aliphatic or cyclic alkyl groups, and may be both the same or different, provided that both are not hydrogen.

Dependent claims 2 to 7 related to elaborations of the complex according to claim 1.

8. A method of preparing a complex of technetium (^{99}Tc or ^{99m}Tc) which contains a moiety Tc=NR, Tc-N=NY or Tc(-N=NY)$_2$, wherein R and Y are defined as in claim 1, which method comprises the derivatisation of a technetium oxo-containing species by condensation with a hydrazine, an amine an isocyanate, a sulphinylamine or a phosphinimine."

9. A method of preparing a complex of technetium (^{99}Tc or ^{99m}Tc) which contains the moiety Tc=NR, Tc-N=NY or Tc(-N=NY)$_2$, wherein R and Y are defined as in claim 1, which method comprises the reaction of a

hydrazine or amine with a complex containing technetium-halogen bonds.

10. A radiopharmaceutical which includes a complex of technetium as claimed in any one of claims 1 to 7."

II. The appellant originally filed notice of opposition requesting revocation in full of the European patent pursuant to Article 100(a) EPC for lack of novelty and inventive step. Of the numerous documents cited during the first-instance opposition and subsequent appeal proceedings, the following are referred to in the present decision:

(1) EP-A-0 384 769

(2) DE-A-3 216 026

(4) EP-A-0 291 281

III. During prosecution of the case before the opposition division, amended sets of claims were filed by the respondent, by way of main and auxiliary requests. In an interlocutory decision posted on 16 April 1998, the opposition division maintained the patent in amended form on the basis of claims 1 to 10 in the respondent's seventh auxiliary request filed during the oral proceedings held before it on 4 March 1998. Claim 1 corresponds to claim 1 as granted (see I above) with the addition of the following proviso at the end of the claim indicated in bold italic letters below:

"1. A complex of technetium <.....> provided that both are

not hydrogen; ***with the proviso that the ligand which confers biological target-seeking properties on the complex is not a macromolecule."***

Claims 2 to 7, 9 and 10 are identical with those in the patent as granted.

Claim 8 has been amended by deleting hydrazine as one of the options for condensation with the technetium oxo-containing species (see I above), the final portion of the claim as amended reading as a follows:

"8. A method of preparing a complex <.....> which method comprises the derivatisation of a technetium oxo-containing species by condensation with an amine, an isocyanate, a sulphinylamine or a phosphinimine."

IV. In its reasons for the decision the opposition division held that amended claims 1 and 8 met the requirements of Article 123(2) and (3) and Article 84 EPC. It found that introduction of the proviso (disclaimer) at the end of product claim 1 (see III above) and deletion of hydrazine as one of the reactants from claim 8 were appropriate amendments to establish novelty of the claimed subject-matter in the patent over the prior art of citations (1) and (2).

Concerning inventive step, the opposition division determined the problem to be solved vis-à-vis the closest state of the art according to citation (2) as that of providing technetium-99m labelled radiopharmaceuticals containing a variety of ligands capable of conferring specific biological target-seeking properties on such radiopharmaceuticals. It

concluded that neither citation (2) nor citation (4) gave any hint to those skilled in the art to solve the problem by the provision of the claimed technetium complexes in the patent.

V. The appellant filed a notice of appeal dated 5 June 1998 and paid the appeal fee on the same date. With its statement of grounds of appeal filed on 26 August 1998, the appellant filed six new documents (Documents (7) to (12)) and four annexes of comparative data.

VI. In its reply dated 1 March 1999 to the grounds of appeal, the respondent objected to the introduction in the appeal proceedings of new evidence without an explanation as to why it was not filed at first instance and requested an apportionment of costs in its favour on the grounds that the appellant's reliance on such evidence had caused the respondent to incur unnecessary costs.

VII. In the Board's communication dated 27 March 2002 accompanying the summons to oral proceedings, the rapporteur indicated the Board's view of the correct interpretation of the claims upheld by the opposition division and informed the respondent that, in the opinion of the Board, the disclaimer (proviso) introduced in claim 1 was neither supported by the disclosure in the application as filed nor by the disclosure in citation (1) and, moreover, that the amendments made during opposition proceedings emphasised a problem of clarity. In support of this opinion a copy of page 699 (entry "ligand") of Hawley's Condensed Chemical Dictionary, eleventh edition, was attached to the Board's communication.

VIII. In reply to the Board's communication, the respondent submitted with its letter of 28 June 2002, in advance of the oral proceedings fixed for 30 July 2002, further arguments supporting its request for the appeal to be dismissed and filed new auxiliary requests 1 to 4.

Claim 1 of auxiliary request 1 is worded as follows:

"A complex of technetium (^{99}Tc or ^{99m}Tc) useful as a radiopharmaceutical of formula:

$L_nTc=NR$, $L_nTc-N=NY$ or $L_nTc(-N=NY)_2$;

wherein

R represents an aryl group, a substituted or unsubstituted alkyl group, or the grouping $-NR^1R^2$;

L represents a mono-dentate or multi-dentate ligand;

n is 1, 2, 3 or 4;

Y represents an aryl group or a substituted or unsubstituted alkyl group; and

R^1 and R^2 are hydrogen, aryl groups or substituted or unsubstituted aliphatic or cyclic alkyl groups, and may be both the same or different, provided that both are not hydrogen;

wherein the biological target seeking properties of the complex are determined by the nature of the ligands present and/or of the substituents R and Y;

with the proviso that when the formula is $L_nTc=N-NR^1R^2$ or $L_nTc-N=NY$, where L is a chelating di-oxygen ligand, and n is 2, the R^1, R^2 or Y groups do not comprise a ***protein.***"

Claim 1 in auxiliary request 2 corresponds to claim 1 in auxiliary request 1, the proviso at the end of the claim differing as follows:

"with the proviso that when the formula is $L_nTc=N-NR^1R^2$ or
$L_nTc-N=NY$, where L is a chelating di-oxygen ligand, and n is 2, the R^1, R^2 or Y groups do not comprise a ***macromolecule***."

Claim 1 in auxiliary request 3 corresponds to claim 1 in auxiliary request 1, the definition of ligand L differing as follows:

"L represents a mono-dentate or multi-dentate ligand ***which confers biological target-seeking properties on the complex".***

Claim 1 in auxiliary request 4 corresponds to claim 1 in auxiliary request 2, the definition of ligand L likewise differing as follows:

"L represents a mono-dentate or multi-dentate ***ligand which confers biological target-seeking properties on the complex".***

IX. During the course of the appeal the name of the respondent company was changed twice and these changes were duly recorded.

X. In a letter of 26 June 2002 the appellant informed the Board that its name, which was The DuPont Merck Pharmaceutical Company when the opposition had been filed, had also been changed twice thereafter, first to DuPont Pharmaceuticals Company and then to Bristol-Myers Squibb Pharma Company. Two documents said to evidence these changes were filed with that letter.

XI. In a communication dated 24 July 2002 the Board

observed, in relation to the appellant's changes of name and those two documents, that:

(A) The first document, an affidavit of 6 July 1998, stated that DuPont Pharmaceuticals Company is "no longer doing business as The DuPont Merck Pharmaceutical Company" and that "said business was terminated on June 30 1998". It was unclear whether that "termination of business" referred, as the context might suggest, just to a cessation of business under the name of The DuPont Merck Pharmaceutical Company or, as the statement taken at face value would suggest, to a cessation of business *per se*. In the latter event, the question would then arise whether there had been a succession to the business by a party entitled to conduct the proceedings as contemplated by decision G 4/88 (OJ 1989, 480) and subsequent jurisprudence of the Boards of Appeal.

(B) The second document, apparently a sworn notification made under the partnership laws of the State of Delaware, indicated both another change of name (from DuPont Pharmaceuticals Company to Bristol-Myers Squibb Pharma Company) and a change of partners (two earlier partners - E I DuPont de Nemours and Company and DuPont Pharma, Inc. - having been replaced by two new partners - E R Squibb & Sons, LLC and Bristol-Myers Squibb Pharma Holding Company, LLC), both changes having occurred on 2 October 2001. This appeared to be the first indication on the file that the appellant was a partnership of two corporations. The Board was accordingly required to consider whether there had been no more than a

mere change of name or whether one partnership had ceased and been replaced by another and whether, in the latter case, there had been a transfer of business from the earlier to the later, again as contemplated by G 4/88 and subsequent jurisprudence.

(C) These matters could affect the admissibility of the appeal and their resolution would appear to require evidence as to the relevant law, as to the construction to be placed on the documents referred to above, and as to the exact terms of the changes of partnership and/or of any transfer of business. While it was hoped that these matters could be explained at the oral proceedings on 30 July 2002, the Board could not (in view of the lateness of filing of these documents and the consequent timing of its communication) require any further evidence to be filed before those proceedings. It might therefore be necessary, at the end of the oral proceedings, to continue the appeal proceedings in writing for the sole purpose of resolving such of these issues as remained unanswered at that time.

XII. At the oral proceedings held on 30 July 2002, the matters raised in the appellant's letter of 26 June 2002 and the Board's subsequent communication were discussed. The appellant produced three further documents, namely sworn notifications under Delaware partnership law of 27 March 1997 showing the original two members of the partnership (E I DuPont de Nemours & Co., Inc. and Merck & Co., Inc.) and that its date of formation was 1 January 1991; of 6 July 1998 showing the replacement as one partner of Merck & Co., Inc. by

DuPont Pharma, Inc.; and of 8 February 1999 showing that change of partner occurred on 17 July 1998. Reference was also made to the document described at XI(B) above to show the further subsequent changes of both partners and name.

In view of the very late notification by the appellant of these matters, the Board proceeded at the oral proceedings to consider the formal and substantive issues in the appeal while leaving the issue of the appellant's status (and thus of the admissibility of the appeal) to be dealt with in further written proceedings as directed by the Board.

XIII. In a communication dated 30 July 2002 the Board made the following directions:

(A) The Appellant was to file, within four weeks after the deemed date of receipt of this communication, written submissions and evidence on the issue whether there had at all times during the appeal proceedings been an appellant which had been either a party adversely affected by the decision under appeal or the universal successor to such a party.

(B) The Respondent might, if it so wished, file written arguments and evidence in reply within four weeks of the deemed date of receipt by it of copies of the Appellant's said written arguments and evidence.

(C) The parties might in their further submissions referred to above make requests for apportionment of costs but otherwise no further requests would

be admissible.

(D) A decision might be issued at any time after the expiry of the time-limit in (B) above. In the event the Board considered any other steps necessary, those would be announced by means of a further communication.

(E) The appeal proceedings were to be continued in writing but only for the purpose of giving effect to the above directions.

XIV. Pursuant to that communication the appellant filed, under cover of a letter of 13 September 2002, the written opinion (and accompanying documents) of its Delaware lawyer that, under the laws of Delaware, the members of a partnership may change without the partnership being dissolved and that this had occurred in the case of the appellant.

XV. In reply to that submission, the respondent filed a letter dated 1 November 2002 (with accompanying documents) in which it argued that, because certain products formerly sold by DuPont Pharmaceuticals Company were now being offered for sale by a separate entity, a corporation entitled Bristol-Myers Squibb Medical Imaging Inc., under trade marks allegedly registered in the United States in the name of that corporation, the business formerly conducted by the appellant partnership was now being conducted by that corporation, which was therefore the successor in business to the partnership. Therefore, in the light of decisions G 4/88 and T 298/97 (OJ EPO 2002, 83), the appellant was not a party adversely affected by the decision under appeal which should be considered either

as inadmissible or withdrawn. The respondent requested an apportionment of costs such that the appellant pay all the respondent's costs incurred after "any date that the Board rules that the appeal no longer existed, plus costs arising as a direct result of Bristol-Myers Squibb Pharma Company's unwarranted participation in, and artificial continuation of, the appeal proceedings".

XVI. In a letter dated 22 November 2002, the appellant refuted those submissions of the respondent. Yet further submissions were filed thereafter, by the respondent in a letter of 20 December 2002 and by the appellant in a letter of 17 February 2003. For the reasons given below (see paragraph 1 of the reasons), the contents of these three submissions are not summarised here.

XVII. The arguments of the appellant, in writing and at the oral proceedings, as regards the issues which are relevant to the present decision can be summarised as follows:

(A) The entity which commenced the opposition proceedings is a Delaware partnership of two corporations which has remained the opponent and, subsequently, the appellant despite changes of participating partners and of name. There has been no dissolution or termination of the partnership which has, despite those changes, remained in being as a partnership under Delaware law.

(B) Claim 1 of the main request, on its proper construction in the light of the disclosure as a whole in the patent specification, including the

formulae $L_nTc=NR$, $L_nTc-N=NY$ and $L_nTc(-N=NY)_2$ provided in the description and dependent claims 2 to 4, clearly related to complexes (coordination compounds) of technetium containing

- at least a nitrogen moiety (A), *viz.* =NR or -N=NY; and

- at least a ligand (B) which confers target-seeking properties on the complex, said ligand (B) being a mono- or multi-dentate ligand "L" as shown in the description and any of dependent claims 2 to 4. The interpretation of claim 1 on the basis of its grammatical construction ("a complex of technetium which contains the moiety ..... **and** a ligand which confers biological target-seeking properties on the complex") made it unambiguously clear that the feature "which confers biological target-seeking properties on the complex" related to the ligand (B) and neither to the complex as such nor the nitrogen moiety (A).

  As indicated in the minutes of the oral proceedings before the opposition division, the disclaimer had been introduced in claim 1 of the seventh auxiliary request before the opposition division to remove an alleged overlap between claim 1 and the state of the art according to (1). Citation (1) related to bifunctional hydrazine or hydrazide compounds capable of linking metal ions, particularly technetium and rhenium, to biologically useful molecules, including macromolecules such as proteins, polypeptides and glycoproteins. In the state of

the art according to (1), in a first step the bifunctional compounds reacted with nucleophilic groups on the macromolecules to yield *conjugates* containing free hydrazine/hydrazide groups as the remaining second functionality. Such *conjugates* were useful in a second step for labelling macromolecules by reacting the *conjugates* with a suitable metal species. It was thus clear that (1) referred to labelled macromolecules comprised of *conjugates* and metal ions. As was derivable from the formulae at page 4, lines 33 to 38 of (1), the biologically active molecules or macromolecules (eg proteins) of the *conjugates* referred to in (1) were, in contrast to the ligands "L" in the patent, clearly no ligands attached to the central atom (technetium) of a coordination compound. It necessarily followed that the disclaimer in claim 1 ("*that the **ligand** which confers biological target-seeking properties on the complex is not a macromolecule")* had no basis in the state of the art according to (1) and that claim 1 as amended was thus contrary to Article 123(2) EPC.

The opposition division was wrong to reject the appellant's objection under Article 84 EPC to the clarity of the definition of the ligand in claim 1 reading "a *ligand which confers biological target-seeking properties on the complex"* and, consequently, to the wording of disclaimer. In the present case, Article 84 EPC had to be taken into account in view of the amendments made by the respondent during opposition proceedings. The meaning of the term

"biological target-seeking properties" was in itself vague and indefinite and was neither explained nor defined anywhere in the patent specification. The meaning and scope of the term macromolecule was similarly obscure, since it related to anything from antibodies to silicones. In accordance with decision T 4/80 (OJ EPO 1982, 149), originally disclosed subject-matter, clearly definable by technical features, may be excluded from a wider claim by a disclaimer, if the subject-matter remaining in the claim cannot technically be defined directly (positively) in a more clear and concise manner. In the present case however, neither the subject-matter excluded by the disclaimer nor the subject-matter remaining in claim 1 was clearly defined by technical features. It was thus clear that the claims in the respondent's main request did not comply with the requirements of Article 84 EPC.

Apart from the fact that the auxiliary requests 1 to 4 were filed only about one month in advance of the oral proceedings, and were thus filed late without any proper justification, none of these requests was admissible under Rule 57a EPC. It was not recognisable that the amendments to the claims in auxiliary requests 1 to 4 were occasioned by grounds for opposition in Article 100 EPC as required by Rule 57a EPC. The claims in auxiliary requests 1 and 2 also contravened Article 123(2) and (3) EPC. The admissibility of all auxiliary requests was, moreover, objectionable as *reformatio in peius*.

Claim 1 as originally filed, as granted and as maintained by the opposition division stipulated that the claimed complex must contain, in addition to any of the moieties Tc=NR, Tc-N=NY or $Tc(-N=NY)_2$, "a ligand which confers biological target-seeking properties on the complex". Deletion of this compulsory feature and its replacement by "wherein the biological target-seeking properties of the complex are determined by the nature of the ligands present and/or of the substituents R and Y" in claim 1 of auxiliary requests 1 and 2 offended against Article 123(2) and (3) EPC and was, moreover, objectionable as *reformatio in peius*. The considerable reduction in scope of the disclaimers in claim 1 of all four auxiliary requests produced some extension of scope of protection compared to claim 1 maintained by the opposition division and thus amounted similarly to *reformatio in peius.*

(C) The respondent's requests for apportionment of costs should be dismissed.

XVIII. As regards the issues which are relevant to the present decision, the respondent argued, in writing and at the oral proceedings, that:

(A) The appeal is either inadmissible or has in effect been withdrawn because the business of the original opponent has been transferred in whole or in part to another entity.

(B) By seeking to imply that the Tc complex of claim 1 must contain a nitrogen moiety (A) [namely =NR or

-N=NY] and "a ligand which confers target-seeking properties" (B), the appellant was attempting to distort the meaning of claim 1 by introducing new terminology into the analysis of its wording. The (A) and (B) terminology was not present in claim 1 and its attempted insertion by the appellant served only to complicate and confuse the picture. With regard to its statement "said ligand being a mono- or multi-dentate ligand L as set forth in claims 2 to 4", this was simply not the case. It was a complete misinterpretation of the text of claim 1, since the term "L" did not appear until claim 2. In response to the comments in paragraphs 2, 3, and 4 of the Board's communication dated 27 March 2002, the respondent remained of the view that there was nothing in claim 1 which required the "ligand which confers biological target-seeking properties" to equate to "L".

The appellant's objections to the lack of support for the disclaimer in citation (1) were based on the erroneous construction of (A) and (B) in claim 1. On its correct and perfectly clear interpretation the disclaimer of claim 1 read on the "ligand which confers biological target-seeking properties" wherever it was located in the claimed technetium complex in the patent. Hence the opponent's objections to the disclaimer were irrelevant, being based on a transparently incorrect interpretation of claim 1. The appellant's contention that the protein indicated in the formulae at page 4, lines 33 to 38 of (1) was merely a substituent and no longer "a ligand which confers biological target-seeking

properties" went against all the teaching of citation (1) where the protein or macromolecule was explicitly described as being used to target imaging or therapy agents. The appellant had also omitted an element in its analysis. If it was to categorise the macromolecule or protein in citation (1) as a substituent and not "the ligand which confers target-seeking properties" then the question remained as to where in this construction was the ligand. The respondent also wished to draw attention to the definition of the term "ligand" which appeared in Butterworths Medical Dictionary, Second Edition. This definition included the statement that this term was applied to a "molecule which is bound specifically to one site on a protein or nucleic acid". Since the field of radiopharmaceuticals included the disciplines of chemistry, biochemistry and medicine, it was, as the Board suggested in its communication, not so clear that a purely chemical definition should be applied to the word "ligand". Thus the disclaimer did not offend against Article 123(2) EPC.

Since the wording "ligand which confers biological target-seeking properties" objected to by the appellant was already in the patent as granted and Article 84 EPC was not a ground for opposition, any attempt to introduce an objection under Article 84 EPC at this stage was clearly inadmissible. Since the text of the subsequently added proviso in claim 1 simply replicated wording which already existed in the claim, attempts now

to attack terms like "biological target-seeking properties" and the clarity of the disclaimer must be held inadmissible. The opposition division had already correctly ruled on this point.

Claim 1 in auxiliary requests 1 and 2 resulted from consolidation of the chemical formulae of claims 2, 3, and 4 as granted, together with the elements of claim 7. Claim 1 in auxiliary requests 3 and 4 resulted from consolidation of the chemical formulae of claims 2, 3, and 4 as granted. The claims in all auxiliary requests were thus clearly derived from the patent specification and hence allowable under Article 123(2) and (3) EPC. The revised disclaimers in all four auxiliary requests were amended to distinguish more clearly over the disclosure of citation (1). Citation (1) was available under Article 54(3) EPC only and as such, a disclaimer to confer novelty over the subject-matter of (1) was allowable. The disclaimers had been made as specific as possible to the disclosure of (1) (following T 434/92, T 653/92 and T 426/94) and were therefore believed to be allowable. The proposed amendments could not therefore contravene the principle of "prohibition of *reformatio in peius*" set out in G 9/92 and G 4/93 (OJ EPO 1995, 875) and G 1/99 (OJ EPO 2001, 381).

(C) There should be an apportionment of costs in its favour because the appellant filed new evidence on appeal without explaining why such evidence could not have been filed at first instance and because many of the submissions in the grounds of appeal were misleading or contradictory. As a result the

respondent considered it had been required to do unnecessary additional work. A further apportionment was also justified by the fact that, if the transfer of business (which the respondent alleged had occurred) had been disclosed earlier than the appellant's letter of 26 June 2002, the appeal would probably have been rejected as inadmissible or withdrawn before the oral proceedings.

XIX. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed and, as auxiliary requests, that the patent be maintained on the basis of one of the four auxiliary requests filed on 28 June 2002; and that there be an apportionment of costs in its favour to reflect the late citation of documents and the late disclosure of the alleged transfer of the opponent's business.

Reasons for the Decision

Procedural matters

1. The directions in the Board's communication of 30 July 2002 (see XIII above) were quite clear. Each party, the appellant first and the respondent thereafter in reply, was directed to file one written submission on the very limited issue "whether there had at all times during the appeal proceedings been an appellant which had been either a party adversely affected by the decision under appeal or the universal successor to such a party". That these submissions were to be limited to one from

each party was abundantly clear not only from the time limits set but also from paragraph (D) of the communication which said "In the event the Board considers any other steps necessary, those will be announced by means of a further communication", and from paragraph (E) which said "The appeal proceedings are to be continued in writing but only for the purpose of giving effect to the above directions".

1.1 In the event, both parties ignored these directions by filing further submissions, in the case of the appellant by its letters of 22 November 2002 and 17 February 2003 and, in the case of the respondent, by its letter of 20 December 2002. While the respondent's first submission on this issue may have appeared to the appellant so far-fetched that the need to reply seemed irresistible, its letter of 22 November 2002 simply prompted further submissions which had the effect of prolonging the appeal proceedings unnecessarily. If either of the parties considered it imperative to make further submissions, it could and should have sought further directions. The Board views the unsolicited submissions as abuses of procedure and has accordingly to ignore them.

Admissibility

2. Although the documents filed by the appellant with its letter of 26 June 2002 gave rise to reasonable doubt as to the continued existence of the partnership which instigated the opposition proceedings, the Board is now satisfied that, under Delaware law, that partnership has, notwithstanding changes of both participating partners and of name, continued in being throughout the appeal proceedings. The relevant provisions of Delaware

law and their application to the appellant are explained in the opinion of the Delaware lawyer filed with the appellant's letter of 13 September 2002 and need not be set out *in extenso* in this decision because, that opinion not having been challenged as such by the respondent, it represents the only evidence on this issue which the Board accepts. It follows that the appellant partnership which, as "any person" (see Article 99 EPC), filed opposition to the patent in suit, was also "a person aggrieved" (see Article 107 EPC) by the decision under appeal and therefore entitled to commence and prosecute the present appeal proceedings. Since, on the only evidence available to the Board, the appellant has throughout remained the same entity, no question arises of any transfer to another party of the appellant's assets or of its status as opponent or appellant.

2.1 While the appellant may be open to criticism for not informing the Board promptly of changes of its name and for producing somewhat ambiguous information when it finally did so, that does not alter the factual position as now disclosed by the evidence produced in response to the Board's inquiries.

2.2 In the Board's judgment the respondent's attempts to question the position (see XV above) were misguided. The respondent did not seek to challenge the opinion provided by the appellant as to the provisions of Delaware law but simply sought to infer, from a collocation of random items of what it called “public record” evidence, that the appellant's business had been transferred to the company Bristol-Myers Squibb Medical Imaging Inc., and then concluded that this disentitled the appellant from continuing these appeal

proceedings. The respondent's arguments are, as to matters of fact, wholly unconvincing and, as to maters of law, wholly incorrect.

2.3 As to matters of fact the respondent, referring to the appellant's statement (in an affidavit of Dr S. K. Larsen, an employee and patent attorney of the appellant, filed with the appellant's letter of 13 September 2002) that the business of the partnership first called The DuPont Merck Pharmaceutical Company and now called Bristol-Myers Squibb Pharma Company has been continuously carried on, the respondent says in its letter of 1 November 2002 "The public record indicates otherwise, and instead shows that a corporation named Bristol-Myers Squibb Medical Imaging Inc., not Bristol-Myers Squibb Pharma Company, carries on the relevant business of The DuPont Merck Pharmaceutical Company". To support this assertion it points to the differences between the former and more recent packaging of certain products, current website information about those products and former and more recent product approvals issued by the US Food and Drug Administration which show that products formerly marketed by DuPont Pharmaceuticals Company (the second name of the appellant partnership) are now marketed by the corporation called Bristol-Myers Squibb Medical Imaging Inc. The respondent appears to rely in particular, although not exclusively, on trade mark and copyright notices attributing ownership of various trade mark and copyright rights to that corporation. After setting out this information as to the alleged "public record", the respondent concludes "Based on the foregoing, it plainly appears that Bristol-Myers Squibb Medical Imaging Inc., and not Bristol-Myers Squibb Pharma Company, is the successor to the medical imaging

business of The Dupont Merck Pharmaceutical Company."

2.4 Although the Board has not taken into account, for the reasons in paragraph 1 above, the appellant's subsequent letter of 22 November 2002, it must in fairness to the appellant be mentioned that it refuted in some detail the information, such as evidence of alleged ownership of various intellectual property rights, on which the respondent relied. However, even if all the respondent's evidence on this issue was to be accepted as correct, it would not prove the very fact the respondent seeks to prove, namely that there has been a transfer of the appellant's business. It does not demonstrate that the appellant is no longer in business, or that it no longer has an interest in opposing the European patent in suit, let alone that it has actually transferred any of its business to anyone else. All that the respondent's evidence (assuming it to be correct) shows is that the marketing of certain products formerly conducted by the appellant is now conducted by someone else. To which the objective inquirer can only ask, to use the vernacular, "So what?".

2.5 In fact, when one considers the respondent's evidence in any detail, it rapidly becomes impossible to accord it any relevance. How can the marketing of products in one country (as it happens, outside the territories to which the European patent relates) necessarily affect the appellant's opposition or appeal? How can any number of "public record" indications of changes in the appellant's trade equate to the transfer of its entire business to a universal successor, let alone to a transfer together with such business of the opposition if, as is clear, neither the appellant nor the alleged

successor have sought even to suggest such has happened? The respondent's evidence could indicate any of several possible scenarios. At one extreme, the appellant might simply have licensed or authorised, exclusively or non-exclusively, another legal entity to market or sell some of its products in a certain territory, but that would not amount to a transfer of even a part of its business. Equally, at another extreme, the appellant might indeed have disposed of its entire business to a universal successor with the exception of its right to prosecute its opposition, so that apart from these proceedings it was dormant. On either scenario, and on the many possible scenarios between those two extremes, it would in the absence of evidence to the contrary remain entitled to bring and pursue this appeal.

2.6 As to its legal argument based on this largely if not wholly irrelevant evidence, the respondent has again misdirected itself. Having erroneously concluded from that evidence that a succession in business took place, the respondent cites opinion G 4/88 of the Enlarged Board of Appeal for the proposition (in itself quite correct) that an opposition may be transferred to a third party as an inseparable part of the opponent's business assets, together with the assets in the interest of which the opposition was filed. It then cites decision T 298/97 of Board 3.3.6, with which it says this present case has parallels, and states there are two possibilities, namely that either (i) the appellant and the corporation Bristol-Myers Squibb Medical Imaging Inc. now jointly own the appellant's former business or (ii) the business is now solely owned by Bristol-Myers Squibb Medical Imaging Inc.

2.7 As to (i), the respondent says this situation closely parallels that in T 298/97 "and the logic therein inevitably leads to the conclusion that the appeal is inadmissible since it is not possible to admit a further party, which is a separate legal entity, to the proceedings". That latter statement, that a further party may not be admitted to proceedings after the time for (as the case may be) opposing or appealing has expired, is in itself correct. But the respondent's conclusion, that an appeal becomes inadmissible because a third party may not so join the proceedings, is wholly incorrect. Apart from interventions under Article 105 EPC, additional parties cannot become parties to proceedings after the time for doing so has expired for the simple reason that the time has expired; and refusal to allow them to do so has no effect on the standing of existing parties. In fact, the respondent appears to have been mistaken in finding a "close parallel" between this case and T 298/97. In that earlier case, the opponent (as here) filed a Notice of Appeal but a quite different opponent, a related company described as a "new legal entity", filed the Grounds of Appeal. It subsequently appeared that various parts of the original opponent's business had beyond doubt been transferred to two other companies. There was no argument by the opponent, and Board 3.3.6 could discover no factual basis for finding, that the Grounds of Appeal were filed by the new company either by mistake or on behalf of the opponent. Nor could the Board on the evidence construe that a transfer of the opposition to a universal successor in business had taken place. The facts in T 298/97 were thus not only highly unusual but far removed from the present case where there is unrefuted evidence (which the respondent has not even sought to

refute) that the same party has throughout been the opponent and no evidence of a transfer has been adduced.

2.8 The respondent then argues that the "public evidence suggests" the alternative possibility (ii), namely that the opponent's business is now solely owned by Bristol-Myers Squibb Medical Imaging Inc., is "the legal situation". It claims that "a different legal entity (Bristol-Myers Squibb Pharma Company) has presented itself as the legitimate successor to the appellant, when it is not". The respondent then concludes first that, since Bristol-Myers Squibb Pharma Company is not the true successor in business of the appellant, it is not adversely affected by the decision under appeal and is not a party to the proceedings; and second, that since Bristol-Myers Squibb Medical Imaging Inc., which the respondent calls "the legitimate owner of the appeal", has "taken no part in the proceedings since the change of business ownership in 2001", there has been a *de facto* withdrawal of the appeal. This argument is, with all due respect to the respondent, wholly fanciful. It not only flies in the face of the appellant's uncontroverted evidence that the appellant has been the same entity throughout but it relies on the respondent's own evidence to suggest that there has been a transfer of the appellant's business when in fact the respondent's evidence shows no such thing (see paragraphs 2.3 to 2.6 above).

2.9 It appears that here again the respondent has misunderstood T 298/97. It quotes a passage from that decision in which Board 3.3.6, agreeing with a yet earlier decision of Board 3.2.2 (T 659/92, OJ EPO 1995, 519), said "it is incumbent on those seeking the

substitution by transfer of a new party to demonstrate by appropriate evidence that a transfer which complies with the conditions allowed by the case-law has taken place". As regards its own option (ii) (and the very fact it is one of two optional scenarios underlines the weakness of the argument), the respondent criticises the appellant's evidence for failing to mention the alleged succession in business. However, the respondent makes no attempt to refute the appellant's case that there has not been, indeed cannot have been, any such transfer at all since the appellant has remained the same legal person throughout the proceedings. If, in the face of that evidence, the respondent wanted to show there had in fact been a transfer then, as the party seeking to make that case, it was incumbent on the respondent to produce the necessary evidence of a transfer but the respondent's evidence, even if assumed to be factually correct as far as it goes, simply does not show that at all. Such a burden of proof would of course have been extremely hard for the respondent to discharge had it actually made an attempt to do so: the appellant, like any other party, would be presumed to know more about its own corporate affairs than another party and dislodging that presumption would in effect require evidence that the appellant's evidence (that of its Delaware lawyer and of Dr Larsen) had been deliberately falsified. There is not a scintilla of the respondent’s case which even hints at any such allegation of syndicated perjury.

2.10 Therefore, the appeal meets all the requirements of Articles 107, 108 and Rule 64 EPC and is admissible.

Main request

Interpretation of the claims as upheld by the opposition division

3. The interpretation of the claims given below was already brought to the attention of the parties in the Board's communication dated 27 March 2002 and appears relevant to the decision on the respondent's main request (seventh auxiliary request in the proceedings before the opposition division).

3.1 Claim 1 as upheld by the opposition division relates to a complex of technetium which is defined as follows:

"A complex of technetium (^{99}Tc or ^{99m}Tc) which contains
***a* moiety** Tc=NR, Tc-N=NY or Tc(-N=NY)$_2$,
and
a ligand which confers biological target-seeking properties on the complex, wherein
R represents an aryl group, a substituted or unsubstituted alkyl group, or the grouping -NR^{1}R^2;
Y represents an aryl group or substituted or unsubstituted alkyl group; and
R^1 and R^2 are hydrogen, aryl groups or substituted or unsubstituted aliphatic or cyclic alkyl groups, and may be both the same or different, provided that both are not hydrogen; with the proviso that the **ligand** which confers biological target-seeking properties on the complex is not a macromolecule."

Dependent claim 2 relates to a complex of technetium which is defined as follows:

"A complex *as claimed in claim 1* of the formula
$L_nTc=NR$, wherein
L represents a mono-dentate or multi-dentate

ligand
n is 1, 2, 3 or 4;
and R is as previously defined."

Dependent claim 3 relates to a complex of technetium which is defined as follows:

"A complex *as claimed in claim 1* of the formula
$L_nTc\text{-}N{=}NY$,
wherein
L represents a mono-dentate or multi-dentate
ligand
n is 1, 2, 3 or 4;
and Y is as previously defined."

Dependent claim 4 relates to a complex of technetium which is defined as follows:

"A complex *as claimed in claim 1* of the formula
$L_nTc(\text{-}N{=}NY)_2$,
wherein
L represents a mono-dentate or multi-dentate
ligand
n is 1, 2, 3 or 4;
and Y is as previously defined."

Dependent claim 7 as upheld by the opposition division relates to a complex of technetium which is defined as follows:

"A complex *as defined in any of the preceding claims* [including claim 1], useful as a radiopharmaceutical, wherein the biological target-seeking properties of the complex are determined by the nature of the ***ligands*** present

and/or

the **substituents** *R and Y.*

3.2 The description in the application as originally filed (see International application PCT/GB 90/01330, published under the PCT on 21 March 1991 as WO 91/03262: page 5, lines 10 to 16) and the patent as granted (see EP-B-0 441 953, Publication of the grant of the patent on 6 December 1995, Bulletin 95/49: page 5, lines 5 to 13) contains the clear and unequivocal statement: *"Complexes in accordance with this invention have the formulae:*

$$L_nTc{=}NR, \quad L_nTc{-}N{=}NY \quad or \quad L_nTc(-N{=}NY)_2$$

wherein L represents a mono- or multi-dentate ***ligand;***
n is 1, 2, 3 or 4
and
R and Y are as defined above".

3.3 It is apparent from the above that the patent itself makes, in the definition of the claimed complexes, a clear distinction between

(a) ***"ligands L"*** [which are correctly shown in the chemical formulae presented to be directly attached to the technetium central atom];

(b) *"moieties Tc=NR, Tc-N=NY or* $Tc(-N{=}NY)_2$*"; and*

(c) ***"substituents R and Y".***

3.4 A **ligand** is **by definition** a molecule, ion or atom that is directly attached to the central atom of a coordination compound, a chelate, or other complex - see e.g.

(a) Hawley's Condensed Chemical Dictionary, eleventh edition, page 699 (copy attached to the Board's communication dated 27 March 2002): "***ligand*** - A molecule, ion or atom that is attached to the central atom of a coordination compound, a chelate or other complex. Thus the ammonia molecules in $[Co(NH_3)_6]$+++ and the chlorine atoms in $PtCl_6$ are ***ligands***";

(b) Butterworths Medical Dictionary, Second Edition (copy attached to the respondent's letter of 24 June 2002): "**ligand**- In chemistry, a molecule which is bonded usually to transition-metal elements, by means of electron-donor bonds. The term is applied to a molecule which is bound specifically to one site of a protein or nucleic acid".

3.5 The range of possible mono- or multi-dentate ***ligands*** envisaged in the patent specification itself for the claimed complexes (see page 5, line 16 to page 7, line 15; page 19, Table 1) includes without exception molecules capable of being bonded to the technetium central atom by means of electron-donor or coordination bonds and are consequently in full agreement with the definition of the term ***"ligand"*** as used in chemistry according to the above-mentioned dictionaries.

3.6 Thus, on the proper construction of claim 1 as upheld by the opposition division in its full context as set

out above, this claim cannot, in the Board's judgment, reasonably be interpreted in any other way than as relating to a complex of technetium containing the moiety Tc=NR, Tc-N=NY or $Tc(-N=NY)_2$ **and** necessarily at least one mono- or multidentate ***ligand L*** which is directly bonded to the technetium central atom by means of an electron-donor or coordination bond and which is functionally defined by its capability of conferring biological target-seeking properties on the complex.

Disclaimer introduced into claim 1

4. The opposition division referred in item 6 (headed "Art. 54 EPC - Novelty") of the decision under appeal to the following disclosures in citation (1):

"The invention relates to bifunctional compounds capable of linking metal ions, particularly technetium and rhenium, to biologically useful molecules" (see (1): page 2, lines 4 to 5);

"In another embodiment of the invention, *conjugates* are formed by reacting bifunctional hydrazine or hydrazide compounds of the invention with macromolecules such as proteins, polypeptides or glycoproteins. The bifunctional compounds react with nucleophilic groups on the macromolecules (e.g. lysine residues) to yield *conjugates* containing free hydrazine/hydrazide groups" (see (1): page 2, lines 39 to 43).

"The technetium atoms are believed to be bound to the *conjugate* via a hydrazide or diazenido linkages:

Protein-linker-N_2TcL_2

or

Protein-linker-N(-R)$NTcL_2$

wherein:
L is an ancillary dioxygen *ligand*.

Examples of this type of linkage have been described for Mo and Re (Comprehensive Coordination Chemistry, Vol. 2, G. Wilkinson ed., Pergamon (Oxford 1987) and several analogues complexes of ^{99}Tc have been prepared by the reaction of an organohydrazine derivative and TC(V) oxo species" (see (1): page 4, line 33 to 42).

In point 6.2 of the reasons for its decision, the opposition division stated that "the term macromolecule is mentioned several times in (1), in particular on page 2, lines 6, 11, 16, 24, 40, 41, 43 and 44 and that the macromolecules described in the examples of (1) are IgG, Fragment E1 and monoclonal antibody 5E8 (see Examples 9 to 12) which (as stated in Patentee's letter dated 07.02.97) have molecular weights of 155000, 56 754 and over 50 000 respectively".

4.1 On the basis of the above disclosure in citation (1) the opposition division considered in its decision the introduction into claim 1 of the disclaimer (*"with the proviso that the ligand which confers biological target-seeking properties on the complex is not a macromolecule"*) as appropriate and necessary to establish novelty of the claimed subject-matter in the patent over the state of the art according to citation (1).

4.2 Contrary to the opinion expressed by the opposition division in the decision under appeal (see especially page 8, fourth full paragraph) and the arguments submitted by the respondent in its reply to the grounds of appeal and during the hearing before the Board,

citation (1) does **not** disclose a complex of technetium containing a ***ligand*** which is a macromolecule as such. On the contrary, citation (1) discloses *conjugates* formed by reacting bifunctional hydrazine or hydrazide compounds with macromolecules such as proteins, polypeptides or glycoproteins. The bifunctional compounds react with nucleophilic groups on the macromolecules to yield *conjugates* containing free hydrazine/hydrazide groups. Labelled macromolecules comprised of *conjugates* and metal ions and a method for labelling macromolecules by reacting a *conjugate* according to (1) with a metal species are also disclosed in (1).

4.3 In (1) a clear distinction is made between a ***conjugate*** (comprising a protein or macromolecule) which is bound to the technetium atom via a hydrazide or diazenido linkages and ancillary dioxygen ***ligand*****s** which are directly attached to the technetium central atom by means of electron-donor or coordination bonds. Even if th**e** Board were nevertheless to accept that the term macromolecule is an acceptable generalisation and that, for example, the complete structures Protein-linker-N_2= or Protein-linker-N(-R)N- represent ***ligands*** attached to the technetium central atom (although this is not said in (1) and appears in fact be incorrect), the macromolecule (e.g. a protein) as such would constitute merely a partial structure of such complete ***ligands*** shown in citation (1) (see especially page 4, lines 33 to 39). The macromolecule or protein itself clearly does not, in the complexes disclosed in (1), form a **ligand** as that term is to be understood in accordance with any of the definitions in point 3.4 above.

It necessarily follows that the disclaimer in claim 1 of the main request reading "with the proviso that the ***ligand*** which confers biological target-seeking properties on the complex is not a macromolecule" is not supported by the application as filed. Moreover, it cannot be derived from the disclosure of citation (1). Such a disclaimer is clearly contrary to Article 123(2) EPC.

4.4 Although an objection under Article 84 EPC cannot in itself be a ground of opposition under Article 100 EPC, it is generally accepted that such an objection can be raised during opposition or opposition appeal proceedings if amendments made in those proceedings emphasise a problem of clarity.

4.5 Since citation (1) does not disclose a complex of technetium containing a ***ligand*** which is a macromolecule or a protein, neither the subject-matter to be excluded from claim 1 nor the subject-matter remaining in the claim for which protection is sought is clearly defined as required by Article 84 EPC.

4.6 The Board is aware that Board 3.3.5 has referred in case T 507/99 (to be published in OJ EPO) the following questions to the Enlarged Board of Appeal:

1. Is an amendment to a claim by the introduction of a disclaimer unallowable under Article 123(2) EPC for the sole reason that neither the disclaimer nor the subject-matter excluded by it from the scope of the claim have a basis in the application as filed?

2. If the answer to question 1 is no, which criteria

are to be applied in order to determine whether or not a disclaimer is allowable?

(a) In particular, is it of relevance whether the claim is to be delimited against a state of the art according to Article 54(3) EPC or against a state of the art according to Article 54(2) EPC?

(b) Is it necessary that the subject-matter excluded by the disclaimer be strictly confined to that disclosed in a particular piece of prior art?

(c) Is it of relevance whether the disclaimer is needed to make the claimed subject-matter novel over the prior art?

(d) Is the criterion applicable that the disclosure must be accidental, as established by prior jurisprudence, and, if yes, when is a disclosure to be regarded as being accidental, or

(e) is the approach to be applied that a disclaimer which is confined to disclaiming the prior art and has not been disclosed in the application as filed is allowable under Article 123(2) EPC, but that the examination of the subject-matter claimed for the presence of an inventive step has then to be carried out as if the disclaimer did not exist?

Board 3.3.4 has referred in case T 451/99 (to be

published in OJ EPO) the following questions to the Enlarged Board of Appeal:

> Is the introduction into a claim of a disclaimer not supported by the application as filed admissible, and therefore the claim allowable under Article 123(2) EPC, when the purpose of the disclaimer is to meet lack-of-novelty objection pursuant to Article 54(3) EPC? If yes, what are the criteria to be applied in assessing the admissibility of the disclaimer?

4.7 Since in the present case the disclaimer has absolutely no basis in the cited state of the art according to (1) and its introduction into claim 1 results in a claim which contravenes Article 84 EPC, the decision of the Enlarged Board of Appeal on the above questions referred to it is not relevant to the decision in the present case. The Board sees therefore no reason to suspend the proceedings until the decision of the Enlarged Board of Appeal (pending cases G 1/03 and G 2/03) has been issued.

4.8 Dependent claim 7 relates to a complex as defined in any of the preceding claims, useful as a radiopharmaceutical, wherein the biological target-seeking properties of the complex are determined by the nature of the ***ligands*** present **and/or** the ***substituents R and Y*****.** Consequently, claim 7 makes, on the one hand, a clear distinction between **ligands** (attached to the technetium central atom) and the **substituents R and Y** forming part of, or differently expressed attached to, the ***$L_nTc=NR$, $L_nTc-N=NY$ or $L_nTc(-N=NY)_2=NR$ moieties***.

On the other hand, claim 7 is broader in scope than

claim 1 as it covers an embodiment of the claimed invention not covered by claim 1, namely complexes wherein solely the ***substituents R and Y*** confer biological target-seeking properties on the complex. In other words, claim 7 would, in contrast to claim 1, cover complexes containing no ***ligand*** which confers biological target-seeking properties on the complex. This contradiction contravenes Article 84 EPC.

5. It follows that the respondent's main request must fail since the claimed subject-matter does not comply with the requirements of Articles 123(2) and 84 EPC.

Admissibility of the Respondent's auxiliary requests

6. In the present case the opponent is the sole appellant. It objected during the hearing before the Board to the admissibility of all auxiliary requests as *reformatio in peius.* This requires that the Board, following the approach it adopted in decision T 724/99 of 24 October 2001 (unpublished in OJ EPO; see reasons, points 3 and 5), considers the following question:

6.1 On a comparison of the claims (in effect claim 1, the broadest independent claim), is the amended form of the claims in the auxiliary requests wider than the claims in the form maintained by the opposition division or, differently expressed, would maintenance of the patent in amended form on the basis of the claims in the auxiliary requests put the opponent/appellant in a worse situation than if it had not appealed? If the answer is no, there can be no *reformatio in peius* and the admissibility objection fails. If, however, the answer to the question is yes, there is a *prima facie* case of *reformatio in peius*.

6.2 Claim 1 in auxiliary requests 1 and 2 contains, in comparison with claim 1 as upheld by the opposition division, the following three amendments (see III and VIII above):

(A) the definition of the claimed complexes in claim 1 as maintained read:

"A complex of technetium (^{99}Tc or ^{99m}Tc) which contains a moiety Tc=NR, Tc-N=NY or $Tc(-N=NY)_2$, and a ligand which confers biological target-seeking properties on the complex, wherein
R represents an aryl group, a substituted or unsubstituted alkyl group, or the grouping $-NR^1R^2$;
Y represents an aryl group or substituted or unsubstituted alkyl group; and
R^1 and R^2 are hydrogen, aryl groups or substituted or unsubstituted aliphatic or cyclic alkyl groups, and may be both the same or different, provided that both are not hydrogen";

and has now been replaced in auxiliary requests 1 and 2 by the definition:

"A complex of technetium (^{99}Tc or ^{99m}Tc) useful as a radiopharmaceutical of formula:
$L_nTc=NR$, $L_nTc-N=NY$ or $L_nTc(-N=NY)_2$;
wherein
R represents an aryl group, a substituted or unsubstituted alkyl group, or the grouping $-NR^1R^2$;
L represents a mono-dentate or multi-dentate ligand;
n is 1, 2, 3 or 4;
Y represents an aryl group or substituted or unsubstituted alkyl group; and

R^1 and R^2 are hydrogen, aryl groups or substituted or unsubstituted aliphatic or cyclic alkyl groups, and may be both the same or different, provided that both are not hydrogen";

(B) whereas claim 1 as upheld stipulated the presence of "a ligand which confers biological target-seeking properties on the complex" in addition to the moieties Tc=NR, Tc-N=NY or $Tc(-N=NY)_2$, claim 1 in auxiliary requests 1 and 2 refers to the options that the biological target seeking properties of the complex are determined by the nature of the ligands present **and/or** of the substituents R and Y;

(C) the scope of the disclaimer in claim 1 as upheld, providing that the ligand in general which confers biological target-seeking properties on the complex is not a macromolecule, has been considerably narrowed by amending the proviso in claim 1 of auxiliary request 1 so as to read "that when the formula is $L_nTc=N-NR^1R^2$ or $L_nTc-N=NY$, where L is a chelating di-oxygen ligand, and n is 2, the R^1, R^2 or Y groups do not comprise a ***protein***"; and likewise in claim 1 of auxiliary request 2 by amending the proviso so as to read "that when the formula is $L_nTc=N-NR^1R^2$ or $L_nTc-N=NY$, where L is a chelating di-oxygen ligand, and n is 2, the R^1, R^2 or Y groups do not comprise a ***macromolecule.***"

6.3 The Board considers that amendment (A) results in a narrowing of claim 1 as upheld to the scope of dependent claims 2 to 4, although the correct interpretation of claim 1 as maintained by the opposition division suggests clearly that the complexes

disclosed in the patent are precisely those now claimed in claim 1 of auxiliary requests 1 and 2 (see 3 to 3.6 above).

6.4 Amendment B produces some extension of the scope of claim 1 to the scope of claim 7 upheld by the opposition division (see point 4.8 above).

6.5 However, there is no doubt that amendment (C) produces a considerable extension of scope, since what was excluded by the disclaimer *[with the proviso that the ligand which confers biological target-seeking properties on the complex is not a macromolecule]* in claim 1 as upheld, namely the presence of a mono- or multi-dentate ligand in general which confers target-seeking properties on the complex and which is a macromolecule wherever it is located on the complex, is no longer excluded from claim 1 in auxiliary requests 1 and 2. Accordingly, claim 1 in both these requests covers ways of performing the claimed invention which were excluded by the amended claims as maintained by the opposition division (with the result that the proposed amendments to the claims in present auxiliary requests 1 and 2 would amount to an extension of scope compared with the amended claims upheld by the opposition division).

6.6 In auxiliary requests 3 and 4, claim 1 contains, in comparison with claim 1 as upheld by the opposition division, the following amendments (see paragraphs III and VIII above):

(A) the definition of the claimed complexes has been replaced by the definition:

"A complex of technetium (^{99}Tc or ^{99m}Tc) useful as a radiopharmaceutical of formula:

$L_nTc=NR$, $L_nTc\text{-}N=NY$ or $L_nTc(\text{-}N=NY)_2$;

wherein

R represents an aryl group, a substituted or unsubstituted alkyl group, or the grouping $-NR^1R^2$;

L represents a mono-dentate or multi-dentate ligand which confers biological target-seeking properties on the complex;

n is 1, 2, 3 or 4;

Y represents an aryl group or substituted or unsubstituted alkyl group; and

R^1 and R^2 are hydrogen, aryl groups or substituted or unsubstituted aliphatic or cyclic alkyl groups, and may be both the same or different, provided that both are not hydrogen";

(B) The scope of the disclaimer in claim 1 as upheld is narrowed in claim 1 of auxiliary requests 3 and 4 by the same amendments as those in claim 1 of auxiliary requests 1 and 2 (see 6.2 (C) above).

6.7 There can be no doubt that amendment (B) produces in the claims of auxiliary requests 3 and 4 the same extension of scope as amendment (C) in the claims of auxiliary requests 1 and 2. Accordingly, claim 1 in the auxiliary requests 3 and 4 likewise covers ways of performing the claimed invention which were excluded by the amended claims as maintained by the opposition division.

6.8 The Board therefore concludes that, by filing auxiliary requests 1 to 4 in the appeal proceedings the

respondent (which has not itself appealed) would, if any its auxiliary requests was to succeed, put the appellant in a worse position than if it had not appealed. This amounts to *reformatio in peius* - a worse outcome for an appellant - as considered and defined in the case law. (See the Enlarged Board decisions G 9/92 and G 4/93 (OJ EPO 1995, 875) and G 1/99 (OJ EPO 2001, 381).

6.9 When repeatedly asked by the Board during discussion of the auxiliary requests at the oral proceedings, the respondent confirmed that it was well aware of the principles governing the admissibility of requests to file amendments in appeal proceedings in view of the principle of prohibition of *reformatio in peius* developed by the decisions mentioned above. Moreover, when the respondent's attention was drawn by the Board to decision G 1/99 (*loc. cit.*), it confirmed its knowledge of and familiarity with this decision. Decision G 1/99 gives a non-appealing patentee three possibilities to amend even if this leads to *reformatio in peius*, provided the prohibition in Article 123(3) EPC against extension of the scope of the patent as granted is observed. As the first possibility, a patentee is allowed to amend by introducing one or more originally disclosed features which limit the scope of the patent as maintained. If, and only if, such a limitation is not possible, a patentee may then, as a second possibility, within the limits of Article 123(3) EPC, file a request which would extend the scope of the patent as maintained.

6.10 Consequently, the conclusion must be drawn that the respondent had every reason to expect that its auxiliary requests would be held inadmissible by the

Board as *reformatio in peius.* Moreover, by the Board's reference to decision G 1/99 (*loc. cit*.), its attention was drawn to the possibility of filing other requests than present auxiliary requests 1 to 4. Finally, it appears that, for example by consolidation of dependent claim 3 with claim 1 in each of the current auxiliary requests, requests could have been filed to make the disclaimer superfluous and which would have overcome the problem of *reformatio in peius.* The respondent's current auxiliary requests 1 to 4 must therefore be held inadmissible.

Costs

7. The respondent's first request for costs relates to new evidence filed by the appellant on appeal. The respondent complains, first, that there is no explanation from the appellant why such evidence could not have been filed at first instance and, second, that many of the submissions in the grounds of appeal were misleading or contradictory. As to the first complaint, nearly all evidence filed on appeal can, unless prompted by a wholly new argument from another party or a communication from the Board, be characterised as late and the appellant should have explained why it did not produce all its evidence at first instance. In fact, of the six items of evidence of which the respondent complains, three, documents (D7) to (D9), were extracts from dictionaries and one, document (D12), was a patent of the respondent itself. Thus the volume of evidence new to the respondent with which it was obliged to deal was not great and the respondent in fact took ample time (from August 1998 to March 1999) in which to consider and answer it.

7.1 As to the second complaint, the Board notes that the respondent simply alleges the appellant's submissions were misleading and contradictory without giving any particulars other than the words "as discussed above", then requests an apportionment of costs saying that "as a direct consequence" it has been required to do "unnecessary additional work and details of the associated costs will be furnished upon request". However, it is for a party making a request to provide the Board with sufficient information to enable it to consider the request. It is not for the Board first to discern the reasons for the underlying complaint from elsewhere in the party's submissions, then secondly to guess how much (if any) additional work the party has been put to, and then lastly to make inquiries of the party for further information. In the present case, even the first of those steps is impossible - as is only to be expected, the respondent's submissions criticise the appellant's case frequently, employing not only the terms "misleading" and "contradictory" but also making liberal use of expressions such as "distortion", "inaccurate", "vague", "inconsistent", "inadequate", and "improper". Yet the respondent gives no indication as to which of its many criticisms form the basis for its request. This request, which is supported only by a further inherent request that the Board in effect finds the substantiation itself, is, in the legal sense of the term, embarrassing.

7.2 The respondent's second request for costs relates to the admissibility issue as to whether throughout the appeal proceedings there was an appellant which was either an adversely affected party or the universal successor to such a party. That request was clearly based on the respondent's confidence in the correctness

of its own arguments, in particular that the appellant's business had been transferred in whole or in part to another legal person. For example, the respondent says that if Bristol-Myers Medical Imaging Inc. had "attempted to record themselves as the legitimate successor appellant at an earlier stage" then "in all probability no oral proceedings would have taken place" (the respondent actually refers here to Bristol-Myers Squibb Pharma Company but must have meant Bristol-Myers Medical Imaging Inc., since otherwise the costs request would make no sense). That argument shows clearly that the costs request is not only based on the respondent’s view of the "legitimate successor" (which it has failed to establish) but also on mere speculation as to how the proceedings would have developed had that unsubstantiated view proved correct. Since the respondent has failed on that issue, the related costs request cannot succeed. The Board would add that (as indicated in section 2 above) the respondent's use of its own evidence and arguments on the admissibility issue was, to use the respondent's own words, misleading and contradictory.

7.3 The Board observes that both parties are open to criticism as regards their conduct of this appeal. The appellant should not have filed new evidence on appeal without any explanation for not producing it at first instance, should not have waited until shortly before the oral proceedings to disclose its changes of name, and should not at that point have produced ambiguous evidence in that respect. The respondent should not have sought on the admissibility issue to make out a case which, on the all the available evidence including its own, was simply devoid of credibility, and should not have made requests for costs which were manifestly

hopeless. And both parties should not have continued the written proceedings beyond the point stipulated by the directions in the Board's communication. An order for apportionment of costs may only be made "for reasons of equity" (see Article 104(1) EPC). In the present case the conduct of both parties would make the balance of equity (or lack of equity) almost impossible to assess. The respondent's costs requests must be dismissed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

3. The respondent's requests for apportionment of costs are dismissed.

The Registrar: The Chairman:

A Townend J Riolo