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Datasheet for the decision of 16 February 2011

Case Number: T 1936/06 - 3.3.02

Application Number: 95922159.9

Publication Number: 0804252

IPC: A61K 51/08

Language of the proceedings: EN

Title of invention:
Monoamine, diamide, thiol-containing metal chelating agents

Patentee:
CIS bio international

Opponent:
BRACCO IMAGING S.p.A.

Headword:
Metal chelating agents/CIS BIO INTERNATIONAL

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC R. 68(2), 67
RPBA Art. 11

Keyword:
"Substantial procedural violation (yes)"
"Fundamental deficiences (yes)"
"Decision not reasoned"
"Reimbursement of appeal fee (yes)"

Decisions cited:
G 0009/91, G 0010/93, T 0543/89, T 0740/93, T 0278/00

Catchword:

-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1936/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 16 February 2011

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 30 October 2006 concerning maintenance of European patent No. 0804252 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
T. Karamanli

Summary of Facts and Submissions

I. European patent No. 0 804 252, which is based on an international application published as WO 95/033497, was granted on the basis of twenty one claims.

Independent claims 1, 7 to 13 and 15 to 21 as granted read as follows:

1. A reagent for preparing a radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, with the proviso that the reagent is neither of the following structures:

   cyclo.(*N*-CH_3)F.YW_DKV.Hcy(CH_2CO.K(ε-K)GC.amide;
   cyclo.(*N*-CH_3)F.YW_DKV.Hcy(CH_2CO.(ε-K)GC.amide; and
   CH_2CO.FFW_DKTFC(ε-K)GC.amide.

7. A scintigraphic imaging agent for imaging sites within a mammalian body that is a composition of matter of any one of Claims 1 to 6 radiolabeled with a radioisotope selected from technetium-99m and copper-64.

8. A method for preparing a scintigraphic imaging agent for imaging sites within a mammalian body comprising either reacting a reagent of any one of Claims 1 to 6 with technetium-99m in the presence of a reducing agent, e.g. stannous ion, or reacting the reagent with Tc-99m wherein the Tc-99m is in a reduced form.

9. A method for preparing a reagent of any one of Claims 1 to 6 wherein the reagent is synthesized by solid phase peptide synthesis.

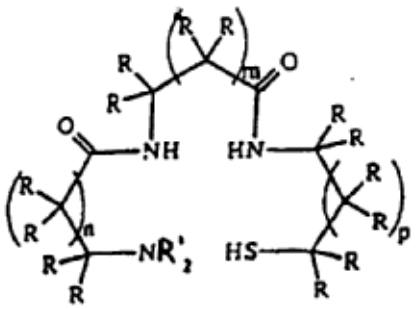
10. A kit for preparing a radiopharmaceutical preparation, said kit comprising sealed vial containing a predetermined quantity of a reagent according to any one of Claims 1 to 6 and a sufficient amount of reducing agent to label said reagent with Tc-99m.

11. The use of a reagent of any one of Claims 1 to 6 or an agent of Claim 7 in the manufacture of a medicament for imaging a target site within a mammalian body.

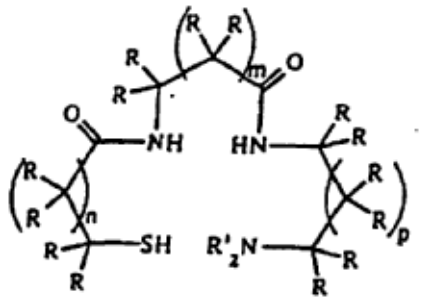
12. A radiotherapeutic agent comprising a reagent of any one of Claims 1 to 6 radiolabeled with a radionuclide selected from the group consisting of Re-186, Re-188, Sn-117m, and Cu-67.

13. A composition of matter comprising a monoamine, diamide, thiol-containing metal chelator selected from:

(i) a group having the formula:



or (ii) a group having the formula:



wherein:

n, m and p are each independently 0 or 1,
each R' is independently H, lower alkyl, hydroxyalkyl (C_2-C_4), or alkoxyalkyl (C_2-C_4);
each R is independently H or R", where R" is substituted or unsubstituted lower alkyl or phenyl not comprising a thiol group;
one R or R' is L, wherein when an R' is L, -NR'_2 is an amine; and
L is a bivalent linking group linking the chelator to the targeting moiety.

15. A radiopharmaceutical agent comprising the composition of matter of Claim 14.

16. A composition of matter comprising, in combination, a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety,
with the proviso that the chelator covalently linked to the targeting moiety does not form any of the following structures:

cyclo.(*N*-CH_3)F.YW$_D$KV.Hcy(CH_2CO.K(ε-K)GC.amide;
cyclo.(*N*-CH_3)F.YW$_D$KV.Hcy(CH_2CO.(ε-K)GC.amide; and
CH_2CO.FFW$_D$KTFC(ε-K)GC.amide.

17. A composition of matter according to Claim 16 wherein the metal chelator is complexed with a metal which is either selected from rhenium, zinc, copper, tin, optionally rhenium-186, rhenium-188, copper-67 or tin-117m, or which metal is technetium-99m or copper-64.

18. A radiopharmaceutical agent comprising a composition of matter of Claim 17.

19. The use of a reagent of any one of Claims 1 to 6 or an agent of Claim 12 in the manufacture of a radiotherapeutic medicament.

20. The use of a composition of matter of Claim 13 or Claim 14, or of an agent of Claim 15, or of a composition of matter of Claim 16 or Claim 17, or of an agent of Claim 18, in the manufacture of a radiopharmaceutical medicament.

21. A reagent of any one of Claims 1 to 6, an agent of Claim 7, an agent of Claim 12, a composition of matter of Claim 13 or Claim 14, or a composition of matter of Claim 16 or Claim 17, in each case for use as a pharmaceutical.

II. Opposition was filed on the grounds pursuant to Article 100(a) EPC 1973 (lack of novelty, vis-à-vis several documents, and lack of inventive step), 100(b) EPC 1973 (insufficiency of disclosure) and 100(c) EPC 1973 (extended subject-matter). The opponent requested revocation of the patent in its entirety.

III. The following documents *inter alia* were cited during the opposition proceedings:

D1 WO 91/17173
D3 WO 92/21383
D5 WO 95/03330
D7 WO 95/00553
D14 US 4986979

Documents D1, D3, D5, and D7 were already cited in the notice of opposition.

IV. With letter dated 23 February 2005 the patent proprietor filed an amended set of claims as its main and sole request.

Claim 1 of the main request filed with the letter of 23 February 2005 read as follows:

1. A reagent for preparing a radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, with the proviso that the reagent is neither of the following structures:

cyclo.(*N*-CH_3)F.YW_DKV.Hcy(CH_2CO.K(ε-K)GC.amide;
cyclo.(*N*-CH_3)F.YW_DKV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW_DKTFC(ε-K)GC.amide;

F_D.Cpa.YW_DK.Abu.Nal.T(ε-K)GC.amide;
Ac.F_D.FYW_DKTFT(ε-K)GC.amide;
(DTPA).F_D.FYW_DKTFT(ε-K)GC.amide;
Ac.F_DFYW_DKTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF_D.FYW_DKTFT.amide;
Ac.F_DFYW_DKTFGGG(ε-K)KC.amide;
(DTPA)F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).Aca.F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GCKK.amide; and
F_D.Cpa.YW_DKTFT(ε-K)GC.amide

V. The parties were duly summoned to oral proceedings by the opposition division. The opposition division sent as an annex to the summons a communication expressing its preliminary opinion.

The passages of the preliminary opinion concerning Articles 123 and 54 and 56 EPC 1973 read as follows:

2. Extension beyond Original Disclosure

The application as originally filed makes frequent reference to radiopharmaceuticals. Furthermore, page 19, lines 20-26 of the original publication WO-A-95/33497 recites a therapeutic effect exerted by the claimed compounds. Therefore, the objection under Article 123 (2) EPC to claim 21 is considered to be unfounded.

3. Novelty, Inventive Step

By restricting the claims, novelty is considered to have been established. The question of novelty and inventive will be discussed in more detail during the Oral Proceedings. The closest prior art document(s) which could stand in the way of novelty and inventive step will have to be identified.

The opposition division did not give any comment about the allowability of the disclaimers introduced in the amended claim 1.

VI. The opponent filed a response to the opposition division's communication with its letter dated 23 December 2005 and filed therewith several additional documents.

VII. The patent proprietor filed a response dated 27 January 2006. It filed therewith a new main request and an auxiliary request.

Claim 1 of the new main request filed with letter of 27 January 2006 read as follows:

New Claims

1. A reagent for preparing a radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, with the proviso that the reagent is neither of the following structures:

cyclo.(N-CH_3)F.YW_DKV.Hcy(CH2CO.K(ε-K)GC.amide;
cyclo.(N-CH_3)F.YW_DKV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW_DKTFC(ε-K)GC.amide;
F_D.Cpa.YW_DK.Abu.Nal.T(ε-K)GC.amide;
Ac.F_D.FYW_DKTFT(ε-K)GC.amide;
(DTPA).F_D.FYW_DKTFT(ε-K)GC.amide;
Ac.F_DFYW_DKTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF_D.FYW_DKTFT.amide
Ac.F_DFYW_DKTFGGG(ε-K)KC.amide;
(DTPA)F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).Aca.F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GCKK.amide; and
F_D.Cpa.YW_DKTFT(ε-K)GC.amide

Claim 1 of the auxiliary request filed with letter of 27 January 2006:

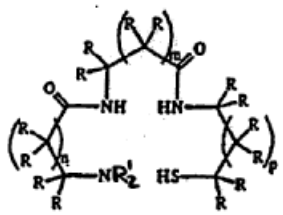
Auxiliary Request

(as filed January 27, 2006)

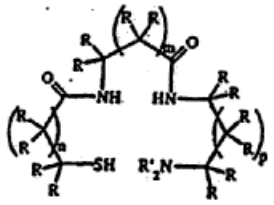
New Claims

1. A reagent for preparing a radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, wherein the metal chelator is selected from:

(i) a group having the formula:



and (ii) a group having the formula:



wherein:

n, m and p are each independently 0 or 1;

each R' is independently H, lower alkyl, hydroxyalkyl (C_2-C_4), or alkoxyalkyl (C_2-C_4);

each R is independently H or R", where R" is substituted or unsubstituted lower alkyl or phenyl not comprising a thiol group;

one R or R' is L, wherein when an R' is L, -NR'_2 is an amine; and

L is a bivalent linking moiety linking the chelator to the targeting moiety and is either a covalent bond or selected from a C_1-C_6 linear, branched chain or cyclic alkyl group, a carboxylic ester, a carboxamide, a sulfonamide, an ether, a thioether, an amine, an alkene, an alkyne, a 1,2-, 1,3- or 1,4-linked, optionally substituted, benzene ring, or an amino acid or peptide of 2 to about 10 amino acids, or combinations thereof;

with the proviso that the reagent is neither of the following structures:

cyclo.(N-CH_3)F.YW_DKV.Hcy(CH2CO.K(ε-K)GC.amide;
cyclo.(N-CH_3)F.YW_DKV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW_DKTFC(ε-K)GC.amide;
F_D.Cpa.YW_DK.Abu.Nal.T(ε-K)GC.amide;
Ac.F_D.FYW_DKTFT(ε-K)GC.amide;
(DTPA).F_D.FYW_DKTFT(ε-K)GC.amide;
Ac.F_DFYW_DKTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF_D.FYW_DKTFT.amide
Ac.F_DFYW_DKTFGGG(ε-K)KC.amide;
(DTPA)F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).Aca.F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GCKK.amide; and
F_D.Cpa.YW_DKTFT(ε-K)GC.amide

VIII. Oral proceedings took place before the opposition division on 23 February 2006.

IX. The electronic file (see Rule 147(3) EPC and the decision of the President of the EPO dated 12 July 2007, OJ EPO, special edition No. 3, 2007) shows EPO Form 2341 07.02 (with the stamp: scanned to Phoenix dated 27 February 2006). This form, which was provided for the sake of information, contains the following handwritten "Information": "*Das Verfahren wird schriftlich forgesetzt*" (*in German in the original*).

X. The minutes of the oral proceedings held on 23 February 2006 were sent to the parties on 17 March 2006 together with EPO Form 2042 04.00CSX. The minutes are accompanied by several annexes numbered as annex 1 to annex 8.

The minutes of the oral proceedings held before the opposition division show *inter alia* the following:

. *Main request*

The opponent raised objections under Articles 123(2), 84 and 54 EPC 1973 against the claims of the main request.

The patentee gave counterarguments thereto.

The opposition division announced the conclusion that the main request met the requirements of Articles 123(2) and 84 EPC 1973 and that claim 1 of the main request lacked novelty vis-à-vis documents D1 and D3.

. (*First*) *Auxiliary request*

The opponent gave specific reasons why the definitions in relation to the linker lacked clarity and did not restore novelty of claim 1.

The patent proprietors answered that the amendments were clear to the skilled person.

The opposition division announced the conclusion that the amendments introduced in the auxiliary request did not limit the claimed subject-matter over the prior art and that the "linker definition did not meet the requirements of Article 84 EPC".

Claim 1 of the second auxiliary request in annex 6 is reproduced as follows:

2nd Auxiliary Request

~~Main Request~~

New Claims

1. A reagent for preparing a radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, * with the proviso that the reagent is neither of the following structures:

cyclo.(N-CH_3)F.YW$_D$KV.Hcy(CH2CO.K(ε-K)GC.amide;
cyclo.(N-CH_3)F.YW$_D$KV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW$_D$KTFC(ε-K)GC.amide;
F$_D$.Cpa.YW$_D$K.Abu.Nal.T(ε-K)GC.amide;
Ac.F$_D$.FYW$_D$KTFT(ε-K)GC.amide;
(DTPA).F$_D$.FYW$_D$KTFT(ε-K)GC.amide;
Ac.F$_D$FYW$_D$KTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF$_D$.FYW$_D$KTFT.amide
Ac.F$_D$FYW$_D$KTFGGG(ε-K)KC.amide;
(DTPA)F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).Aca.F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW$_D$KTFT(ε-K)GCKK.amide; and
F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide

* <wherein said targeting moiety localizes to a greater extent at the target site than to surrounding tissues, ...>

(There is no further written text in the set of claims in annex 6 for completing the incomplete amendment shown by means of "...").

The opponent raised objections under Articles 123(2) and 84 EPC 1973.

The patent proprietor gave counterarguments thereto.

The opposition division announced the conclusion that the second auxiliary request met the requirements of Articles 123(2) and 84 EPC 1973.

The opponent raised objections against the novelty of claim 1 of the second auxiliary request.

The patent proprietor gave counterarguments.

The opposition division announced the conclusion that claim 1 of the second auxiliary request lacked novelty vis-à-vis D2 or D3.

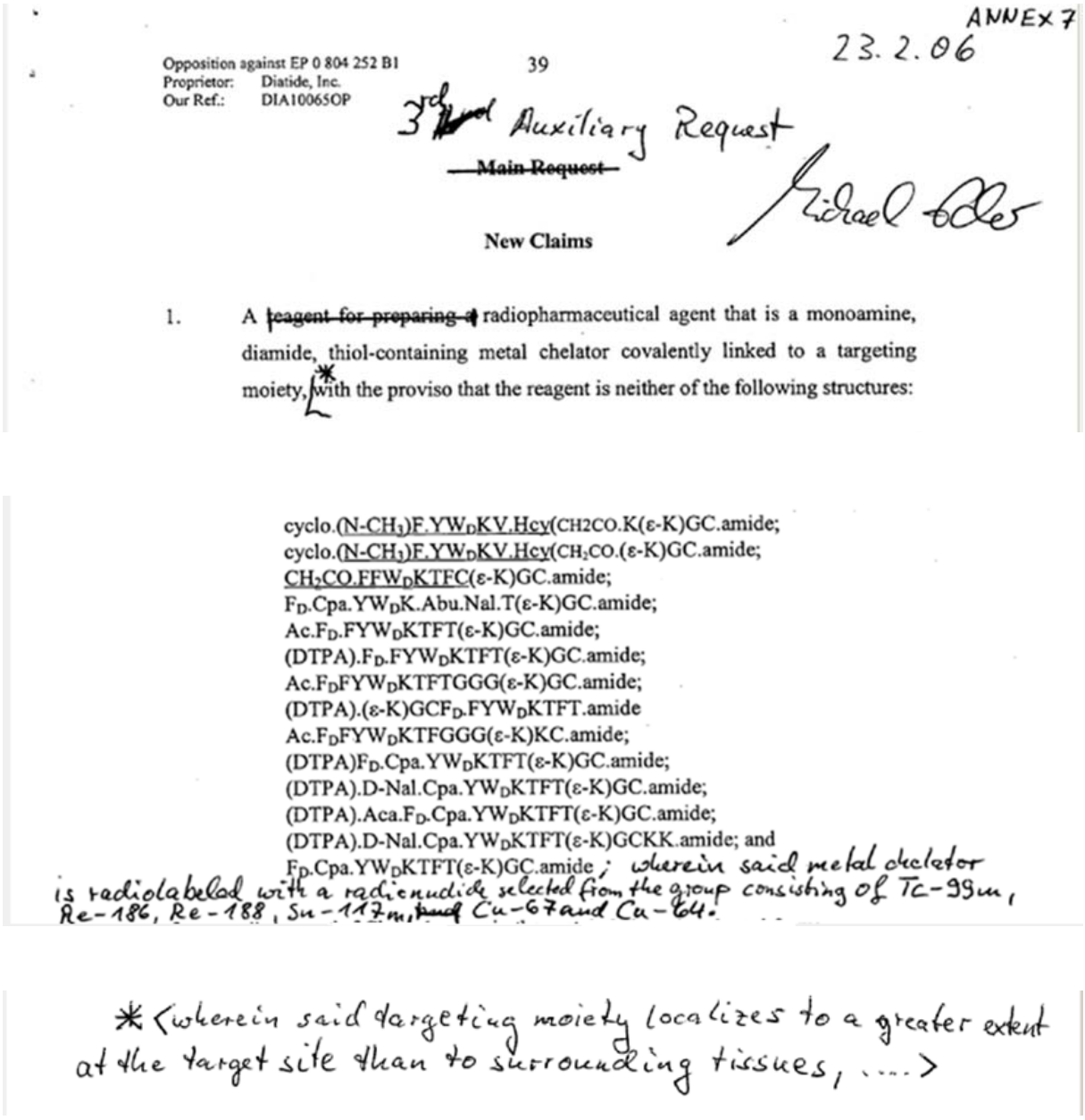
. *Third auxiliary request filed at the oral proceedings (both annexes 7 and 8 are entitled "Third auxiliary request")*

The differences between the two different "3rd auxiliary request" in annexes 7 and 8 concern a different claim 1 and different claims 8 and 9. The version in annex 8 appears to correspond to the second version of the third auxiliary request filed at the oral proceedings, which was later on further modified by deletion of claim 9 and renumbering of subsequent claims.

It becomes evident from the reading of the minutes that the opposition division announced a positive conclusion for the third auxiliary request previously on file even before the written version in annex 8 was filed (identified in the minutes as "corrected version" although it still contains an incomplete claim 1).

Claims 1, 8 and 9 of the third auxiliary request as in annex 7 and of the third auxiliary request as in annex 8 are reproduced as follows:

Claim 1 of the third auxiliary request in annex 7 reads as follows:



ANNEX 7
23.2.06

Opposition against EP 0 804 252 B1
Proprietor: Diatide, Inc.
Our Ref.: DIA10065OP

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3rd ~~Main~~ Auxiliary Request
~~Main Request~~

New Claims

1. A ~~reagent for preparing a~~ radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, * with the proviso that the reagent is neither of the following structures:

cyclo.(N-CH_3)F.YW$_D$KV.Hcy(CH2CO.K(ε-K)GC.amide;
cyclo.(N-CH_3)F.YW$_D$KV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW$_D$KTFC(ε-K)GC.amide;
F$_D$.Cpa.YW$_D$K.Abu.Nal.T(ε-K)GC.amide;
Ac.F$_D$.FYW$_D$KTFT(ε-K)GC.amide;
(DTPA).F$_D$.FYW$_D$KTFT(ε-K)GC.amide;
Ac.F$_D$FYW$_D$KTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF$_D$.FYW$_D$KTFT.amide
Ac.F$_D$FYW$_D$KTFGGG(ε-K)KC.amide;
(DTPA)F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).Aca.F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW$_D$KTFT(ε-K)GCKK.amide; and
F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide ; wherein said metal chelator is radiolabeled with a radionuclide selected from the group consisting of Tc-99m, Re-186, Re-188, Sn-117m, ~~and~~ Cu-67 and Cu-64.

* <wherein said targeting moiety localizes to a greater extent at the target site than to surrounding tissues, ...>

(There is no further text in said annex 7 for completing the incomplete amendment shown with "...").

Claims 8 and 9 according to the third auxiliary request in annex 7 read as follows:

8. A method for preparing a scintigraphic imaging agent for imaging sites within a mammalian body comprising either reacting a reagent of any one of Claims 1 to 6 with technetium-99m in the presence of a reducing agent, e.g. stannous ion, or reacting the reagent with Tc-99m wherein the Tc-99m is in a reduced form.

9. A method for preparing a reagent of any one of Claims 1 to 6 wherein the reagent is synthesized by solid phase peptide synthesis.

Claim 1 of third auxiliary request in annex 8 reads as follows:

ANNEX 8
23.2.2006

Opposition against EP 0 804 252 B1 39
Proprietor: Diatide, Inc.
Our Ref.: DIA10065OP

3rd Auxiliary Request ~~Main Request~~

New Claims

1. A ~~reagent for preparing a~~ radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, [* with the proviso that the ~~re~~agent is neither of the following structures: [**

cyclo.(N-CH_3)F.YW$_D$KV.Hcy(CH_2CO.K(ε-K)GC.amide;
cyclo.(N-CH_3)F.YW$_D$KV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW$_D$KTFC(ε-K)GC.amide;
F$_D$.Cpa.YW$_D$K.Abu.Nal.T(ε-K)GC.amide;
Ac.F$_D$.FYW$_D$KTFT(ε-K)GC.amide;
(DTPA).F$_D$.FYW$_D$KTFT(ε-K)GC.amide;
Ac.F$_D$FYW$_D$KTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF$_D$.FYW$_D$KTFT.amide
Ac.F$_D$FYW$_D$KTFGGG(ε-K)KC.amide;
(DTPA)F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).Aca.F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW$_D$KTFT(ε-K)GCKK.amide; and
F$_D$.Cpa.YW$_D$KTFT(ε-K)GC.amide; wherein said metal chelator is complexed with a radionuclide selected from the group consisting of Tc-99m, Re-186, Re-188, Sn-117m, Cu-67 and Cu-64.

*< wherein said targeting moiety localizes to a greater extent at the target site than to surrounding tissues in a mammalian body>

**< >

(There is no further text in said annex 8 for completing the incomplete amendment shown with **< >).

Claims 8 and 9 of the third auxiliary request in annex 8 read as follows:

8. A method for preparing a scintigraphic imaging agent for imaging sites within a mammalian body comprising either reacting ~~a reagent~~ <an uncomplexed agent> of any one of Claims 1 to 6 with technetium-99m in the presence of a reducing agent, e.g. stannous ion, or reacting ~~the reagent~~ <said uncomplexed agent> with Tc-99m wherein the Tc-99m is in a reduced form.

~~9. A method for preparing a reagent of any one of Claims 1 to 6 wherein the reagent is synthesized by solid phase peptide synthesis.~~

9. ~~10.~~ A kit for preparing a radiopharmaceutical preparation, said kit comprising sealed vial containing a predetermined quantity of ~~a reagent~~ an agent according to any one of Claims 1 to 6 and a sufficient amount of reducing agent to label said reagent with Tc-99m.

It is recorded in the minutes that the patent proprietor requested "that the term "mammalian body" be introduced in the claims" (*this amendment does not appear in claim 1 of the third auxiliary request in annex 7, but it appears in claim 1 of the third auxiliary request in annex 8*)

The opponent raised some objections within the sense of Article 84 EPC 1973.

The patent proprietor gave counterarguments thereto.

The opposition division announced before the set of claims in annex 8 was filed that the third auxiliary request met the requirements of Article 84 EPC.

The opponent objected to the novelty of the third auxiliary request in relation to documents D1 and D3.

The patent proprietor gave arguments thereto.

The following is recorded in point 22 of the minutes (*OD, means opposition division*):

> 22. OD remarked that a proper basis for claim 1 seemed to be a wording "wherein said metal chelator is complexed with" as was present in original claims 27 and 28. P agreed to that amendment and O did not object under Article 123(2) EPC.

(*this amendment does not appear in claim 1 of the third auxiliary request in annex 7, but it appears in claim 1 of the third auxiliary request in annex 8*).

The opponent maintained its objection of lack of novelty vis-à-vis documents D1 and D3.

The opposition division announced, before the set of claims in annex 8 was filed, the conclusion that "the subject-matter of claim 1 was novel over documents D1 and D3 given that the disclaimer was rectified as the opponent had not proven that D3 was detrimental to novelty" (*verbatim reproduction*).

The discussion on inventive step took then place.

Thereafter the opposition division announced (before the set of claims in annex 8 was filed) the conclusion that "the subject-matter of claim 1 of the third

auxiliary request was inventive over the closest prior art D14, as there was no indication how to modify the chelators of said document".

The opponent objected to the inconsistency of the other claims in the set of claims of the third auxiliary request (Article 84 EPC 1973).

The filing of an amended version for the third auxiliary request, identified as "Annex 8" is reported in point 29 of the minutes after the opposition division had already announced a positive conclusion on the basis of hypothetical amendments for Articles 84, 54 and 56 EPC 1973.

Thereafter, it is recorded in the minutes that the opponent stated that claim 9 of the third auxiliary request did not make sense and commented that it appeared that two more compounds from a further document (*the international application D5*) still fell within the scope of amended claim 1 and had not been disclaimed.

Without further discussion in relation to the incomplete wording of claim 1 of the version in annex 8, the opposition division announced the "conclusion" that "the present claims 1 to 17 (*i.e. with deletion of claim 9 of a previous version*) fulfilled the requirements of the EPC **under the condition that the correct disclaimers were introduced"** (*emphasis added*). There is no mention to the form or text for such disclaimers and no further information is given in the minutes except that it was "stressed that no further

amendments would be accepted and that the description had to be adapted".

At the end of the Form of the minutes it is stated: "**The proprietor is/are given a period of 2 months to introduction of disclaimers and adaptation of description**" (*emphasis added*).

XI. With a letter dated 27 March 2006 the opponent stated that it had received a copy of the minutes of the oral proceedings with an accompanying invitation "to file observations and correct the deficiencies" within a two month period. The opponent expressed that it presumed that this invitation was intended for the patentee since the addressee was requested to file "a corrected disclaimer and an adapted description".

XII. The patent proprietor filed with a letter dated 17 May 2006 a **modified 3rd auxiliary request** and an adapted description thereto. It also filed as annex to said letter the priority documents (numbered D5P and D7P) of the two international applications D5 and D7.

In fact, the patent proprietor stated the following in its letter of 17 May 2006: "The Proprietor herewith files an amended claim set (claims 1 to 17) that essentially corresponds to the 3rd auxiliary request filed during the oral proceedings on February 23, 2006 **save for an adaptation of the disclaimer in claims 1 and 14 to exclude the entire overlapping subject matter from D5** (**only subject matter that itself validly claims priority from D5P**, USSN 08/095760) and two minor amendments in claim 2 and 16" (*emphasis added*).

Claim 1 of third auxiliary request filed with the letter of 17 May 2006 reads as follows:

1. A radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, wherein said targeting moiety localizes to a greater extent at the target site than to surrounding tissues in a mammalian body, and wherein said metal chelator is complexed with a radionuclide selected from the group consisting of Tc-99m, Re-186, Re-188, Sn-117m, Cu-67 and Cu-64,

with the proviso that the agent, when complexed with Tc-99m, Re-186, Re-188, or Cu-67, is neither of the following structures:

cyclo.(N-CH_3)F.YW_DKV.Hcy(CH2CO.K(ε-K)GC.amide;
cyclo.(N-CH_3)F.YW_DKV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW_DKTFC(ε-K)GC.amide;
F_D.Cpa.YW_DK.Abu.Nal.T(ε-K)GC.amide;
Ac.F_D.FYW_DKTFT(ε-K)GC.amide;
(DTPA).F_D.FYW_DKTFT(ε-K)GC.amide;
Ac.F_DFYW_DKTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF_D.FYW_DKTFT.amide
Ac.F_DFYW_DKTFGGG(ε-K)KC.amide;
(DTPA)F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).Aca.F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GCKK.amide;
F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
AKCGGGF_D.Cpa.YW_DKTFT.amide; and
AF_DCFW_DKTC_{Me}T(CH_2OH).

The patent proprietor also stated the following in its letter of 17 May 2006: "Finally, a copy of D5P and D7P is also attached **to allow a convenient evaluation of the amendments in the disclaimer**" (emphasis added).

Additionally, said letter of the patent proprietor contains a reasoned explanation of the amendments concerning the disclaimer in view of the alleged validity or non-validity of the priority for the products disclosed in the international applications D5 and D7.

XIII. A copy of the letter from the patent proprietor dated 17 May 2006, together with the cited documents, was sent to the opponent as a "Brief communication" (EPO Form 2912). With this form a period of two months was given to the opponent for filing observations. The opposition division did not add any substantive comments to EPO Form 2912.

XIV. The opponent filed a letter dated 3 August 2006 in which it can be read the following: "In response to the Brief Communication dated 26 May 2006, the Opponent has no observations to make at present".

XV. An interlocutory decision maintaining the patent in amended form (Articles 102(3) and 106(3) EPC 1973) on the basis of the 3rd auxiliary request filed with the letter of 17 May 2006 was issued on 26 October 2006 (a copy of this set of claims was annexed to the decision, together with a copy of the adapted description).

Point 10 (pages 3 to 5) of the facts and submissions in the opposition division's decision is dedicated to the oral proceedings held on 23 February 2006. The following can be read on pages 4 and 5 of the decision of the opposition division:

> During the Oral Proceedings, the Patentee filed a 2nd Auxiliary Request and a 3rd Auxiliary Request.
>
> ...
>
> Claim 1 of the **3rd Auxiliary Request** read as follows:
>
> "1. A radiopharmaceutical agent that is a monoamine, diamide, thiol-containing metal chelator covalently linked to a targeting moiety, wherein said targeting moiety localizes to a greater extent at the target site than to surrounding tissues in the mammalian body, and wherein said metal chelator is complexed with a radionuclide selected from the group consisting of Tc-99m, Re-186, Re-188, Sn-117m, Cu-67 and Cu-64,

with the proviso that the agent, when complexed with Tc-99m, Re-186, Re-188, or Cu-67 is neither of the following structures:

cyclo.(*N*-CH_3)F.YW_DKV.Hcy(CH_2CO.K(ε-K)GC.amide;
cyclo.(*N*-CH_3)F.YW_DKV.Hcy(CH_2CO.(ε-K)GC.amide;
CH_2CO.FFW_DKTFC(ε-K)GC.amide;
F_D.Cpa.YW_DK.Abu.Nal.T(ε-K)GC.amide;
Ac.F_D.FYW_DKTFT (ε-K)GC.amide;
(DTPA).F_D.FYW_DKTFT(ε-K)GC.amide;
Ac.F_DFYW_DKKTFTGGG(ε-K)GC.amide;
(DTPA).(ε-K)GCF_D.FYW_DKTFT.amide;
Ac.F_DFYW_DKTFGGG(ε-K)KC.amide;
(DTPA)F_D.Cpa.YW_DKTFT (ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).Aca.F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
(DTPA).D-Nal.Cpa.YW_DKTFT(ε-K)GCKK.amide; and
F_D.Cpa.YW_DKTFT(ε-K)GC.amide;
AKCGGGF_D.Cpa.YW_DKTFT.amide; and
AF_DCFW_DKTC_{Me}T(CH_2OH).

wherein said metal chelator is complexed with a radionuclide selected from the group consisting of Tc-99m, Re-186, Re-188, Sn-117m, Cu-67 and Cu-64."

The Main Request, 1st and 2nd Auxiliary Requests were rejected for lack of novelty.

Claim 1 of the 3rd Auxiliary Request was found to fulfil the requirements of the EPC. Claims 9 and 10 as granted were deleted and the remaining claims renumbered and/or brought into line with claim 1. At the end of the Oral Proceedings, the Patentee was given a time limit of two months upon receipt of the Minutes to file a clean-typed version of the accepted claims and a description adapted thereto.

Moreover, points 11 and 12 of the facts and submissions read as follows:

11. With his letter dated 17 May 2006, the Patentee filed clean copies of the claims of the 3rd Auxiliary Request together with description pages which had been adapted to the said claims.

12. On 3 August 2006, the Opponent notified in reply to the Office's communication of the newly filed pages of the patent that he had no observations.

Additionally, the reasons for the decision (two pages) under the heading of "3rd auxiliary request" is herewith reproduced in its full:

3. 3rd Auxiliary Request

Since complexes with radionuclides have not been mentioned in D1 and D3, the 3rd Auxiliary Request is considered to be novel.

The problem underlying the patent was the provision of new radiopharmaceuticals.

The closest prior art is D14. The present claimed radiopharmaceuticals differ from those known from D14 by the mandatory presence of an amino and a thiol group. D14 neither when taken alone nor in combination with any other document cited during the procedure would suggest introduction of both an amino and a thiol group into radiopharmaceuticals and thus allow one skilled in the art to arrive at the present claimed radiopharmaceuticals.

Therefore, the solution to the problem, i.e. the radiopharmaceuticals of claim 1, are considered to be inventive.

For the reasons set out above, the claims of the 3rd Auxiliary Request and the description adapted thereto are considered to fulfil the requirements of the EPC.

Thus, there is no comment whatsoever or reasoning in relation to the disclaimers and there is no specific mention to the applications D5 and D7.

XVI. The patent proprietor and the opponent filed appeals to the interlocutory decision of the opposition division. They both filed counterarguments to the other party's appeal.

XVII. The board sent a communication on 26 February 2010 in which it expressed essentially the opinion that a substantial procedural violation had taken place since the opposition division decision's was not reasoned.

The board also referred to Article 11 RPBA (Rules of Procedure of the Boards of Appeal, OJ EPO 2007, 536) which requires remittal of the case to the first instance if fundamental deficiencies are apparent in

the first instance proceedings unless special reasons are present for doing otherwise.

The board informed the parties, that it intended to set aside the decision under appeal and remit the case to the opposition division. The board also expressed the opinion that under the circumstances of the case it was equitable to order reimbursement of the appeal fee for each appeal. However, since both appellants had requested oral proceedings the parties were requested to inform the board within two months whether they maintained their request for oral proceedings and to file any observations in case that any special reasons were known to them not to remit the case to the department of first instance.

XVIII. The appellant-opponent filed a response with its letter dated 26 April 2010. In said letter the opponent stated the following:
"under the circumstances depicted by the Board (i.e. that the Board will set aside the Opposition Division's (OD's) decision, order **reimbursement of the appeal fee** (*emphasis added*) and remit the case to the OD), we **withdraw** our request for oral proceedings; and we agree with the Board that there is no special reason not to remit".

XIX. No response of the appellant-patent proprietor was filed during the given period.

XX. The board sent to the parties on 11 June 2010 a summons to oral proceedings to be held on 14 October 2010. It sent as an annex thereto a communication pursuant to Article 15(1) RPBA in which it clarified that since the

appellant-patent proprietor had not withdrawn its request for oral proceedings, which were requested unless the board indicated that the patent could be upheld on the basis of the new main request submitted with the statement of the grounds of appeal, oral proceedings had to be held before issuing a decision.

The board also mentioned that in the oral proceedings the issue of remittal in view of the fundamental deficiencies in the first instance proceedings will be discussed and that the parties should be prepared to discuss a possible different apportionment of costs according to Article 104(1) and Rule 88 EPC.

XXI. The appellant-patent proprietor filed a response with its letter dated 14 July 2010. In said letter it stated that it **withdrew** its request for oral proceedings and that the board "may proceed to remit the case to the first instance if it is so inclined without hearing the parties on this issue".

Moreover, the patent proprietor stated the following: "it is respectfully submitted that in view of the withdrawal of applicant's request for Oral Proceedings there should be no reason for deciding on such a disproportionate apportionment of costs between the parties. For the record, we note that the Patentee has had no influence whatsoever on the reasoning given by the OD in the appealed decision and therefore bears no responsibility for the procedural violation apparently committed by the OD. It would therefore not seem justified to have one party bear more than their own costs generated for the present appeal proceedings".

It also expressed that it understood that "as a next step the Board will issue a decision in writing remitting the case to the first instance and to **reimburse the appeal fee for both appellants**".

XXII. The oral proceedings appointed for 14 October 2010 were cancelled.

Reasons for the Decision

1. *Admissibility*

1.1 The appeals are admissible.

2. Both parties have been given the opportunity to file observations in writing in relation to the board's intention to set aside the first instance decision and to remit the case to the opposition division (the reasons for this were analysed in detail in the board's communication dated 26 February 2010). In fact, both parties have filed brief observations.

Additionally, both appellants have withdrawn their request for oral proceedings, thus there are no grounds left to hold oral proceedings for discussing the reasons for the remittal.

Therefore, the board cancelled the oral proceedings and informed the parties accordingly.

3. *Rule 68(2) EPC 1973*

3.1 The first question to be decided in this appeal is whether the first instance decision was sufficiently reasoned. Therefore the board has to establish whether the impugned decision complies with the relevant provisions of EPC 1973, in force at the date of said decision.

3.2 Rule 68(2), first sentence EPC 1973 provides that decisions of the European Patent Office open to appeal shall be reasoned. According to established jurisprudence of the Boards of Appeal, to satisfy the requirement of Rule 68(2) EPC 1973 a decision must contain, in logical sequence, those arguments which justify its tenor. The conclusions drawn by the deciding body from the facts and evidence must be made clear. Therefore all the facts, evidence and arguments which are essential to the decision must be discussed in detail in the decision including all the decisive considerations in respect of the factual and legal aspects of the case. The purpose of the requirement to reason the decision is to enable the parties and, in case of an appeal, also the board of appeal to examine whether the decision could be considered to be justified or not (see e.g. T 278/00, OJ EPO, 2003, 546).

3.3 Therefore, even if the opponent chose not to file any further observations on the new third auxiliary request filed with the letter dated 17 May 2006, the opposition division should have given the reasons for the dismissal of the objections previously submitted by the opponent in opposition proceedings and which were still applicable to the amended claims.

3.4 Reasoning does not mean that all the arguments submitted should be dealt with in detail, however, it is a general principle of good faith and fair proceedings that reasoned decisions contain, in addition to the logical chain of facts and reasons, at least some motivation on crucial points of dispute insofar as this is not already apparent from other reasons given (see for example T 740/93, Reasons, point 5.4). This ensures not only that the party concerned has a fair idea as to why its submissions were not considered convincing so that it can react accordingly, but also that the board of appeal is in a position to review the decision taken by the first instance department, as is the primary purpose in appeal proceedings (see *inter alia* G 10/93, OJ EPO 1995, 172; T 534/89, OJ EPO 1994, 464).

3.5 In the present case, several amendments were introduced in the claims of the third auxiliary request filed with the letter of 17 May 2006, which formed the basis for the opposition division’s decision to maintain the patent in amended form in accordance with Articles 102(3) and 106(3) EPC 1973. According to the Enlarged Board of Appeal decision G 9/91, OJ EPO 1993, 408 (see Reasons, point 19), in case of amendments made by the proprietor during the opposition proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC, e.g. Article 123 EPC.

3.6 In the board's judgement, the above principles for a sufficiently reasoned decision have not been followed by the opposition division for the reasons as follows.

3.6.1 Although the patent proprietor filed at the oral proceedings an incomplete version of claim 1 with the last version of the third auxiliary request (annex 8), the opposition division asserted the following at the end of point 10 of the facts and submissions: "At the end of the oral proceedings, the patentee was given a time limit of two months upon receipt of the minutes to file a **clean-typed version** of the accepted claims and a description adapted thereto" (*emphasis added*). This is in clear contradiction with the reading of the minutes and their accompanying annexes 7 and 8, which makes it clear that the disclaimers in claim 1 had to be completed.

Thus, the last third auxiliary request filed at the oral proceedings (annex 8) was incomplete and required, as expressed in the minutes, further amendments to the disclaimers.

3.6.2 On top of that, the patentee's letter dated 17 May 2006 makes it absolutely clear that the third auxiliary request filed with said letter contained further, not yet discussed amendments. Therefore, it was manifest from the content of the letter dated 17 May 2006 that the enclosed third auxiliary request **was not** a "clean-typed version" of any version "accepted at the oral proceedings before the opposition division".

In fact, the patent proprietor stated in said letter that the new claim's wording (meaning amended claim 1) was the result of the analysis it had made about the relevance of the international applications D5 and D7 in consideration of the validity of their respective

priority (for this purpose it filed a copy of the priority documents of D5 and D7, namely D5P and D7P, respectively).

3.6.3 However, the decision under appeal does not give any reasons in relation to the international applications **D5 and D7** as prior art documents, nor about the validity of their respective priority. In fact, it is unclear from the decision under appeal whether the opposition division considered the content (or part of the content) of the international applications D5 and D7 as forming part of the state of the art within the meaning of Article 54(3) EPC 1973, or even within the meaning of Article 54(2) EPC.

Thus, the decision under appeal **is not reasoned in respect of the disclaimers** in claim 1 of the third auxiliary request which were introduced in view of the international applications D5 and D7. This lack of reasoning affects the assessment of the allowability of the disclaimers under Article 123(2) EPC 1973 and of the novelty of the subject-matter claimed (and it may even affect the assessment of inventive step).

3.7 Since the patent proprietor's letter dated 17 May 2006 is explicitly mentioned in the opposition division decision, and the amended set of claims of the third auxiliary request filed with said letter was annexed to the decision under appeal (together with an adapted description), it is to be assumed that the opposition division had that particular set of claims when the decision of maintenance in amended form was issued and sent to the parties. The reasons why the amended set of claims filed with the letter of 17 May 2006 was wrongly

qualified in the opposition division's decision as "clean copy" of the claims accepted at the oral proceedings remain unclear, but are irrelevant for achieving the conclusion that the decision under appeal is deficient in view of a lack of reasoning.

3.7.1 Moreover, it has to be stressed that novelty of the subject-matter claimed in the patent in suit was challenged right from the beginning in the opposition proceedings (i.e. with the notice of opposition) vis-à-vis (*inter alia*) documents D5 and D7. The objections of lack of novelty vis-à-vis these international applications were never abandoned by the opponent, as can be inferred from the content of the minutes of the oral proceedings before the opposition division, since even after the second filing of the third auxiliary request (annex 8 according to the minutes of the oral proceedings) by the patent proprietor, the opponent still raised an objection of lack of novelty vis-à-vis document D5 (see facts and submissions, above). As a consequence of this specific objection raised by the opponent in the oral proceedings, the opposition division asked the patent proprietor to provide for further disclaimers into claim 1 and gave the patentee two months time for the introduction of the appropriate disclaimers.

3.7.2 Additionally, the apparent reasons for the presence of the disclaimers are stated in the facts and submissions of the opposition division's decision (to be found on page 4 within the account given on the oral proceedings): "It was recorded that the provisos were **intended** to exclude compounds known from D5, D5P and D7", D5P is the priority document of the application D5,

(*emphasis added*). This statement implies a discussion with the parties in relation to the validity of the priority of the international application D5 (followed by a conclusion of the opposition division in this respect) which is neither reflected in the minutes of the oral proceedings nor in the reasons given in the decision under appeal for the maintenance on the basis of the third auxiliary request.

3.7.3 In point 3 of the Reasons for the impugned decision under the heading "3rd Auxiliary Request", the opposition division dealt with novelty only in relation to documents D1 and D3 and, as already said, remained silent in relation to the reasons why the amendments introduced into claim 1 serving as basis for the maintenance (in particular the introduction of several disclaimers) complied with the requirements Articles 84 and 123(2) EPC 1973.

3.7.4 The reasons for the introduction of the individual disclaimers are not self-evident and required therefore, inter alia, a detailed examination of several documents and their priority documents in order to conclude which parts, if any, of the international applications D5 and D7 form part of the state of the art within the meaning of Article 54(3) EPC 1973 (depending on the validity of the priority of these two applications), or (also depending on the validity of the priority of the patent in suit) within the meaning of Article 54(2) EPC 1973. Hence, the opposition division should have stated in the decision under appeal the reasons for the compliance of the amendments with Articles 84 and 123(2) EPC 1973 and the specific reasons why the amendments

were considered to be sufficient for establishing novelty over the international applications D5 and D7.

3.8 The first instance decision is the maintenance of the patent in amended form, therefore the opposition division had to fully examine the amendments as to their compatibility with the requirements of the EPC before it decided to maintain the patent in amended form (see Article 102(3) EPC 1973 and G 9/91, loc. cit.). Additionally, the opponent had raised objections under Article 84 EPC 1973 during the oral proceedings before the opposition division. Finally, disclaimers were introduced in claim 1 of the third auxiliary request to delimit and distinguish the claimed subject-matter from the state of the art on file (in particular D5 and D7).

Since some of the disclaimers were introduced in the claims during the opposition proceedings, it was necessary before deciding on novelty, to establish their allowability (Articles 84 and 123 EPC 1973), since it would have been futile to acknowledge novelty on the basis of an unallowable disclaimer.

3.9 As a matter of fact, in view of the lack of any specific reasoning in relation to claim 1 of the third auxiliary request and its compliance with Articles 84 and 123 EPC 1973, and Article 54 EPC 1973 (in relation to the international applications D5 and D7), the board cannot assess whether or not the opposition division examined all amendments, including the disclaimers, as to their compatibility with the requirements of the EPC.

It remains also unclear whether the objection and arguments submitted by the opponent with respect to Article 84 EPC 1973 have been considered by the opposition division and, if they were considered, for which reasons this objection does not anticipate the maintenance of the patent in amended form.

3.10 Therefore, in the absence of any reasoning in relation to the allowability of the amendments introduced in the claims of the third auxiliary request, the board cannot review the decision under appeal as to its merits, and the parties cannot express any opinion as to whether or not they consider the reasons for the decision to be justified.

Additionally, in view of this lack of reasoning in relation to Article 84 EPC 1973, the appellant-opponent cannot challenge the impugned decision in relation to the allowability of the amendments.

Thus, the logical chain of reasoning is missing in relation to Articles 84 and 123(2) EPC 1973 and the decision is also deficient in this respect.

3.11 Therefore, the decision of maintenance of the patent in amended form based on the amended third auxiliary request is not reasoned with respect to allowability of the disclaimers and is not sufficiently reasoned in relation to novelty, contrary to the requirements of Rule 68(2) EPC 1973.

3.12 Summarising, the omission of reasoning for the allowability of the amendments in claim 1, in particular in relation to the reformulated disclaimers

as a means for establishing novelty of the subject-matter in claim 1, and the insufficient reasoning for establishing novelty (this also applies to inventive step) pre-empted the filing of specific grounds of appeal properly challenging the opposition division's decision as to its merits. The lack of sufficient reasoning in relation to amended claim 1 of the third auxiliary request filed with letter of 17 May 2006 also hinders the board of appeal to perform a substantive revision of the first instance decision. Hence, the violation of Rule 68(2) EPC 1973 amounts to a procedural violation of a substantial nature since it affects the entire proceedings.

4. *Remittal to the department of first instance (Article 11 RPBA)*

Article 11 RPBA stipulates that a board shall remit a case to the department of first instance if fundamental deficiencies are apparent in the first-instance proceedings, unless special reasons present themselves for doing otherwise.

The above mentioned substantial violation of Rule 68(2) EPC 1973 amount to fundamental deficiencies in the sense of Article RPBA.

In the present case, the board sees no special reasons for not remitting the case to the department of first instance. None of the appellants submitted any special reason which would justify not to remit the case to the opposition division.

Thus, the board concludes that the decision under appeal must be set aside and the case remitted to the department of first instance in accordance with Article 11 RPBA.

5. *Reimbursement of the appeal fees (Rule 67 EPC 1973)*

The appeals are allowable insofar as the decision under appeal is set aside. The Board considers that in view of substantive procedural violation committed in the first instance proceedings, it is equitable to reimburse **both** appeal fees (Rule 67 EPC 1973).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

3. Both appeal fees are to be reimbursed.

The Registrar: The Chairman:

N. Maslin U. Oswald