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**Datasheet for the decision
of 13 March 2014**

Case Number: T 1980/09 - 3.3.02

Application Number: 01309145.9

Publication Number: 1203957

IPC: G01N33/543, G01N33/94

Language of the proceedings: EN

Title of invention:

Multi-analyte immunoassay

Patent Proprietor:

Randox Laboratories Ltd.

Opponent:

Roche Diagnostics GmbH

Headword:

Multi-analyte immunoassay/RANDOX

Relevant legal provisions:

EPC Art. 123(2), 123(3), 100(c)

Keyword:

"Main request, auxiliary requests 1 and 5: extension of protection conferred (yes)"

"Auxiliary request 2: added subject-matter (yes)"

"Auxiliary requests 3 and 4: admissibility (no)"

Decisions cited:

Catchword:



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Chambres de recours**

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Case Number: T 1980/09 - 3.3.02

**D E C I S I O N
of Technical Board of Appeal 3.3.02
of 13 March 2014**

Appellant:
(Opponent)

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
14 July 2009 concerning maintenance of the
European Patent No. 1203957 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: K. Giebeler
R. Cramer

Summary of Facts and Submissions

- I. European patent No. 1 203 957, based on European patent application No. 01309145.9 and entitled "Multi-analyte immunoassay", was granted with 4 claims.
- II. The claims of the granted patent read:
- "1. An assay for analytes in a sample, wherein the sample is contacted with a biochip presenting an array of ligands each specific for an analyte, and which additionally comprises including a scavenger material that binds an analyte and thereby reduces its available concentration.
2. An assay according to claim 1, wherein the analytes are drugs of abuse.
3. An assay according to any preceding claim, wherein the scavenger material is an antibody.
4. An assay according to claim 1 to 3, wherein the amount of the antibody that is added maximises the sensitivity of a standard curve at around the cut-off region."
- III. An opposition was filed against the granted patent on the grounds of lack of novelty and inventive step (Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).
- IV. The opposition division decided that the subject-matter of the claims of the main request before it (claims as granted) lacked novelty (Article 54 EPC), but that

- auxiliary request 1, filed during the oral proceedings on 7 Mai 2009, met all the requirements of the EPC.
- V. The opponent filed an appeal against the interlocutory decision of the opposition division.
- VI. With the statement of grounds of appeal, the appellant submitted the following documents D9 to D14 for the first time:
- D9: US 5,939,272
 - D10: WO 90/08319
 - D11: Kricka, Clin. Chem. (1994) 40(3), 347-357
 - D12: Wu et al., J. Anal. Toxicol. (1993) 17, 241-245
 - D13: Mendoza et al., BioTechniques (1999) 27, 778-788
 - D14: Rowe et al., Anal. Chem. (1999) 71, 3846-3852
- VII. The respondent replied to the appeal with letters dated 12 April 2010 and 23 July 2010.
- VIII. The appellant filed further submissions with letter dated 22 November 2010.
- IX. The board summoned the parties to oral proceedings and expressed its preliminary opinion in a communication dated 17 September 2013.
- X. The appellant filed further observations with letter dated 11 February 2014.
- XI. With letter dated 13 February 2014, the respondent filed a new main request and five auxiliary requests, together with further observations.
- XII. Claims 1-4 of the **main request** read as follows:

"1. An assay for analytes in a sample, wherein the sample is contacted with a biochip presenting an array of different ligands having specificity for different analytes, and which additionally comprises including a scavenger material that binds an analyte and thereby reduces its available concentration.

2. An assay according to claim 1, wherein the analytes are drugs of abuse.

3. An assay according to any preceding claim, wherein the scavenger material is an antibody.

4. An assay according to claim 3, wherein the amount of the antibody that is added maximises the sensitivity of a standard curve at around the cut-off region."

XIII. Claim 1 of **auxiliary request 1** reads as follows:

"An assay for analytes in a sample, wherein the sample is contacted with a biochip presenting an array of different ligands having specificity for different analytes, and which additionally comprises including a scavenger material that binds an analyte and thereby reduces its available measurable concentration."

XIV. Claim 1 of **auxiliary request 2** reads as follows:

"An assay for analytes in a sample, wherein the sample is contacted with a biochip presenting an array of different ligands each having specificity for different analytes, and which additionally comprises including a scavenger material that binds an analyte and thereby reduces its available concentration."

XV. Claim 1 of **auxiliary request 3** reads as follows:

"An assay for detecting a panel of analytes in a sample, wherein the sample is contacted with a biochip presenting an array of different ligands having specificity for different analytes on the panel, and which additionally comprises including a scavenger material that binds an analyte on the panel and thereby reduces its available concentration."

XVI. Claim 1 of **auxiliary request 4** reads as follows:

"An assay for analytes in a sample, wherein the sample is contacted with a biochip presenting an array of different ligands having specificity for different analytes, and which additionally comprises including an antibody that binds an analyte and thereby reduces its available concentration."

XVII. Claim 1 of **auxiliary request 5** reads as follows:

"An assay for analytes in a sample, wherein the sample is contacted with a biochip presenting an array of different ligands having specificity for different analytes, and which additionally comprises including a scavenger material that binds an analyte and thereby reduces its available concentration, wherein the scavenger material is an antibody and wherein the amount of the antibody that is added maximises the sensitivity of a standard curve at around the cut-off region."

XVIII. Oral proceedings were held on 13 March 2014.

XIX. The appellant's arguments, insofar as they are relevant for the present decision, can be summarised as follows:

Admissibility of late-filed requests

Auxiliary requests 1-5 should not be admitted into the proceedings. Auxiliary requests 1-4 raised serious issues under Articles 84 and 123(2) EPC and Rule 80 EPC, and auxiliary request 5 had been withdrawn before the opposition division. Moreover, auxiliary requests 1-3 added different features from the description in a non-convergent, "pick and mix" approach and thus represented an abuse of procedure.

Main request and auxiliary requests 1 and 5 - Article 123(3) EPC

Claim 1 of these requests encompassed the situations whereby (i) one ligand had specificity for a group of analytes, (ii) a plurality of ligands had specificity for the same analyte, and (iii) the array contained ligands that did not have specificity for an analyte; none of these situations was encompassed by claim 1 as granted. Hence there was an extension of scope. Moreover, it was not clear from the wording of claim 1 whether the array or the different ligands had specificity for different analytes; this additionally contributed to an extension of the scope of protection.

Auxiliary request 2 - Article 123(2) EPC

The wording of claim 1 implied that a single ligand had specificity for different analytes; this subject-matter was not based on the application as originally filed.

- XX. The respondent's arguments, insofar as they are relevant for the present decision, can be summarised as follows:

Admissibility of late-filed requests

The auxiliary requests were genuine attempts to address issues that had come out of the board's communication and did not create any difficulties. If formal issues arose, they could be dealt with at the oral proceedings.

Main request and auxiliary requests 1 and 5 - Article 123(3) EPC

A skilled person with a mind willing to understand would read the expression "an array of different ligands having specificity for different analytes" used in claim 1 as meaning that each different ligand had specificity for an analyte; any other reading of the claim would not make technical sense. Moreover, claim 1 referring to "an array of different ligands" was narrower in scope than claim 1 as granted referring to "an array of ligands".

Auxiliary request 2 - Article 123(2) EPC

The skilled person would read claim 1 in such a way that each ligand had specificity for an analyte, not that a single analyte had specificity for several analytes; otherwise, the invention would not work.

XXI. The final requests of the parties were:

The appellant requested that the decision under appeal be set aside and that the patent be revoked. The appellant further requested that documents D9 to D14 be introduced into the proceedings.

The respondent requested that the decision under appeal be set aside and the patent maintained on the basis of the main request or, alternatively, on the basis of one of auxiliary requests 1 to 5, all filed with letter of 13 February 2014. The respondent furthermore requested that documents D9 to D14 not be admitted into the proceedings and, if the board decided to admit them, that the case be remitted to the opposition division and/or that the appellant should pay the costs incurred by the proprietor in attending the oral proceedings before the opposition division.

Reasons for the Decision

1. The appeal is admissible.

Admissibility of late-filed requests

2. The main request and auxiliary requests 1 to 5 were filed one month before the oral proceedings.
3. According to Article 12(2) of the Rules of Procedure of the Boards of Appeal (RPBA), the statement of grounds of appeal and the reply thereto must contain the party's complete case. Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion, which is to be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA). Amendments sought to be made after oral proceedings have been arranged are not to be admitted if they raise issues which the board or the other party cannot reasonably be

expected to deal with without adjournment of the oral proceedings (Article 13(3) RPBA).

4. *Admissibility of auxiliary requests 3 and 4*

- 4.1 Claim 1 of auxiliary request 3 differs from claim 1 held allowable by the opposition division in that it specifies that the assay is for detecting **"a panel"** of analytes in a sample, that different ligands have specificity for different analytes **"on the panel"**, and that a scavenger material binds an analyte **"on the panel"**.

The board considers that the newly introduced terms "a panel" and "on the panel" generate new, complex issues, at least of clarity (Article 84 EPC) and added subject-matter (Article 123(2) EPC). In view of the complexity of these new issues, the board considers it inappropriate to admit the amendments into the proceedings.

- 4.2 Claim 1 of auxiliary request 4 differs from claim 1 held allowable by the opposition division in that the term "a scavenger material" has been replaced by the term "an antibody". Due to this replacement, the amendment goes beyond the mere introduction of the feature of dependent claim 3 into claim 1, and generates new issues under Article 123(2) and (3) EPC. For this reason, the board does not consider it appropriate to admit the amendment into the proceedings.

- 4.3 Thus the board, in the exercise of its discretion, decides not to admit auxiliary requests 3 and 4 into the proceedings.

5. *Admissibility of the main request and of auxiliary requests 1, 2 and 5*

5.1 The claims of the main request differ from the claims held allowable by the opposition division in that claim 4 is dependent on claim 3 only, instead of being dependent on claims 1 to 3. The appellant did not object to the admissibility of this request, and the board thus sees no reason not to admit the request into the proceedings.

5.2 The claims of auxiliary request 1 differ from the claims held allowable by the opposition division in that the word "measurable" has been introduced in line 4 of claim 1 before the word "concentration". The board can follow the respondent's argument that this request represents an attempt to address issues pointed out in the board's communication, notably the issues of novelty and inventive step over the late-filed documents D9 to D12. Since the amendment in question is neither complex nor raises issues which the board or the appellant could not reasonably be expected to deal with at the scheduled oral proceedings, the board sees no reason not to admit it into the proceedings.

5.3 The claims of auxiliary request 2 differ from the claims held allowable by the opposition division in that the word "each" has been introduced in line 2 of claim 1 after the term "different ligands". The board takes the position that this amendment is a simple and straightforward attempt to address the appellant's objection under Article 123(3) EPC and does not raise issues which the board or the appellant could not reasonably be expected to deal with at the scheduled oral proceedings.

5.4 Auxiliary request 5 corresponds to auxiliary request 2 submitted by the respondent with its first response of 12 April 2010 to the grounds of appeal; its claim 1 combines all the features of claims 1, 3 and 4 held allowable by the opposition division. Therefore, auxiliary request 5 does not constitute an amendment to the respondent's case under Article 13(1) RPBA.

5.5 In view of these considerations, the board considers it appropriate to admit the main request and auxiliary requests 1, 2 and 5 into the proceedings.

Main request

6. *Article 123(3) EPC*

6.1 Article 123(3) EPC stipulates that the claims of a patent as granted may not be amended during opposition/appeal proceedings in such a way as to extend the protection conferred. In order to decide whether or not an amendment of the patent in suit satisfies that requirement, it is necessary to compare the protection conferred by the claims before amendment, i.e. as granted, with that of the claims after amendment. It is the established case law of the Boards of Appeal that a very rigorous standard, namely that of "beyond reasonable doubt", is to be applied when checking the allowability of amendments under Article 123(3) EPC, such that the slightest doubt that the scope of the patent as amended could cover embodiments not covered by the unamended patent would preclude the allowability of the amendment.

6.2 Claim 1 of the main request is directed to an assay for analytes in a sample, wherein the sample is contacted with a biochip presenting **an array of different ligands**

having specificity for different analytes, and which additionally comprises including a scavenger material that binds an analyte and thereby reduces its available concentration.

Claim 1 as granted is directed to an assay for analytes in a sample, wherein the sample is contacted with a biochip presenting **an array of ligands each specific for an analyte,** and which additionally comprises including a scavenger material that binds an analyte and thereby reduces its available concentration.

- 6.3 The question to be answered is thus whether claim 1 of the main request covers an assay which was not covered by claim 1 as granted. This question arises in particular with respect to the array of ligands presented on the biochip to be used in the claimed assay.
- 6.4 The respondent has submitted that the expression "an array of different ligands having specificity for different analytes" would be understood by the skilled person as an array wherein a first ligand has specificity for a first analyte, a second ligand has specificity for a second analyte, and so on, such that each ligand has to have specificity for an analyte. According to the respondent, any other reading of the wording of the claim would not be technically meaningful and would imply that the claimed assay would not work.
- 6.5 The board cannot agree with the respondent's argument and takes the position that the wording of the expression "an array of different ligands having specificity for different analytes" does not exclude the presence in the array of ligands not having

specificity for an analyte. Moreover, the board is convinced that the presence of such ligands which do not have specificity for an analyte would be technically meaningful in the context of the patent in suit. In this regard, the board can follow the appellant's submission that immobilising ligands which are not specific for an analyte in the array may serve to minimise so-called "matrix effects", i.e. effects of interfering substances present in a sample, which substances can affect the measurement of an analyte in an assay. Therefore, using a biochip presenting an array of different ligands including ligands which have specificity for an interfering substance present in a sample represents a technically meaningful and desirable embodiment of the assay according to claim 1 of the main request.

However, claim 1 as granted, referring to an array of ligands **each** specific for an analyte, does **not** cover assays wherein a biochip is used which presents an array of different ligands including ligands which are not specific for an analyte.

- 6.6 Consequently, the board concludes that claim 1 of the main request has been amended in such a way that the extent of protection conferred has been extended, contrary to Article 123(3) EPC.

Auxiliary requests 1 and 5

7. *Article 123(3) EPC*

Like claim 1 of the main request, claim 1 of both auxiliary requests 1 and 5 refers to an "assay for analytes in a sample, wherein the sample is contacted

with a biochip presenting an array of different ligands having specificity for different analytes...".

For the same reasons as those set out in points 6.1 to 6.5 above, claim 1 of auxiliary requests 1 and 5 has been amended in such a way that the scope of protection conferred has been extended, contrary to Article 123(3) EPC.

Auxiliary request 2

8. *Article 123(2)*

8.1 Claim 1 of auxiliary request 2 refers to "a biochip presenting an array of different ligands **each** having specificity for different analytes...".

8.2 Article 123(2) EPC stipulates that a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. It is the established case law of the Boards of Appeal that the content of an application comprises the disclosure that is directly and unambiguously derivable from this application.

8.3 The application as originally filed underlying the patent in suit states in paragraph [0013] on page 3 of the A2-publication that "[s]uch a biochip presents an array of ligands, e.g. antibodies. There may be several different ligands having specificity for different analytes".

The board cannot recognise in that passage any disclosure of a biochip presenting an array of different ligands **each** having specificity **for different analytes**. In particular, it cannot discern any direct

and unambiguous disclosure of an array including a ligand which has specificity for different analytes.

- 8.4 The respondent has referred to the passage in paragraph [0010] on page 2, lines 47-50 of the application as filed (A2-publication), which states that "[t]he present invention is based on the realisation that the optimisation of the dynamic range can be difficult when it is considered that each analyte must be detected at often very different concentrations to the others on the panel and that each conjugate must be represented in the multi-conjugate reagent at a concentration/dilution appropriate to the particular analyte it recognises."

However, the board cannot recognise in that passage, or in any other passage of the application as filed, any direct and unambiguous disclosure of an array of different ligands **each** having specificity **for different analytes**.

- 8.5 The board cannot follow the respondent's submission that a skilled person would understand claim 1 as meaning that each ligand had specificity for only a single analyte, because this is not what the claim says. The claim explicitly states that **each** of the different ligands of the array has specificity **for different analytes**.

- 8.6 The board concludes that auxiliary request 2 does not comply with Article 123(2) EPC.

9. In view of the above, none of the admissible claim requests fulfills the requirements of Article 123(2) and (3) EPC.

10. Consequently, the board does not need to decide whether or not to admit the late-filed documents D9 to D14 into the proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated