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**Datasheet for the decision
of 15 December 2011**

Case Number: T 2278/09 - 3.3.08
Application Number: 03018643.1
Publication Number: 1369691
IPC: G01N 33/543, B01L 3/00,
G01N 33/53
Language of the proceedings: EN

Title of invention:

Device and method utilizing arrays of structures for analyte capture

Applicant:

ABBOTT LABORATORIES

Headword:

Analyte capture device/ABBOTT

Relevant legal provisions:

EPC Art. 84
RPBA Art. 12(4)

Keyword:

"Main request and first auxiliary request - clarity (no)"
"Admissibility of the second and third auxiliary requests (no)"

Decisions cited:

G 0010/93

Catchword:

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Case Number: T 2278/09 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 15 December 2011

Appellant:
(Applicant)

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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted on 13 July 2009
refusing European patent application
No. 03018643.1 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: M. Wieser
Members: P. Julià
R. Moufang

Summary of Facts and Submissions

- I. The applicant (appellant) lodged an appeal against the decision of the examining division posted on 13 July 2009, whereby European patent application No. 03 018 643.1 (published as EP 1 369 691, hereinafter "*the application as filed*") was refused. The application is a divisional application of the earlier European patent application No. 95 936 210.4 published as International patent application WO 96/10747.
- II. The decision was based on a main request, filed with letter of 12 June 2007, and on an auxiliary request 1 filed on 28 May 2009. Both requests were considered not to fulfil the requirements of Articles 123(2), 54 and 56 EPC. Moreover, auxiliary requests 2 and 3 filed on 28 May 2009 were not admitted into the examination proceedings because they were considered to have been amended to contain technical features from the description which had not been searched.
- III. With the statement setting out its grounds of appeal, the appellant submitted copies of the main request and of auxiliary requests 1 to 3 which were identical to these requests pursuant to the decision under appeal.
- IV. The examining division did not rectify its decision and referred the case to the Board of Appeal under Article 109(2) EPC.
- V. On 15 June 2011, the board issued a summons to oral proceedings to be held on 15 December 2011. A communication pursuant to Article 15(1) of the Rules of

Procedure of the Boards of Appeal (RPBA) was attached to the summons. In this communication the appellant was informed of the board's preliminary, non-binding view on the issues to be discussed at the upcoming oral proceedings. In particular, the board raised objections under Article 84 EPC and referred to the issues concerning Articles 76(1) and 123(2) EPC as well as to the admissibility of auxiliary requests 2 and 3. The final date for receipt of any written submissions was fixed at one month before the oral proceedings.

VI. On 9 December 2011, the appellant replied to the board's communication, announced that it would not attend oral proceedings, and maintained the requests set out in the grounds of appeal, including the request for oral proceedings. No submissions were made on the substantive issues raised or commented by the board in its communication.

VII. Oral proceedings took place on 15 December 2011, in the absence of the appellant. At these proceedings, the chairman announced the decision of the board.

VIII. The claims of the main request read as follows:

"1. A method for determining the presence or amount of analyte in a test sample comprising the steps of:
providing an analytical device comprising a base layer, a test sample inlet port, a vent, an array of structures arising from said base layer, and a plurality of channels adjacent to said structures, each of said structures having a surface to which a cationic material is immobilized, said cationic material capable of binding a polyanionic material;

providing a polyanionic material coupled to a specific binding member which is specific for said analyte;

mixing said polyanionic material coupled to said specific binding member with said test sample whereby said specific binding member binds said analyte;

adding said mixture to said inlet port, said mixture being transported to said array of structures; and

detecting the presence or amount of analyte in said test sample immobilized at said cationic material.

2. An analytical device comprising a base layer, a test sample inlet port, a vent, an array of structures arising from said base layer, and a plurality of channels adjacent to said structures, each of said structures having a surface to which a cationic material is immobilized, said cationic material capable of binding a polyanionic material, said polyanionic material coupled to an analyte-specific binding member."

IX. The claims of the auxiliary request 1 read as those of the main request except for the following amendments made, respectively, to the first and to the fourth steps of the method of claim 1 (amendments in bold):

"... an array of structures, **said structures arising from said base layer**, and a plurality of channels, **said channels being the space between** adjacent structures ..." and "... adding said mixture to said inlet port, **and transporting** said mixture to said array of structures ...".

Corresponding amendments were also made to claim 2. Additionally, the term "cationic" present in the main request was replaced by "**polycationic**" in auxiliary request 1.

- X. In addition to the amendments introduced into auxiliary request 1, the claims of auxiliary request 2 further differed from those of the main request by the following additional characterisation of the "structures" in both claims 1 and 2:

"... an array of **uniform** structures ..." and "... said structures arising from said base layer **and being made of the same material of the base layer** ...".

In auxiliary request 3, the "structures" were further characterised in both claims 1 and 2 in the following way:

"... an array of uniform structures, **said structures having shapes selected from diamonds, hexagons, octagons, rectangles, squares, circles, semi-circles, triangles and ellipses,...**".

- XI. Appellant's arguments, insofar as they are relevant to the present decision, may be summarized as follows:

Article 84 EPC

The appellant did not comment on the objections raised by the board under Article 84 EPC in its communication pursuant to Article 15(1) RPBA - see points V and VI *supra*.

Admissibility of auxiliary requests 2 and 3

The limitations to the "structures" as being uniform and being made of the same material as the base layer introduced into auxiliary requests 2 and 3 related to preferred embodiments encompassed by the claims as originally filed. Article 92 EPC stated that the search report had to be drawn up "on the basis of the claims, with due regard to the description and any drawings". Thus, in the present case, the search report had to be drawn up taking into consideration the section "Methods of manufacturing the devices of the present invention" which started at paragraph [0042] on page 6 of the application as filed in which all these limitations were disclosed. As also stated in the "Guidelines for Examination" (B-III, 3.5), amendments to the claims had to be anticipated in that "the search should cover the entire subject-matter to which the claims are directed or to which they might be reasonably expected to be directed after they have been amended". Thus, there was no reason to believe that the search did not cover easily identified preferred embodiments such as those represented by the claims of auxiliary requests 2 and 3.

- XII. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, the first, second or third auxiliary request, all requests filed with the statement of grounds of appeal dated 23 November 2009.

Reasons for the Decision

Procedural issues

1. According to the Order of the decision G 10/93 of the Enlarged Board of Appeal (OJ EPO, 1995, page 172) "*in an appeal from a decision of an examining division in which a European patent application was refused, the board of appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC. The same is true for requirements which the examining division did not take into consideration in the examination proceedings or which it regarded as having been met. If there is reason to believe that such a requirement has not been met, the board shall include this ground in the proceedings*". Thus, the board is not limited to the examination of the objections raised in the decision under appeal but has to examine whether appellant's requests fulfil all requirements of the EPC.

2. Although in the decision under appeal the objection raised under Article 84 EPC was directed only to the incorporation by reference of prior art documents in the description of the application, the board informed the appellant in its communication pursuant to Article 15(1) RPBA that a complete assessment of the claims within the meaning of Article 84 EPC was - in the present case - important for examining whether or not the claims fulfilled the other requirements of the EPC, in particular those of Article 123(2) EPC. In this communication, several objections were raised under Article 84 EPC for the first time in the proceedings. The appellant was given five months to react to these

objections and to bring forward its arguments thereon. However, it chose not to file any substantive submissions and not to attend the oral proceedings before the board (cf. points V to VII *supra*). The present decision is based on grounds and evidence on which the appellant had had an opportunity to present its comments, as required by Article 113(1) EPC.

Main request

Article 84 EPC

3. According to established case law, a claim must be comprehensible from a technical point of view and define the object of the invention clearly, that is to say indicate all the essential technical features thereof. All features which are necessary for solving the technical problem with which the application is concerned have to be regarded as essential features (cf. "Case Law of the Boards of Appeal of the EPO", 6th edition 2010, II.B.1.1.4, page 257).
- 3.1 Claim 1 is directed to a method for determining the presence or amount of analyte in a test sample using an "analytical device" as defined in the first step of this method and in claim 2 (cf. point VIII *supra*). This device is characterized by several elements which are defined in broad, generic terms and, for some of them, without connection with the other features of the claim. Several properties of these elements are however essential for the claimed device to function as disclosed, i.e. with acceptable rates of fluid flow and acceptable efficiencies of analyte capture (cf. paragraph [0011] of the application as filed).

- 3.2 In particular, the application refers, *inter alia*, to controlling the transport of the (mixture) fluids through the analytical device and, in this context, reference is made to the dimensions (depth, width) of the (narrow) channels as being critical factors as well as to the height and width of the structures and the arrangement of the arrays of these structures (cf. paragraphs [0063] and [0053] of the application as filed). In another context, reference is also made to the type and nature of these structures (cf. paragraph [0042], in particular lines 20 to 24 of the application as filed). These features of the analytical device are thus essential features and should be present in the claims. Their absence renders claims 1 and 2 unclear.
4. There is no definition for the term "*cationic material*" in the application as filed. This term is only mentioned in Example 7 of the application as filed, while originally filed claims 1 and 2 refer only to "*polycationic material*" instead. Whereas it might be argued that the terms "*polycationic material*" and "*cationic material*" would be clearly understood by the skilled person drawing upon his/her common general knowledge, it is however not apparent whether the two terms are synonymous or whether the former has a broader meaning than the latter or else whether they are alternatives with some or no overlap at all. In addition, it is noted that, in the application as filed, polyglutamic acid (PGA) is mentioned as an example of a cationic solution (cf. page 15, line 42 of the application as filed). However, PGA is usually disclosed in the literature as an anionic polymer (cf. page 14, lines 5 and 6 of document D3, WO 92/21770). Thus, even in view of the little information given in

- the application as filed, the term "*cationic material*" is considered to be ambiguous and unclear, so that it is not apparent what is actually encompassed by the term "*cationic material*" in claims 1 and 2.
5. The feature "*said polyanionic material coupled to an analyte-specific binding member*" in claim 2 is considered redundant in the context of the claimed analytical device. The polyanionic material is not part of the device and does not influence in any way the structure of the device. Indeed, the "*cationic material*" should be capable of binding the polyanionic material no matter if the latter is coupled to an analyte-specific binding member or not.
6. Thus, the main request is considered not to fulfil the requirements of Article 84 EPC.

First auxiliary request

Article 84 EPC

7. At least the objections under points 3 and 5 *supra* also apply to this auxiliary request, while it is questionable whether the terms "*polyanionic material*" and "*polycationic material*" would be clear to the skilled person in the context of the invention (cf. point 4 *supra*). Accordingly, the first auxiliary request is considered not to fulfil the requirements of Article 84 EPC.

Second and third auxiliary requests
Admissibility into the proceedings

8. In exercising its discretion, the examining division decided not to admit the second and the third auxiliary requests into the proceedings (cf. point II *supra*).

9. The features introduced into both requests, namely "*uniform structures*" and "*structures... being made of the same material as the base layer*", are found in paragraph [0042] of the application as filed. The last sentence of this paragraph, which constitutes the only reference in the application as filed to structures being made of the same material as the base layer, starts with the words "*(g)enerally and preferably*". There is, however, no reference to the possible advantages or effects associated with these features in the entire application. Indeed, none of these features is found in paragraphs [0099] to [0107] relating to the preferred embodiments of the invention. They are not mentioned in any of the examples of the application as filed and they are not even found in the definition of "*structures*" which is provided in paragraph [0039] of the application as filed. Thus, the board considers that, contrary to appellant's arguments (cf. point XI *supra*), these amendments could not have been reasonably and necessarily expected when the prior art search was carried out.

10. The additional feature introduced into the third auxiliary request, namely "*said structures having shapes selected from ... [list of shapes]*" (cf. point X *supra*), is cited in paragraph [0100] of the application as filed, with some of these shapes being also

mentioned in paragraphs [0039] and [0053] of the application as filed. However, any possible advantages or effects derived from these specific shapes are not apparent from the application.

11. In view of the above comments, the board considers that the examining division exercised its discretion correctly when deciding not to admit auxiliary requests 2 and 3 into the proceedings and it does not see any reason to deviate from this decision of the examining division (Article 12(4) RPBA).

12. The board further notes that the objections raised under Article 84 EPC in points 3 and 5 *supra* apply to the second and third auxiliary requests. In addition, there is no definition provided for the term "*uniform*" in the application as filed, whose meaning is considered not to be clear: does it relate to the size, height, width, form, etc. of the structures? Hence, the term "*uniform*" introduces a further ambiguity to the actual scope of the claims.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Wolinski

M. Wieser