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D E C I S I O N
of 12 November 1997

Case Number: T 0282/94 - 3.3.4

Application Number: 84900765.3

Publication Number: 0134236

IPC: G01N 33/543

Language of the proceedings: EN

Title of invention:
Method, porous matrix and device for analytical biospecific affinity reactions

Patentee:
Pharmacia & Upjohn Diagnostics AB

Opponent:
Boehringer Mannheim GmbH Patentabteilung

Headword:
Porous matrix/PHARMACIA-UPJOHN

Relevant legal provisions:
EPC Art. 54

Keyword:
"Novelty (yes) - after amendments"

Decisions cited:
-

Catchword:
-

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Case Number: T 0282/94 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 12 November 1997

Appellant: (Proprietor of the patent)
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Respondent: (Opponent)
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Representative:
-

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 22 February 1994 revoking European patent No. 0 134 236 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
S. C. Perryman

Summary of Facts and Submissions

I. The appeal was lodged by the appellants-patentees against the decision of the opposition division issued on 22 February 1994 whereby the European patent No. 0 134 236, which had been opposed by the respondents-opponents under Article 100(a) EPC, was revoked pursuant to Article 102(1) EPC on the grounds that the subject-matter of claims 1, 6 and 12 lacked novelty having regard to the following document:

(2) DE-A-2 755 689.

Claims 1, 6 and 12 as granted read as follows:

"1. A method of performing analyses based upon biospecific reactions in heterogeneous systems, comprising the steps of

(a) providing a self-supporting carrier matrix body capable of absorbing and retaining liquid and having a first receptor component immobilized to the pore surfaces thereof,

(b) sampling a predetermined volume of a liquid having dissolved therein a second ligand component that is to be determined,

(c) contacting said predetermined sample volume with the matrix body to be completely absorbed and retained thereby,

(d) permitting said first and second components to react to form an immobilized complex, and

(e) detecting, and optionally quantitating the formation of said immobilized complex in said matrix,

characterized by optimizing the total reaction rate of said second component with said first component by providing said first receptor component covalently bonded to the pore surfaces of said matrix and by minimizing the dependency of the diffusion of said

second component by selecting the pore dimensions of said matrix body so that the total diffusion process therein substantially corresponds to that of a matrix having cylindrical pores with a diameter of less than about 100 µm, but sufficiently large to permit easy passage of the reagents, to thereby make said total reaction rate substantially independent of said diffusion.

6. A porous matrix for carrying out analyses based upon biospecific reactions in heterogeneous systems, comprising reaction of a first immobilized receptor component with a second ligand component dissolved in a liquid to form an immobilized complex, which complex formation is detected and optionally quantitated, said matrix comprising a self-supporting carrier matrix body with an open porous system capable of absorbing and retaining liquid and having said first receptor component immobilized to the pore surfaces thereof, characterized in that said first receptor component is covalently bonded to the pore surfaces of said matrix body and that in order to minimize the dependency of the diffusion of said second component in liquid phase absorbed by the matrix body the matrix body has such small pore dimensions that the total diffusion process therein substantially corresponds to that of a matrix having cylindrical pores with a diameter of less than about 100 µm, but sufficiently large to permit easy passage of the reagents, said total reaction rate thereby being substantially independent of said diffusion.

12. A device for carrying out analyses based upon biospecific reactions in heterogeneous systems, characterized in that it comprises at least one matrix body according to any one of claims 6-11 supported on a holder (2)."

Dependent claims 2 to 5 related to embodiments of the method according to claim 1. Dependent claims 7 to 11 related to embodiments of the matrix according to claim 6.

II. With letter dated 14 May 1996, the appellants filed new claims 1, 6, 12 and 13 together with an experimental report by Dr Rolf Axen.

III. On 30 December 1996, the board issued a communication wherein some objections under Articles 84 and 54 EPC were raised against the claims on file.

IV. With letter dated 9 June 1997, the appellants filed amended claims 1, 2, 6, 7 and amended page 5 of the patent specification. These were commented upon by the respondents in the letter dated 8 July 1997.

V. In the annex to the summons to oral proceedings, the board outlined the points to be discussed and requested the appellants to file a complete set of claims. In reply thereto, on 29 August 1997, the appellants filed claims 1 to 13 as their only claim request.

VI. Oral proceedings took place on 12 November 1997. During oral proceedings, the appellants filed a **new claim request** in substitution of the previous one. This consisted of claims 1 to 9, of which independent claims 1, 4 and 9 read as follows (the relevant changes to the granted claims are marked in bold by the board):

"1. A method of performing analyses based upon biospecific reactions in heterogeneous systems, comprising the steps of

(a) providing a self-supporting carrier matrix body capable of absorbing and retaining liquid and having a first receptor component immobilized to the pore surfaces thereof;

(b) sampling a predetermined volume of an **aqueous** liquid having dissolved therein a second ligand component that is to be determined;

(c) contacting said predetermined sample volume with the matrix body to be completely absorbed and retained thereby;

(d) permitting said first and second components to react to form an immobilized complex; and

(e) detecting, and optionally quantitating the formation of said immobilized complex in said matrix,

characterized by optimizing the total reaction rate of said second component with said first component by providing said first receptor component covalently bonded to the pore surfaces of said matrix and by minimizing the dependency of the diffusion of said second component by selecting the pore dimensions of said matrix body so that the total diffusion process therein substantially corresponds to that of a matrix having cylindrical pores with a diameter of less than about 100 µm, but sufficiently large to permit easy passage of the reagents, to thereby make said total reaction rate substantially independent of said diffusion, **and by the matrix material being cellulose so that said predetermined sample volume is immediately and completely absorbed and retained by said matrix body during the reaction of said second component with said first component.**

4. A porous matrix for carrying out analyses based upon biospecific reactions in heterogeneous systems, comprising reaction of a first immobilized receptor component with a second ligand component dissolved in an **aqueous** liquid to form an immobilized complex, which complex formation is detected and optionally quantitated, said matrix comprising a self-supporting carrier matrix body with an open porous system capable of absorbing and retaining **a predetermined volume of**

said liquid and having said first receptor component immobilized to the pore surfaces thereof, characterized in that said first receptor component is covalently bonded to the pore surfaces of said matrix body, that in order to minimize the dependency of the diffusion of said second component in liquid phase absorbed by the matrix body the matrix body has such small pore dimensions that the total diffusion process therein substantially corresponds to that of a matrix having cylindrical pores with a diameter of less than about 100 µm, but sufficiently large to permit easy passage of the reagents, said total reaction rate thereby being substantially independent of said diffusion, **and that the matrix material is cellulose so that said predetermined sample volume is immediately and completely absorbed and retained by said matrix body during the reaction of said second component with said first component.**"

9. A device for carrying out analyses based upon biospecific reactions in heterogeneous systems, characterized in that it comprises at least one matrix body according to any one of claims 4-8 supported on a holder (2)."

Dependent claims 2 and 3 relate to embodiments of the method according to claim 1. Dependent claims 5 to 8 relate to embodiments of the matrix according to claim 4.

VII. The respondents maintained that in the context of the claimed method and porous matrix the selection of cellulose as matrix material generated specific subject-matter which extended beyond the content of the application as filed. They, however, acknowledged that the claimed subject-matter of the amended claims was novel over the disclosure of document (2).

VIII. The appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims submitted at the oral proceedings.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

Formal admissibility of the new claims: Article 123(2) and (3) EPC.

Article 123(3) EPC

1. Comparison of claims 1 to 9 on file with claims 1 to 12 as granted brings out the following:

(a) In independent claims 1 and 4, which correspond to granted claims 1 and 6 respectively, it is now specified that the liquid is "aqueous", that the matrix material is "cellulose" and that the predetermined sample volume is immediately and completely absorbed and retained by the matrix body during the reaction of the second component with the first component;

(b) Claim 8 is a new claim dependent upon claim 4 which specifies that the matrix material is "soft";

(c) dependent claims 2 to 3, 5 to 7 and 12 are respectively identical to dependent claims 4 to 5, 9 to 11 and 12 as granted, except for the amendments in the claim dependencies.

2. The above analysis reveals that all the amendments introduced in the claims at issue in comparison with the claims as granted result in a limitation of the extent of protection conferred. Thus, there is no violation of Article 123(3) EPC.

Article 123(2) EPC

3. All the amendments reported in point 1, above find a basis in the application as filed. In particular, the application as filed states on page 6, lines 19 to 20 that the liquid medium is usually water and on line 28 that the matrix may be "soft".

The feature requiring that the predetermined sample volume is immediately and completely absorbed and retained by the matrix body during the reaction of the second component with the first component is based on page 2, lines 15 to 26, and page 6 lines 17 to 19 of the application as filed.

As for the limitation of the claimed subject-matter to the specific embodiments wherein the matrix material is "cellulose", these find an **explicit** basis eg on page 6, line 33, in the examples and in claims 3 and 9 of the application as filed. Thus, no new subject-matter extending beyond the content of the application as filed is generated by this specific limitation. This holds true also for the subject-matter of the dependent claims for which **explicit** support is found eg in claims 3 to 6 and 9 to 11 as well as on page 8, lines 19 to 24 of the application as filed.

4. In conclusion, no objection under Article 123(2) EPC is seen by the board.

Novelty of the claimed subject-matter over document (2)

5. The respondents no longer objected to the novelty of the amended claims over the disclosure of document (2). Nor does the board see any objections in this respect. The microporous membranes used as support in document (2) are of cellulose acetate and nitrate mixed esters as it is derivable from page 22, first paragraph and further from the reference to the German patent application DE-A-2 539 657 on pages 15, 21, 22 and 28. This is a thermoplastic matrix material chemically derived from cellulose and as such is **different** from cellulose. Thus, this limitation in the matrix material has restored novelty of the claimed subject-matter over document (2).

Remittal of the case to the first instance (Article 111 EPC)

6. The patent is suit had been revoked by the first instance on the ground of lack of novelty vis-à-vis document (2), nothing being said about further substantive issues such as inventive step. At oral proceedings before the board, at least one party (the appellants) indicated their preference for a referral of the case to the first instance under Article 111 EPC, the other party (the respondents) not being opposed thereto.

7. In order to ensure that the parties have the opportunity of having the substantial questions of patentability of the amended claims decided by the opposition division, and with the possibility of a further appeal remaining open, the board considers it appropriate to make use of the power granted to it under Article 111(1) EPC to remit the case to the first instance for further examination.

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 examination.

The Registrar: The Chairperson:

D. Spigarelli U. M. Kinkeldey