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Aktenzeichen / Case Number / N^o du recours : W 15/90 - 3.2.3

Anmeldenummer / Filing No / N^o de la demande : PCT/EP 89/01602

Veröffentlichungs-Nr. / Publication No / N^o de la publication :

Bezeichnung der Erfindung: **Methods and materials for improved high gradient
Title of invention: magnetic separation of biological materials
Titre de l'invention :**

Klassifikation / Classification / Classement : B03C 1/00

ENTSCHEIDUNG / DECISION
vom / of / du 14 August 1990

Anmelder / Applicant / Demandeur : **Miltenyi, Stefan**

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPU / EPC / CBE PCT Article 17(3)(a); Rules 13.1, 40.1

Schlagwort / Keyword / Mot clé : **"Substantiation of the invitation pursuant to
Article 17(3)(a) and Rules 13 and 40 PCT"**

Leitsatz / Headnote / Sommaire



Case Number : W 15/90 - 3.2.3
International Application No. PCT/EP 89/01602

D E C I S I O N
of the Technical Board of Appeal 3.2.3
of 14 August 1990

Applicant : Miltenyi, Stefan
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Subject of the Decision : Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fee) of the European Patent Office (branch at The Hague) dated 30 March 1990.

Composition of the Board :

Chairman : C.T. Wilson
Member : F. Brösamle
Member : W. Moser

Summary of Facts and Submissions

- I. On 22 December 1989 the applicant filed International application No. PCT/EP 89/01602.
- II. On 30 March 1990 the European Patent Office as International Search Authority (ISA) sent the applicant an invitation pursuant to Article 17(3)(a) and Rule 40.1 PCT.

In this invitation the following six groups of claims were indicated constituting in the assessment of the ISA six inventions not so linked as to form a single general inventive concept, Rule 13.1 PCT:

1. Claims 1-9: A method to prepare a composition of superparamagnetic colloidal particles by HGMS and a composition by this method.
2. Claims 10-14: A method to separate biological materials using HGMS.
3. Claim 15: A method to effect separation of at least two components from a mixture using a magnetic gradient.
4. Claims 16-17: An apparatus for conducting HGMS comprising the use of a permanent magnet.
5. Claim 18: A method to separate biological materials using HGMS and using a magnetic fluid in the eluting step.

6. Claim 19: A method to separate a sample containing magnetic particles using HGMS and using a magnetic fluid to remove the retained particles.

The ISA invited the applicant to pay within 30 days from the date of mailing (i.e. by 30 April 1990) additional search fees for the search of the subject-matter of groups 2 to 6, i.e. five times DEM 2095.-; the total amount of additional fees being DEM 10475.-.

The ISA consequently carried out the search on the subject-matter of group 1 only, see "Notification concerning the result of the partial International Search" dated 30 March 1990 forming an annex to the above-mentioned invitation to pay additional fees.

- III. On 24 April 1990 the applicant paid three additional fees i.e. DEM 6285.- for Claims 10 to 14 (group 2), Claim 15 (group 3) and Claim 18 (group 5).

No additional fees for the claims of groups 4 and 6 were paid.

The additional fees for the claims of groups 3 and 5 were paid under protest pursuant to Rule 40.2 PCT and it was requested to refund DEM 4190.-, since the subject-matter of Claims 15 and 18 in the Appellant's contention does not lack unity of invention in view of the subject-matter of Claims 10 to 14.

Should the Board of Appeal, acting in the capacity of Article 154(3) EPC to decide on the protest of the applicant, come to the conclusion that the above-mentioned request cannot be met, then a substantial reduction of the above-mentioned two additional fees is requested.

Reasons for the Decision

1. Pursuant to Article 154(3) EPC the Boards of Appeal are responsible for deciding on protests made by applicants against additional search fees charged under Article 17(3)(a) PCT by the EPO.
2. The protest was made only with respect to the additional fees for Claims 15 and 18 (groups 3 and 5) and not for Claims 16/17 (group 4) and Claim 19 (group 6). The protest is admissible since, within the prescribed time limit of 30 days, the applicant paid the additional fees under protest and accompanied his protest by a reasoned statement, within the meaning of Rule 40.2(c) PCT, to the effect that the International application concerning the claims of groups 2, 3 and 5 complied with the requirement of unity of invention.
3. In requesting additional search fees the ISA indicated in the form of a list (see "Supplemental sheet" accompanying the "invitation to pay additional fees" dated 30 March 1990) that the International application does not comply with the requirements of unity of invention.

The applicant did not pay additional fees for the claims of groups 4 and 6 so that, in accordance with Article 17(3)(a) PCT, the subject-matter of these groups will not be searched by the ISA.

By paying the additional fee for the subject-matter of Claims 10 to 14 (group 2) without protest, the applicant has accepted the assessment of the ISA; the additional fees for the subject-matter of Claims 15 and 18 were, however, paid under protest.

4. It has to be decided in the following whether or not the above-mentioned "invitation to pay additional fees" was justified.
- 4.1 In Rule 40.1 PCT it is laid down that the invitation to pay additional fees shall specify the reasons for which the International application is not considered as complying with the requirement of unity of invention. Contrary to Rule 40.1 PCT no reasons were given to support this view.
- 4.2 In the decision W 4/85 dated 22 April 1986 and published in OJ EPO 1987, 63, the Board of Appeal expressed the opinion that the requirement to give reasons in an invitation pursuant to Article 17(3)(a) PCT is so fundamental that an unsubstantiated invitation cannot be regarded as legally effective. The present Board supports that view.
- 4.3 In the cited decision it was further stated that in straightforward cases all that may be necessary to substantiate lack of unity is a list of the application's various subject-matter. But it seems appropriate to add that this is only exceptionally the case and will rarely occur in the technical field of the present application.
- 4.4 The present case is not a straightforward one. On pages 1 to 6 of the present application the prior art is discussed. In the last sentence of page 6 it is set out that "the present invention is directed to methods and materials which result in more versatile and more effective magnetic separations of biological materials". This is the only part of the International application which can be interpreted as a statement of the problem underlying the claimed invention. Without identifying, however, the nearest prior art to be considered - often

unknown to the applicant before the communication of the International Search Report - it is not possible to define clearly the objectively remaining problem to be solved, which is indispensable for the assessment of unity of invention. The ISA did not consider any problem to be solved by the application when assessing unity of invention. The invitation does not make clear why the inventions listed -in particular those according to groups 2, 3 and 5 -cannot be considered to form a single general inventive concept within the meaning of Rule 13.1 PCT. The applicant was, therefore, not able to establish whether the invitation to pay additional fees was correctly issued. Since, therefore, it was issued in violation of the obligation to specify the reasons laid down in Rule 40.1 in conjunction with Rule 13.1 PCT, it cannot be considered to be legally effective. This being so, the applicant paid the additional fees without valid reason and, consequently, requests that they be repaid.

5. Apart from the considerations under points 4.1 to 4.4 above, the Board is of the opinion that the subject-matter of Claims 10, 15 and 18 is based on a single general inventive concept so that the invitation to pay additional fees is not supported by the facts, at least not for groups 2, 3 and 5.

5.1 Claim 10 is based on a method for separating biological materials using HGMS comprising the steps of binding the biological material to a particle which is conjugated to a specific binding portion complementary to the biological material, separating in a separation chamber magnetized particles from a sample containing the biological material and eluting the magnetized particles from the separation chamber. Whilst the term "magnetic" separation chamber is not used in Claims 10 and 18, it is clearly defined that "HGMS" is used, i.e. high gradient magnetic separation.

For a skilled person it is clear that a separation chamber using "HGMS" is a "magnetic separation chamber".

- 5.2 This same principle is followed in the method of Claim 15, though there are two compositions of magnetic particles being used and separate fractions being eluted from the separation chamber, complementary portions being again conjugated and bound to magnetic particles, and this mixture being treated in a separation chamber and eluted be it in one or in separate fraction(s).
- 5.3 Claim 18 is nearly literally identical with the wording of Claim 10, the only difference being the eluting step.
- 5.4 From the above it follows that the teachings of Claims 10, 15 and 18 are based on a single general inventive concept as defined in Rule 13.1 PCT, though the scope of these claims is slightly different.
- 5.5 It is true that in Claim 15 the words "biological materials" are missing. By implication it can, however, be seen that the words "conjugated to a specific binding partner" are synonymous with the term "biological material". Since the whole application, having regard to its title and introductory part ("Technical Field") on page 1, paragraph 1 and on page 6, last paragraph, only deals with the separation of biological material (cells, organelles) it appears justified to interpret the term "conjugated to a specific binding partner" on the basis of its biological meaning so that Claim 15 may also be interpreted as dealing with biological material.
- 5.6 To sum up, the Board comes to the conclusion that Claims 10, 15 and 18 relate to one invention only so that the payment of an additional search fee - as carried out by the applicant - is sufficient and the two other fees must consequently be reimbursed.

6. Since the main request (full reimbursement of two fees) is acceptable, the auxiliary request (substantial reduction of the additional search fees) does not need to be dealt with.

Order

For these reasons, it is decided that:

Reimbursement of two additional fees paid by the applicant is ordered.

The Registrar:



S. Fabiant

The Chairman:



C.T. Wilson

Bv. 30.9.90
W Moser 30.8.90
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