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File Number: T 800/90 - 3.3.2

Application No.: 84 303 800.1

Publication No.: 0 129 998

Title of invention: A composition for controlling hemophilia in mammals

Classification: A61K 35/16

D E C I S I O N  
of 23 March 1993

Applicant: QUEEN'S UNIVERSITY AT KINGSTON

Headword: Hemophilia/QUEEN'S UNIVERSITY

EPC Articles 97(1), 113(1); Rule 67

Keyword: "Refusal based on new document - substantial procedural violation  
(yes) - reimbursement of appeal fee (yes)"  
"Remittal to the Examining Division"



Case Number : T 800/90 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 23 March 1993

**Appellant :** QUEEN'S UNIVERSITY AT KINGSTON  
Kingston  
Ontario K7L 3N6 (CA)

**Representative :** Wood, Anthony Charles  
Urquhart-Dykes & Lord  
91 Wimpole Street  
London W1M 8AH (GB)

**Decision under appeal :** Decision of the Examining Division of the  
European Patent Office dated 30 April 1990  
refusing European patent application  
No. 84 303 800.1 pursuant to Article 97(1) EPC.

**Composition of the Board :**

**Chairman :** P.A.M. Lançon  
**Members :** A.J. Nuss  
S.C. Perryman

**Summary of Facts and Submissions**

- I. European patent application No. 84 303 800.1 (publication No. 0 129 998) was refused by a decision of the Examining Division for the reason that the subject-matter of Claims 1 to 9 filed in a letter dated 28 November 1989 was not patentable according to Article 97(1) EPC.

The independent Claims 1, 6 and 7 read as follows:

"1. A pharmaceutical composition for the treatment of hemophilia in mammals characterised by containing, as the only physiologically-active ingredients, a synergistic mixture of phospholipid vesicles and mammal blood Factor Xa in relative proportions just sufficient to arrest bleeding when administered.

6. Use of composition according to any of Claims 1 to 5 for the manufacture of a medicament for the treatment of hemophilia in mammals.

7. A method for producing a pharmaceutical composition for the treatment of hemophilia in mammals characterised by forming a mixture containing, as its only physiologically-active ingredients, phospholipid vesicles and mammal blood Factor Xa in relative proportions just sufficient to arrest bleeding when administered."

The remaining claims, viz. 2 to 5, 8 and 9, relate to particular embodiments of the subject-matter set out in the independent claims.

- II. In its decision the Examining Division held that the claims on file lacked novelty or inventive step in view of the teaching of document (B), i.e. Proceedings of the International Workshop On Regulation of Coagulation, when

taken either alone (absence of novelty of Claims 1, 2 and 5 to 9) or in combination with document (4), i.e. Bio-electrochemistry and Bioenergetics, vol. 6 (1979), 537 to 541 (absence of inventive step in case the claims were limited to phosphatidylcholine to establish novelty).

In addition, Claim 1 was considered to be not allowable under Article 84 EPC for the reason that its subject-matter was in part defined by the result to be achieved ("just sufficient to arrest bleeding"). Reference was made to C-III, 4.7 of the Guidelines. Moreover, the expression "synergistic mixture" was objected to be vague and therefore did not meet the requirements of Article 84 EPC either.

Finally, Claims 3 and 4 were rejected under Rule 29(1) EPC for the reason that the characterising feature, viz. the amount of the active ingredients per kg of body weight, was not considered to be a feature of the claimed product but a feature of its application. Reference was made to C-III, 2.1 of the Guidelines.

III. The Appellants lodged an appeal against this decision.

In their Statement of Grounds of Appeal, the Appellants pointed out that the application had been refused on the basis of documents cited by themselves as Applicants for the first time in their letter dated 28 November 1989. Since these documents were brought into the proceedings in support of their own case they could not foresee that they would be used as the basis for rejecting the application. By not giving an opportunity to present arguments before refusal of the application on the basis of the said documents a substantial procedural violation was committed. Therefore, reimbursement of the appeal fee should be ordered in accordance with Rule 67 EPC. In

support of this petition reference was made to decisions T 18/81 and T 30/81 of the Boards of Appeal.

The Appellants further submitted that the documents filed in support of their case had been misintepreted by the Examining Division. In order to substantiate this they provided a detailed technical argumentation supplemented by evidence in form of three colour microphotographs (i.e Exhibits 1, 2 and 3). In a subsequent letter dated 30 November 1990, they filed additional observations together with two more photographs (i.e. Exhibits 4 and 5) and a letter from Dr Michael E. Nesheim, Professor of Medicine and Biochemistry at Queen's University, one of the authors of document (B). Accordingly, they contended to have demonstrated that there were very solid reasons for doubting the identity of the compositions disclosed in document (B) and those now claimed.

The Appellants also provided arguments against the additional findings in the contested decision, viz. that Claim 1 did not meet the requirements of Article 84 EPC and that Claims 3 and 4 contravened Rule 29(1) EPC.

IV. The Appellants requested that the rejection of the application be withdrawn and that a patent be granted on the basis of the claims now on file and, in addition, that the appeal fee be reimbursed.

Oral proceedings were requested in case the Board would not accept the Appellants' arguments.

## Reasons for the Decision

1. The appeal is admissible.
2. In a first communication dated 27 October 1988, the Examining Division raised various objections against the then valid claims whereby, in particular, Claims 1 and 2 were considered to lack novelty in view of the teaching of three "abstracts" (documents D1, D2 and D3) cited in the European search report. The Appellants filed a revised set of claims which the Examining Division considered to be still not novel in the second communication dated 31 July 1989. This time reference was made to the full text of the scientific publications corresponding to the said three "abstracts" (documents D4, D5 and D6). In response thereto, the Appellants filed with a letter dated 28 November 1989 a set of amended claims based on the previous claims, except that certain amendments had been made "to stress the novelty of the invention as claimed and to meet specific objections set out in the communication of July 31st", as was pointed out by the Appellants. Also enclosed were copies of two documents which they believed to "be of assistance to the Examining Division in assessing the novelty and inventiveness of this application". These two documents were discussed in detail in the said letter. The Appellants concluded this discussion with the following statement: "It has been shown above that the claimed invention does indeed possess novelty having regard to the disclosure of these documents. It is submitted that the invention also exhibits an inventive step". The Examining Division then refused the application on the basis of one of the said documents (i.e. document (B)) (see point II above).
3. It is apparent from the above that before the decision to refuse the application the Examining Division had never informed the Appellants that it considered document (B) to

be of particular significance. The reasons why the Examining Division were of the opinion that this document was relevant for the question of novelty, and inventive step in case the claims were further limited clearly appear first in the grounds for the decision issued in writing on 30 April 1990. In the present case, this way of proceeding must be considered to be particularly unfair since document (B) is one of two documents cited by the Appellants to strengthen their position especially with regard to the novelty objection raised by the Examining Division on the basis of the three scientific publications mentioned in all two official communications.

4. It is only at the stage of appeal that, for the first time, the Appellants could respond to the objections based on document (B) by submitting comments and evidence (see point III, second paragraph above). Since it is not normally the function of a Board of Appeal to examine and decide upon issues which have been raised for the first time during appeal proceedings, remittal of the case to the Examining Division would seem to be justified in the present case especially since, prima facie, it cannot be excluded that as a consequence of the situation created by the Examining Division substantial new aspects deserving consideration by two instances could come up during the further prosecution of the case.

The Board has accordingly decided to exercise its power under Article 111(1) EPC to remit this case to the Examining Division for further prosecution.

5. As set out above, the Appellants were not given an opportunity to present their comments on the grounds on which the contested decision is based, which is clearly contrary to the provisions of Article 113(1) EPC. This

constitutes a substantial procedural violation in view of which the reimbursement of the appeal fee is equitable (Rule 67 EPC) (see decision T 18/81, OJ EPO 1985, 166).

6. Considering the particular circumstances of the case, the Board would like to draw the attention of the Examining Division to the following points to be considered when re-examining the case:

- in view of the established jurisprudence of the Boards of Appeal, feature(s) of a claim which define a result to be achieved may be allowed under Article 84 EPC in appropriate cases if, from an objective viewpoint, such features cannot otherwise be defined more precisely without unduly restricting the scope of the invention, and if these features provide instructions which are sufficiently clear to the skilled person to reduce them to practice without undue burden, if necessary with a reasonable number of experiments (cf. decision T 68/85, OJ EPO 1987, 228, in particular points 8.4.2 and 8.4.3 of the reasons for the decision);
- a "technical feature" within the meaning of Rule 29(1) EPC may be defined as one that can be read by a skilled person as an instruction as to the technical procedure to be followed to achieve a given result (see decision T 68/85 mentioned above, in particular point 8.4.1 of the Reasons for the Decision).



Order

For these reasons, it is decided that:

1. The contested decision is set aside.
2. The case is remitted to the Examining Division for further prosecution.
3. The appeal fee is reimbursed.

The Registrar:



P. Martorana

The Chairman:



P.A.M. Lançon

A. I. G.