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File Number: W 31/90 - 3.3.2

Application No.: PCT US 90/00 673

Publication No.: WO 9012588

Title of invention: Treatment and prevention of oral mucositis with growth factors

Classification: A61K 37/36

**D E C I S I O N**  
of 30 November 1990

Applicant: Triton Biosciences Inc.

Proprietor of the patent:

Opponent:

Headword:

EPC PCT Art. 17(3)(a) and Rule 40.1

Keyword: "Invitation to pay additional fee - no legal basis - obligation to search the invention first mentioned in claims"

**Headnote**



Case Number : W 31/90 - 3.3.2

International Application No. PCT/US 90/00 673

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 30 November 1990

Applicant : TRITON BIOSCIENCES INC.  
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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 16 May 1990.

Composition of the Board :

Chairman : P. Lançon  
Members : I. Holliday  
C. Holtz

## Summary of Facts and Submissions

- I. The Applicant filed International Patent Application PCT US 90/00 673.
- II. The European Patent Office (EPO) acting as International Search Authority (ISA) sent to the Applicant an invitation to pay an additional search fee in accordance with Art. 17(3)(a) and Rule 40.1 PCT. The said invitation indicated that the ISA considered that the above mentioned application related to the following groups of subject-matter which did not satisfy the criteria of unity of invention:
1. Claims 26, 34, 36, 37; partly 33, 35 and 44 :  
Use of a growth factor for preventing or treating chemotherapy or radiotherapy induced oral mucositis.
  2. Claims 27-32, 38-43; partly 33, 35 and 44 :  
Use of a growth factor containing a certain peptide sequence for preventing or treating chemotherapy or radiotherapy induced oral mucositis.
- Claims 1-25 and 45-48 which related to non-patentable subject-matter were not searched, in accordance with Rule 39.1(iv) PCT.
- III. The Applicant paid the additional search fee under protest (Rule 40.2(c) PCT). In support of the protest, the Applicant argued that Rule 13.4 PCT permitted dependent claims which recite specific forms of the invention claimed in an independent claim. Claim 26 is a claim to a composition based on a growth factor for use in preventing oral mucositis. The dependent claims 27-33 merely set out specific growth factors containing polypeptide sequences

all of which fall within the broader class defined by claim 26. There is accordingly a single general inventive concept. An analogous argument applies to claim 34 and dependent claims 35-44. The Applicant chose not to comment on the prior art cited in the International Search Report.

#### Reasons for the decision

1. The protest is admissible.
2. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. If the ISA considers that the claims lack this essential unity, it is empowered, under Article 17(3)(a) PCT, to invite the applicant to pay additional fees.
3. Lack of unity may be directly evident "a priori", i.e. before considering the claims in relation to any prior art. Alternatively, having regard to decision G 1/89 of the Enlarged Board of Appeal, dated 2 May 1990 (to be published in O.J. EPO), the ISA is also empowered to raise an objection "a posteriori", i.e. after having taken the prior art into consideration. The Enlarged Board reached this conclusion having considered the agreement (dated 7.10.87) between the EPO and the World Intellectual Property Organization (WIPO) relating to the international search according to which the EPO, when acting as ISA, shall be guided by the "Guidelines for International Search", issued by WIPO (dated 18.11.77). Such objections "a posteriori" are mentioned in Chapter VII, point 9 of the said "Guidelines". The Enlarged Board indicated that this represented only a provisional opinion on novelty and

inventive step which was in no way binding upon the authorities subsequently responsible for the substantive examination of the application (Reasons, Point 8.1).

- 3.1 However, the Enlarged Board in point 8.2 of the Reasons mentioned that such invitations to pay additional fees should always be made with a view to giving the applicant fair treatment and should only be made in clear cases.
- 3.2 Rule 40.1 PCT stipulates that the invitation provided for in Article 17(3)(a) PCT must specify the reasons for which the international application is not considered as complying with the requirements of unity of invention. It is also established EPO case law that the requirement to give reasons is so fundamental that an unsubstantiated invitation cannot be regarded as legally effective (cf. Decisions W 04/85, OJ EPO, 1987, 63 and W 07/86, OJ EPO 1987, 67).
4. As well as listing the two alleged inventions set out in Point II above, the ISA indicated that it considered that "the general problem underlying the invention is not novel and a solution to it has already been found or does not involve an inventive step having regard to the state of the art". The following documents were cited:

- (1) Gabrilove et al., 1988, N. Engl. J. Med., vol. 318(2), p. 1414-1422
- (2) Bronchud et al., March 1989, Blood Rev., vol. 3(1), p. 66-70
- (3) EP-A-0 161 817 (ICI), 1985.

The ISA then argued that "the original single inventive concept is not acceptable anymore, making it necessary to

reconsider the technical relationship or interaction between the different solutions mentioned". An objection "a posteriori" was thus apparently intended.

5. Although the reasons of the ISA which accompanied the invitation according to Rule 40.1 PCT are difficult to follow, it is apparent from paragraph 2 of the Applicant's letter dated 2 July 1990 that they had been understood to an extent sufficient to prepare a rebuttal.
  
6. According to the description, there have been no studies done on wound healing of oral mucosal tissue where the epithelial layer and underlying stromal tissue have been damaged or destroyed as a result of chemotherapy (cf. page 4, lines 1-5). Accordingly, the technical problem appeared to be the provision of a composition for the prophylactic and therapeutic use of growth factors in the treatment of lesions due to chemotherapy or radiotherapy induced oral mucositis (page 4, lines 15-19). The solution claimed in Claims 26 to 44 relates to compositions comprising generally an amount of one or more growth factors with a pharmaceutically acceptable non-toxic vehicle or carrier therefor (Claims 26 and 34) as well as, more specifically, growth factors which bind to epidermal growth factor receptors and which contain six essential residues spaced in a specific pattern (Claims 27-32 and 38-43).
  
- 6.1 The ISA cited three documents together with the invitation. From document (1), especially Table 5 and the second complete paragraph in the right-hand column of page 1420, it is apparent that growth factors had already been employed in the prevention of chemotherapy induced oral mucositis. It is also apparent from document (3) (see page 4, lines 4-9) that growth factors have been used in the treatment of a damaged alimentary tract. Thus, the

problem set out above in relation to Claims 26 and 34 is known and a solution has been proposed.

- 6.2 In view of the said prior art, the technical problem has to be redefined. In relation to Claim 27 and sub-claims 28 to 32 as well as 38-43, the problem can be seen in the selection of better growth factors for the prevention or treatment of chemotherapy or radiotherapy induced oral mucositis. The solution would lie in the choice of a specific growth factor.
- 6.3 As far as Claim 35 as well as sub-claims 36 and 37 are concerned, the problem could be in the provision of alternative compositions, but the solution claimed is the provision of a composition comprising one or more growth factors and a therapeutic agent whereby the growth factor need not necessarily be restricted in the same way as for Claim 27. In other words, it is the Board's opinion that a posteriori there are potentially two inventions.
7. However, in Article 17 PCT, relating to the procedure before the ISA, there is clear wording in paragraph 3(a) stating that "if the International Searching Authority considers that the international application does not comply with the requirement of unity of invention as set forth in the regulations, it shall invite the Applicant to pay additional fees. The International Searching Authority shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims ("main invention") and, provided the required additional fees have been paid within the prescribed time limit, on those parts of the international application which relate to "inventions in respect of which the said fees were paid" (emphasis added).

- 7.1 Under Article 17(3)(a) PCT, the ISA is obliged to establish the International Search Report on the basis of that part of the application which has been mentioned first in the claims. It appears to the Board acceptable to group Claims 26 and 34 together as did the ISA, i.e. the prophylactic or therapeutic medical indication can be regarded as a single inventive concept. Accordingly, if Claim 26 falls, the ISA is obliged to search the invention first mentioned thereafter in the claims, i.e. that of Claims 27-32. The ISA did not, however, follow this course, since the first invention mentioned in the invitation refers to Claims 36 and 37. In the Board's opinion, this clearly corresponds to the second group of subject-matter mentioned in the claims and cannot be regarded as the "main invention".
- 7.2 There is an inconsistency between what the ISA should have done according to Article 17(3)(a) PCT and what the invitation states as having been done. Accordingly, there is confusion as to the object of the international search. In any event, it remains the case that when it issued the invitation, the ISA did not produce any search result in respect of the "main invention". The Board thus concludes that the ISA did not act according to its obligation as clearly defined in Article 17(3)(a) PCT.
8. Under these circumstances, there was no legal basis to invite the Applicant to pay an additional search fee.



**Order**

**For these reasons, it is decided that:**

**Reimbursement of the additional fee to the Applicant is ordered.**

**The Registrar:**

**The Chairman:**

**M. Beer**

**P. Lançon**