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D E C I S I O N
of 9 October 1997

Case Number: T 0529/94 - 3.3.2

Application Number: 87300248.9

Publication Number: 0231070

IPC: A61K 9/10

Language of the proceedings: EN

Title of invention:
Fluorocarbon blood substitutes

Applicant:
ALLIANCE PHARMACEUTICAL CORP.

Opponent:

-

Headword:
Blood substitutes/D.LONG

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 67, 86(3)

Keyword:

"Amendments (yes) - late submitted amendments disclosed in the
filed application"
"Procedural violation (no) - sufficient reasons to exercise the
discretion provided for by Rule 86(3)"
"Second oral proceedings correctly denied"

Decisions cited:

-

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0529/94 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 9 October 1997

Appellant: ALLIANCE PHARMACEUTICAL CORP.
3040 Science Park Road
San Diego
California 92121 (US)

Representative: Armitage, Ian Michael
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 3 February 1994
refusing European patent application
No. 87 300 248.9 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: C. Germinario
J. H. van Moer

Summary of Facts and Submissions

- I. European patent application No. 87 300 248.9 (publication number 0 231 070) was refused by the examining division.
- II. The examining division issued the communication under Rule 51(4) EPC, informing the appellants of the text in which it intended to grant a European patent and requesting the applicants' approval of such notified text within a set period. The text had been agreed upon during the oral proceedings held on 18 May 1993.

In a letter received on 14 June 1993, which crossed with the Rule 51(4) communication (8 June 1993), the appellants requested that the sets of claims proposed for grant be replaced by two new sets of claims, one for all the contracting states except AT and ES and the second for AT and ES, each comprising two additional dependent claims, namely claims 3 and 4. In the accompanying comments, the applicants erroneously indicated that the new claims merely repeated the subject-matter of original claim 2, although they actually meant claim 2 of a set of claims filed during the examination proceedings (2 October 1990) and deleted, along with others, during the oral proceedings on 18 May 1993. They also requested that a second oral proceedings be scheduled in the event that the amendments were not accepted by the examining division.

In an official communication dated 4 August 1993, the examining division indicated that original claim 2 did not disclose the subject-matter of newly filed claims 3 and 4, and that these claims contravened the requirements of Article 123(2) EPC.

In response, the appellants recognised that the subject-matter of newly filed claims 3 and 4 was indeed to be found in claim 2 filed on 2 October 1990. They further stressed that support for this claim, for the purposes of Article 123(2) EPC, had been indicated to the examining division in a letter dated 23 December 1991.

In a further official communication, the examining division maintained the objection under Article 123(2) EPC. Additionally, making use of the discretionary power under Rule 86(3) EPC, it refused to give its consent to the requested amendments, firstly because they were not intended to meet an objection from the examining division and secondly because they had been filed very late in the proceedings and after the text to be granted had been agreed upon by the appellants' representative during the oral proceedings.

As to the request for an additional oral proceedings, the examining division held that the subject-matter of the dependent claims had already been properly discussed during the first oral proceedings, therefore there was no reason for a second hearing, which would have had the same subject as the first one.

In conclusion, on the basis that there was no text to which the applicants had given their approval and since the amendments proposed were neither admissible nor allowable, a decision to refuse the European patent application was issued on 3 February 1994.

III. The appellants lodged an appeal against this decision. Their arguments may be summarised as follows:

Newly filed claims 3 and 4 repeat the subject-matter of claim 2 filed on 2 October 1990, which was dropped during the oral proceedings because its subject-matter was partially integrated within the subject-matter of the new claims formulated at the oral proceedings.

The basis, for the purposes of Article 123(2) EPC, for said claim 2 was properly indicated in the appellants' letter of 23 December 1991. It was the appellant's view that neither during the written proceedings nor during the oral proceedings was this claim discussed or objected to by the examining division with respect to Article 123(2) EPC. Therefore, in refusing further oral proceedings to discuss the allowability under Article 123(2) of newly filed claims 3 and 4, which derive from said claim 2, the examining division committed a substantial procedural violation which would justify the refund of the appeal fee.

As to the substantive aspects of the two claims, 3 and 4, the appellants pointed out all the passages in the original application which, in their opinion, disclosed the subject-matter of the two new claims. They also maintained that the examining division failed to identify precisely the reason for the rejection under Article 123(2) EPC, and ignored the appellants' letter of 23 December 1991 indicating unambiguously the passages of the original document disclosing the requested amendments. This situation would amount to a further procedural violation justifying the refund of the appeal fee. Finally, the appellants requested the introduction of an additional amendment into the text of claim 1.

- IV. The board issued a communication in which it expressed some doubts about the real identity of the cumulative subject-matter of the new claims 3 and 4 and that of claim 2 of 2 October 1990.

V. In response to the board's communication, a further amended form of claims 3 and 4 was filed by telefax on 11 April 1997. In the new text the expression "long-term stability" was replaced by "long-term particle size stability". The request for further amendments was withdrawn.

VI. The text of independent claims 1 and 2 and dependent claims 3 and 4 of the first set reads as follows:

"1. A brominated perfluorocarbon (BPFC) aqueous phase emulsion, having a BPFC content of greater than 50W/V%, with a minor amount of an emulsifying agent and a biocompatible quantity of a compound selected from steroid hormone, cholesterol, tocopherol and combinations thereof, and having long term particle size stability and being acceptable for oxygen transport or contrast enhancement in the human or animal body.

2. A monobrominated perfluorocarbon (BPFC) aqueous phase emulsion, having a BPFC content of greater than 50W/V%, with a minor amount of an emulsifying agent, and having long term particle size stability and being acceptable for oxygen transport or contrast enhancement in the human or animal body.

3. An emulsion according to claim 2, having long term particle size stability in the non-frozen state.

4. An emulsion according to claim 2 or claim 3, having long term particle size stability following heat sterilation."

VII. The appellants confirmed by telefax on 19 August 1997 their request that the decision of the examining division be set aside, that the patent be granted on the basis of the amended sets of claims 1 to 23 for all the contracting states except AT and ES and claims 1 to 23 for the contracting states AT and ES received by the EPO on 14 June 1993 with claims 3 and 4 amended by telefax of 11 April 1997, and both sets resubmitted in complete by telefax of 15 September 1997 that the appeal fee be reimbursed, and that oral proceedings be held before the board take any adverse decision.

Oral proceedings were not requested if the only remaining issue concerned the refund of the appeal fee.

Reasons for the decision

1. The appeal is admissible.
2. *Article 123(2) EPC*

Although the examining division has exercised the discretionary power under Rule 86(3) EPC to refuse to give its consent to the requested amendments, with the result that the claims were considered as inadmissible, *de facto*, in its decision, the examining division has also considered the substance of new claims 3 and 4 and has concluded that they were not allowable pursuant to Article 123(2) EPC.

Claims 3 and 4 as amended on 11 April 1997 are dependent on claim 2 which is directed to a monobrominated BPFC aqueous phase emulsion comprising the emulsifying agent but no compound selected from steroid hormones, cholesterol, etc.

Compositions as claimed in claim 2 are clearly disclosed in the original application on page 9, line 16, to page 10, line 11. The stability of these compositions following heat sterilisation according to claim 4 is clearly disclosed at page 10, lines 5 to 11.

As to the feature of stability in the non-frozen state according to claim 3, this feature is not cited *expressis verbis* in the original application but, in the board's view, it is implicit in its context. The object of the present invention is indeed that of providing stable emulsions of fluorocarbon capable of sterilisation, preferably by heat, and having long-term size and functional stability in the fluid or non-frozen state (original application, page 2, first paragraph). Nothing in the paragraphs disclosing the specific compositions of claim 2 (pages 9 and 10) would allow the reader to conclude that the size stability up to sixteen months reported on page 10, lines 5 to 11 is achieved in the frozen state. On the contrary, the reader would understand, in consideration of the object of the invention, that the size stability was evaluated in the non-frozen state for instance at the conditions given in example V (page 16, lines 1 to 7). A size stability of more than one month in the non-frozen state is also disclosed in the original claim 3.

In conclusion, claims 3 and 4 meet the requirements of Article 123(2) EPC.

3. *Procedural violation*

- 3.1 The appellants envisaged two procedural violations each of which, in their opinion, would justify the refund of the appeal fee.

The one lies in the fact that the examining division disregarded the applicants' letter dated 23 December 1991 indicating the passages of the original application disclosing, for the purposes of Article 123(2) EPC, the support for the new claims 3 and 4.

The other resides in the decision of the examining division not to hold the requested second oral proceedings to discuss the allowability of new claims 3 and 4.

The board's view is that Rule 67 EPC requires *inter alia* the existence of a substantial procedural violation and that a procedural violation is substantial where it has an effect on the outcome of the procedure, ie the order issued.

In the board's opinion, the examining division, in exercising the discretionary power under Rule 86(3), has considered newly filed claims 3 and 4 as inadmissible (letter of 29 October 1993 and decision). The legal consequence of this measure was that claims 3 and 4 were never integrated into the text of the application and never became part of it.

For this reason denying a second oral proceedings intended to discuss the allowability of proposed amendments already judged as inadmissible cannot constitute a procedural violation.

- 3.2 Furthermore, although in the board's judgement there was no need for the examining division to consider, during the written phase of the proceedings, the substantive matter of claims 3 and 4 as it did when examining their allowability under Article 123(2) EPC, no procedural abuse can be envisaged in the fact that the examining division had performed the additional

examination of allowability which, in the present instance, was not mandatory. Nor may the paucity or insufficiency of the arguments presented by the examining division be considered as a procedural violation, due to the fact that this step of the examination was completely redundant.

4. The way in which the examining division should exercise its discretion under Rule 86(3) to allow or to refuse an amendment depends on the circumstances of each individual case, and e.g. on the stage of the pre-grant procedure.

Claims 3 and 4 were received by the EPO on 14 June 1993, thus shortly after the despatch of the Rule 51(4) communication (8 June 1993) and after a text ready for grant had been agreed upon during oral proceedings. The scope of these two claims was not so clear as to allow the examining division to decide without delay on the compliance of the requested amendments with the requirements of Article 123(2) EPC. As a matter of fact, the board itself had to issue a communication requesting a clarification of the text of the claims. Moreover, while submitting the new claims, the appellants indicated, for the purposes of Article 123(2) EPC, that the cumulative subject-matter of the new claims derived in its entirety from the subject-matter of original claim 2, which however was not correct, since, as admitted by the appellants' representative, support for the purposes of Article 123(2) EPC had to be found instead in claim 2 filed on 2 October 1990, which, as such, was not part of the original application.

Finally the decision to refuse the application was issued by the examining division as the final action in an examining procedure comprising a total of six communications and oral proceedings.

In consideration of the specific circumstances of the case, the board's judgment is that the examining division had sufficient reasons to exercise the discretion provided for in Rule 86(3) EPC as it did and that no substantial procedural violation justifying a refund of the appeal fee can be envisaged anywhere in the examining procedure.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

The case is remitted to the department of first instance with the order to grant a patent with the following claims and description:

claims 1 to 23 for all the contracting states except AT and ES, filed on 14 June 1993, and
claims 1 to 23 for the contracting states AT and ES, filed on 14 June 1993, with claims 3 and 4 of both sets as amended with the appellants' letter of 11 April 1997 and resubmitted in their entirety by telefax of 15 September 1997;
description: pages 1 to 16 as set out in the communication under Rule 51(4) EPC dated 8 June 1993.

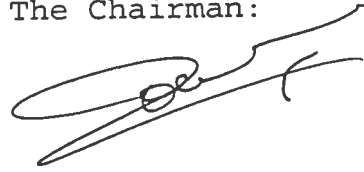
2. The request for reimbursement of the appeal fee is refused.

The Registrar:



P. Martorana

The Chairman:



P. A. M. Lançon

