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**Datasheet for the decision
of 4 February 2016**

Case Number: T 0024/14 - 3.3.07

Application Number: 10196245.4

Publication Number: 2308466

IPC: A61K9/00, A61K47/02, A61K47/10,
A61K31/535, A61K31/5575

Language of the proceedings: EN

Title of invention:
Aqueous pharmaceutical compositions containing borate-polyol
complexes

Applicant:
Alcon Research, Ltd.

Relevant legal provisions:
EPC Art. 111(1), 123(2)

Keyword:
Amendments - added subject-matter (no)
Appeal decision -
remittal to the department of first instance (yes)



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0024/14 - 3.3.07

**D E C I S I O N
of Technical Board of Appeal 3.3.07
of 4 February 2016**

Appellant: Alcon Research, Ltd.
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Fort Worth, TX 76134-2099 (US)

Representative: Teipel, Stephan
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 6 August 2013
refusing European patent application No.
10196245.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Semino
P. Schmitz

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division posted on 6 August 2013 refusing European patent application n° 10 196 245.4.

Claim 1 as originally filed read as follows:

"1. A multi-dose ophthalmic composition, comprising:
first polyol, the first polyol being selected from mannitol, sorbitol or a combination thereof wherein the first polyol is at least 0.01 but less than about 0.5 w/v % of the composition;
second polyol, the second polyol being selected from propylene glycol, glycerine or a combination thereof wherein the second polyol is at least about 0.1 but less than about 5 w/v % of the composition;
borate, wherein the borate is at least 0.05 w/v% of the composition but less than 0.5 w/v % of the composition;
antimicrobial preservative wherein the preservative is at least about 0.0003 but less than about 0.003 w/v % of the composition and wherein the preservative is a polymeric quaternary ammonium compound;
a therapeutic agent; and
water."

- II. The decision was based on a single set of claims filed with letter of 9 July 2012 as second auxiliary request, which became the single request after the higher ranking requests had been withdrawn.

Claim 1 of that request corresponded to claim 1 as originally filed with the deletion of the term "about" at five instances and the amendment of two end points of the quantity ranges ("the first polyol is at least 0.15", "the borate is at least 0.25").

- III. In the decision under appeal, the examining division found that the subject-matter of claim 1 did not meet the requirements of Article 123(2) EPC, because it was based on a selection of the upper and lower limits for each individual compound from different values, which did not refer to the most preferred limits, but was arbitrary and therefore created subject-matter which extended beyond the application as filed.
- IV. The applicant (appellant) filed an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted nine sets of claims as main request and as first to eight auxiliary requests respectively.
- The main request included 14 claims which corresponded to the claims as originally filed with the deletion of the term "about" at several instances and the amendment of the lower limit for the quantity of the borate to "0.25 w/v %" and a further dependent claim (claim 15), which had no direct correspondent in the original application.
- V. After a telephone conversation on 30 September 2015 with the rapporteur, the appellant filed with letter of 26 October 2015 an amended main request, in which claim 15 had been deleted.
- VI. The appellant hold that by virtue of the amendments in claim 1 the reasons for refusing the application were no longer applicable. As the examining division had not decided on novelty and inventive step, the case should be remitted.

VII. The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution on the basis of the main request filed with letter of 26 October 2015 or, in the alternative, according to one of the first to eighth auxiliary requests filed with the statement setting out the grounds of appeal.

Reasons for the Decision

Reasons for the refusal - Article 123(2) EPC

1. Claim 1 of the main request includes a single amendment of the concentration ranges with respect to claim 1 as originally filed, namely the lower limit for the quantity of borate is amended from "0.05 w/v%" to "0.25 w/v%".
 - 1.1 The amended lower limit is disclosed on page 7, last line of the original description as a typical value for such a lower limit. This disclosure together with original claim 1 provides a direct and unambiguous disclosure of the subject-matter of claim 1 of the main request. As a single value has been amended, the issue of an arbitrary combination of upper and lower limits for each individual compound, which formed the basis of the decision under appeal, does not hold any longer.
 - 1.2 The only additional amendment of claim 1, namely the deletion of the term "about" before the indication of the lower and upper limits of the concentration ranges at several instances, does not change the meaning of the amended features and therefore does not result in an extension beyond the content of the application as filed.

1.3 The same holds for dependent claims 2 to 13, which also include as single amendment the deletion of the term "about" (claims 8 and 13).

1.4 In view of that it is concluded that the reasons for the refusal of the application no longer apply and the claims of the main request meet the requirements of Article 123(2) EPC.

Remittal

2. The examining division decided that the subject-matter of claim 1 of the request filed before it did not meet the requirements of Article 123(2) EPC and did not address the patentability requirements.

2.1 While pursuant to Article 111(1) EPC the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision or remit the case for further prosecution, in a case such as the one at hand, where essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance, the case is normally remitted to the first instance, so that the outstanding issues may be properly examined by two instances.

2.2 Thus, in view of the above considerations and of the request for remittal of the appellant, the Board considers it appropriate to remit the case to the examining division for further prosecution on the basis of the claims according to the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of the main request filed with letter of 26 October 2015.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated