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Datasheet for the decision of 7 October 2024

Case Number: T 3253/19 - 3.3.07

Application Number: 11184501.2

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Language of the proceedings: EN

Title of invention:

Aqueous pharmaceutical compositions containing borate-polyol complexes

Patent Proprietor:

NOVARTIS AG

Opponents:

Generics [UK] Limited (trading as Mylan)
Alfred E. Tiefenbacher (GmbH & Co. KG)

Headword:

Compositions containing borate-polyol complexes / NOVARTIS

Relevant legal provisions:

EPC Art. 123(2), 76(1)

Keyword:
Amendments - added subject-matter (yes)

Decisions cited:
T 0002/81, T 1170/02, T 1621/16, T 1511/07

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Case Number: T 3253/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 7 October 2024

Appellant: (Patent Proprietor)	NOVARTIS AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Appellant: (Opponent 1)	Generics [UK] Limited (trading as Mylan) Building 4 Trident Place Mosquito Way Hatfield Hertfordshire AL10 9UL (GB)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Appellant: (Opponent 2)	Alfred E. Tiefenbacher (GmbH & Co. KG) Van-der-Smissen-Straße 1 22767 Hamburg (DE)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 December 2019 concerning maintenance of the European Patent No. 2420223 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	A. Jimenez

Summary of Facts and Submissions

I. The appeals were filed by the patent proprietor and both opponents against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 1, the patent met the requirements of the EPC.

The decision was based on the patent as granted as main request and on auxiliary request 1 filed on 16 July 2019.

Claim 1 as granted read as follows:

"A multi-dose ophthalmic composition configured for topical application as drops directly to the eye, comprising:

first polyol, the first polyol being mannitol, wherein the first polyol is at least 0.25 but less than 1.5 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 0.1 but less than 5 w/v % of the composition;

borate, wherein the borate is at least 0.25 w/v % of the composition but less than 0.5 w/v % of the composition;

antimicrobial preservative wherein the preservative is at least 0.0003 but less than 0.003 w/v % of the composition and wherein the preservative is a polymeric quaternary ammonium compound;

travoprost;

polyoxyethylene (40) hydrogenated castor oil wherein the polyoxyethylene (40) hydrogenated

castor oil is at least 0.03 but less than 0.5 w/v % of the composition; and
water,
wherein the pH of the composition is from 6.4 to 7.2; and
wherein the composition is substantially free of any benzalkonium chloride."

In claim 1 of auxiliary request 1, the range for the amount of borate was amended to "at least 0.25 w/v % of the composition but less than 0.35 w/v % of the composition".

II. The opposition division decided in particular that the combination, in claim 1 of the main request, of the ranges for the amounts of mannitol and of borate required multiple selections and contravened Article 100(c) EPC. In contrast, auxiliary request 1 met the requirements of Articles 123(2) and 76(1) EPC.

III. In appeal, the patent proprietor initially defended their case on the basis of the patent as granted (main request), auxiliary request 1 as considered by the opposition division, or auxiliary requests 2 and 3 filed on 28 August 2020 with the reply to the appeals of the opponents.

IV. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA.

V. By letters dated 15 August 2024, both opponents withdrew their requests for oral proceedings.

Oral proceedings were held before the Board in the presence of the patent proprietor only. During the oral proceedings, the patent proprietor withdrew their

appeal and made auxiliary request 1 their main and sole request.

VI. The parties' final requests were the following:

(a) Both appellants (opponent 1 and opponent 2) request that the decision under appeal be set aside and that the patent be revoked.

(b) The respondent (patent proprietor) requests that the opponents' appeals be dismissed, i.e. the maintenance of the patent on the basis of auxiliary request 1 as filed on 16 July 2019.

VII. The appellants' arguments regarding added subject-matter may be summarised as follows:

In claim 1 of auxiliary request 1, the range for mannitol combined an upper limit of 1.5 w/v% generalised from the discussion of the examples on page 18 with a lower value selected from a list on page 7 of the application as filed. This mannitol range thus represented an impermissible combination of features selected from lists and embodiments without clear pointer. Combined with the selection required to arrive at the borate range, claim 1 of auxiliary request 1 represented an impermissible extension of subject-matter compared to the application as filed.

VIII. The respondent's arguments regarding added subject-matter may be summarised as follows:

Regarding the range for the amount of mannitol, the upper limit of 1.5 w/v % was described as "typically preferred" and "generally preferred" (on pages 18 and 19) and thus presented as a preferred embodiment in a

general sense. Its combination with the most preferred (i.e. "even more typically") lower limit of 0.25 w/v% on page 7 did not amount to any undisclosed selection. As to the borate amount, the claimed range combined the narrowest upper and lower limits of the passage on pages 7-8, and would also be recognised as preferred. Thus auxiliary request 1 met the requirements of Articles 123(2) and 76(1) EPC.

Reasons for the Decision

1. Claim 1 of the sole pending request (i.e. auxiliary request 1) specifies the following ranges:
(a) the first polyol being mannitol is at least 0.25 but less than 1.5 w/v % of the composition; and
(b) the borate is at least 0.25 but less than 0.35 w/v % of the composition.

The relevant question is whether the amendments remain within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, from the whole of the application as filed as filed.

1.1 The application as filed does not disclose the above ranges as such. Instead, these ranges combine end points disclosed in the following passages of the application as filed:

1.1.1 The range 0.25-1.5 w/v% for the amount of the first polyol being mannitol combines:

- the narrowest lower limit recited, for the first polyol in general, on page 7, lines 8-12:

"The first polyol is typically at least about 0.01 w/v %, more typically at least about 0.15 w/v % and even more typically at least about 0.25 w/v % of the ophthalmic composition. The first polyol is also typically less than about 5 w/v %, more typically less than about 1.6 w/v % and even more typically less than about 0.5 w/v % of the ophthalmic composition.";

with

- the upper limit mentioned on page 18, lines 32-34 (or similarly on page 19, lines 16-17) as part of a discussion of the examples:

"Thus, for the present invention, it is generally preferred to keep mannitol concentration below about 1.5%".

1.1.2 As to the amount of borate, the range 0.25-0.35 w/v% combines the narrowest lower and upper limits recited in the paragraph bridging pages 7 and 8:

"Typically, for the present invention, the borate is at least about 0.05 w/v %, more typically at least about 0.1 w/v % and still more typically at least about 0.25 w/v % of the ophthalmic composition. Furthermore, the borate can advantageously be less than about 0.75 w/v %, more typically less than about 0.5 w/v % and still more typically less than about 0.4 w/v %, and even possibly less than about 0.35 w/v % of the ophthalmic composition."

1.2 However, in the Board's opinion, the application as filed does not disclose these ranges in combination. The above passages provide lists of lower and upper limits, from which a host of ranges may potentially be created respectively for the amounts of mannitol and borate. Yet the application as filed contains no

pointer to the combination of ranges selected in claim 1, such that this combination does not emerge directly and unambiguously from the application as filed.

1.3 The respondent argues that the use of descriptors "typically", "more typically" and "still more typically" makes it clear to the skilled person that they are presented as increasingly preferred embodiments. At the same time, the respondent emphasizes that the upper limit of 1.5 w/v % for mannitol is identified on pages 18 and 19 as "typically preferred" and "generally preferred". Accordingly, these end points and the resulting ranges defined in claim 1 would not require any element of selection.

The Board does not share this view. While it is established case law that the fact that the relevant features have been mentioned in the description as "preferred" *may* act as a pointer, the respondent's argument amounts to seeing a preference for several alternatives for the same feature at the same time, e.g. the "generally preferred" 1.5 w/v % and the "even more typically" 0.5 w/v % upper limits for the first polyol mannitol. In other words, the combination of claim 1 of auxiliary request 1 involves the selection of the narrowest range for borate and the selection of an intermediate range for mannitol, and no pointer to this combination can be recognised in the application as filed.

1.4 None of the decisions T 2/81, T 1170/02 and T 1621/16 cited by the respondent lead to a different conclusion.

T 2/81 and T 1170/02 are concerned with the issue of deriving an amended range by combining general and preferred ranges. The present case differs firstly in

that the end points are not shown in the application as filed as part of ranges, but among lists of upper and lower limits (see the Case Law of the Boards of Appeal, 10th edition, 2022, II.E.1.5.1, in particular c)). Secondly, the issue here does not relate solely to the amended borate and mannitol ranges separately, but to the lack of pointer to their combination (ibid, II.E. 1.6.2.a; see T 1511/07, point 2.1 of the reasons). Lastly, T 1621/16 is any case not applicable to the present case, because the ranges possibly derivable from the lists of upper and lower limits disclosed in the application as filed, respectively for the borate and for the first polyol, may partially overlap but do not amount to lists of converging alternatives.

1.5 Accordingly, auxiliary request 1 does not comply with the requirements of Article 123(2) EPC.

Since the patent derives from a divisional application, and that the divisional application as filed and the parent application as filed contain the same description, the same conclusion applies under Article 76(1) EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chairman:

A. Vottner A. Usuelli

Decision electronically authenticated