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Datasheet for the decision of 26 September 2006

Case Number: T 1350/05 - 3.3.02

Application Number: 01124282.3

Publication Number: 1172098

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Pharmaceutical compositions comprising ketotifen

Applicant:
Novartis AG, et al

Opponent:
-

Headword:
Ketotifen composition/NOVARTIS AG, et al

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"Added matter - no - claim restricted to a disclosed embodiment"

Decisions cited:
-

Catchword:
-

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Case Number: T 1350/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 26 September 2006

Appellant: Novartis AG
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Representative: de Weerd, Petrus G.W.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 3 May 2005 refusing European application No. 01124282.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Willems

Summary of Facts and Submissions

I. European patent application No. 01 124 282.3 was refused by a decision of the Examining Division posted on 3 May 2005 on the grounds of Articles 76(1) and 84 EPC.

II. The decision was based on the claims of the main request submitted during the oral proceedings before the Examining Division, the claims of the first auxiliary request previously filed as main request with the applicant's letter dated 11 March 2005, the claims of the second auxiliary request filed during the oral proceedings before the Examining Division and claims of the third auxiliary request previously filed as first auxiliary request with the applicant's letter dated 11 March 2005 .

III. According to the decision under appeal, the Examining Division was of the opinion that the main request and auxiliary requests 1 to 3 did not fulfil the requirements of Article 76(1) EPC and Article 84 EPC.

The Examining Division rejected these requests, which all involved compositions without chelating agent, because, in its opinion, they did not comply with the requirement of Art. 76(1) EPC, since the application as filed did not disclose an embodiment without a chelating agent as a suitable eye drop formulation.

It moreover held that the absence of this mandatory feature in the claims infringes the requirements of Article 84 EPC.

Accordingly, all requests were rejected.

IV. The appellant (applicant) lodged an appeal against this decision.

V. Oral proceedings were held on 26 September 2006.

During the oral proceedings, the appellant filed a main request with a single claim as its only request.

The claim reads:

"1. Eye drop composition in 10 ml white-colored polypropylene (PP) bottles consisting of 0.0345% ketotifen hydrogen fumarate, 2.125% glycerol, 0.01% benzalkonium chloride, 1 N sodium hydroxide to adjust the pH of said composition to 5.32 and water, wherein said composition is autoclavable."

The appellant argued that the subject matter of claim 1 of the main request was clear and supported by example 3 of the description of the application as filed.

VI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the claim of the main request filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Claim 1 of the main request mainly differs from claim 1 of the requests before the Examining Division in that its subject-matter has now been strictly restricted to the third embodiment of example 3 of the description of the application as originally filed without any generalisation of any feature of this example.

2.2 The present wording of claim 1 satisfies the requirements of Article 84 EPC.

The claimed composition is defined in terms of clear and unambiguous features, namely, its components and its pH together with an indication of the method and conditions used to achieve said pH.

2.3 Article 123(2) EPC

The application as originally filed discloses in example 3 an embodiment relating to an eye drop composition in 10 ml white-colored polypropylene (PP) bottles consisting of 0.0345% ketotifen hydrogen fumarate, 2.125% glycerol, 0.01% benzalkonium chloride, and water, wherein the pH is adjusted with 1 N sodium hydroxide to 5.32 (page 8, example 3, third embodiment referred to as "comparative").

In the decision under appeal, the Examining Division argued in relation to the various requests that the

presence of a chelating agent as stabiliser was a mandatory feature which could not be omitted without contravening of Article 76(1) EPC.

The Board agrees with the Examining Division that the application as originally filed teaches that the "invention further describes a method for stabilizing such compositions" (see page 3, second sentence).

This does not, however, change the fact that the specific composition of claim 1 of the main request as such, ie this very composition without stabiliser, is also disclosed in the application as originally filed.

For these reasons, the Board concludes that claim 1 of the main request which is strictly restricted to this disclosed embodiment meets the requirements of Article 76(1) EPC.

3. *Remittal*

It follows from the above that the subject matter of claim 1 of the main request fulfils the requirements of Articles 84 and 123(2) EPC. The examination of the present application should therefore proceed on the basis of the text as amended according to the appellant's main request.

Having so decided, the Board has not taken a decision on the whole matter since the decision under appeal was solely based on deficiencies of claim 1 with respect to Articles 84 and 123(2) EPC. It is noted that the Examining Division has not yet ruled on the other

requirements for granting a European patent, and these issues clearly require careful consideration.

In the light of the above findings, it is necessary to remit the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of the claim filed as main request during the oral proceedings.

The Registrar The Chairman

A. Townend U. Oswald