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**Datasheet for the decision
of 3 February 2009**

Case Number: T 1469/07 - 3.3.02

Application Number: 97944240.7

Publication Number: 0948320

IPC: A61K 9/20

Language of the proceedings: EN

Title of invention:

Pharmaceutical compositions for sustained release of the HMG-CoA reductase inhibitor fluvastatin

Patentee:

NOVARTIS AG, et al

Opponent:

Ratiopharm GmbH
Actavis UK Ltd
Actavis GmbH

Headword:

Pharmaceutical compositions/NOVARTIS AG, et al

Relevant legal provisions:

EPC Art. 111

Relevant legal provisions (EPC 1973):

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Keyword:

"Remittal - yes: fresh case"

Decisions cited:

G 0001/94

Catchword:

-



Case Number: T 1469/07 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 3 February 2009

(Opponent 01)

Ratiopharm GmbH
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Representative:

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(Opponent 02)
Intervener 1

Actavis UK Ltd
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Representative:

Gillard, Richard Edward
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(Opponent 03)
Intervener 2

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Respondent: NOVARTIS AG
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
20 August 2007 concerning maintenance of
European patent No. 0948320 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
P. Mühlens

Summary of Facts and Submissions

- I. European patent No. 0 948 320 based on application No. 97 944 240.7 was granted on the basis of a set of 11 claims.

Independent claim 1 as granted read as follows:

"1. A sustained release pharmaceutical composition comprising a water soluble salt of fluvastatin as active ingredient and being selected from the group consisting of matrix formulations, diffusion-controlled membrane coated formulations and combinations thereof."

- II. Notice of opposition was filed against the granted patent by the appellant (opponent O1).

The patent was opposed under Article 100(a) EPC for lack of inventive step and under Article 100(b) EPC for insufficiency of disclosure.

Opponent O1 cited 12 documents ((1) to (12)) to substantiate its objections during the opposition proceedings.

- III. In its interlocutory decision dated 27 March 2007 the Opposition Division held that the patent could be maintained in an amended form, on the basis of a text submitted during the oral proceedings and which met the requirements of Articles 123, 83, 54 and 56 EPC.

During the prosecution, the Opposition Division introduced a new document, namely document (13), which

was cited in the description of the patent in suit as relevant prior art.

It considered this document to represent the closest prior art and examined its relevance for the assessment of novelty, of its own motion, and inventive step.

IV. The appellant lodged an appeal against the said decision with its letter dated 3 August 2007.

It filed 16 new documents ((14) to (29)) with its grounds of appeal. The arguments set out in the grounds of appeal were supported by reference not only to these documents but also to those filed during the opposition proceedings.

Moreover, 7 documents (14) to (20) were cited against novelty of the subject-matter of the contested patent.

V. Notice of opposition dated 17 January 2008 was filed by intervener I1 (opponent O2).

The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for added subject-matter.

With its notice of intervention, opponent O2 cited 19 new documents ((30) to (47) and document BNF) to substantiate its objections.

VI. A Request for accelerated prosecution was filed by the intervener on 20 March 2008.

- VII. The respondent (patent proprietor) argued in written submissions of 5 August 2008 that the appellant and opponent 02 were making a fresh case on appeal which had not been considered by the first instance and requested that the case be immediately remitted to the first instance.
- VIII. In a communication dated 22 September 2008, the Board informed the parties of its intention to remit the case to the first instance, and invited the parties to reconsider their request for the oral proceedings scheduled for 3 February 2009.
- IX. Notice of intervention dated 23 January 2009 was filed by intervener I2 (opponent 03).
- The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.
- With its notice of intervention, opponent 02 cited 3 new documents ((48) to (50)) to substantiate its objections.
- X. In the oral proceedings held before the Board on 3 February 2009 the question of possible remittal was dealt with as announced in the Board's communication dated 22 September 2008.
- XI. The appellant and opponents 02 and 03 argued against the request for remittal. They contended that the respondent had had enough time to study the new documents, which moreover they had cited on appeal in order to react to the appellant's change of strategy

for establishing inventive step during the oral proceedings before the Opposition Division.

They also submitted that it would not be appropriate to remit the case to the first instance, thereby delaying the result for several more years. That would be contrary to the public interest and legal certainty, especially when in accelerated prosecution had been requested.

- XII. The respondent submitted in substance in support of its request for remittal that the nature of the prior art relied upon by the appellant had dramatically changed its case, which was now based on 39 new prior art documents which had not been considered by the Opposition Division, including 7 new documents cited against novelty a ground not raised by opponent 01 during the opposition procedure, including new closest prior art, (i.e. document (14)), and an expert's opinion, i.e. document (50).

In its opinion, this constituted a fresh case, and it should not be deprived of the opportunity of having the validity of the patent over the new prior art considered at two instances.

- XIII. The appellant and opponents 02 and 03 requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the case be immediately remitted to the Opposition Division or that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. The question to be considered by the Board is whether, in a case where a large volume of new evidence has been filed on appeal by the appellant and the interveners, remittal of the case to the first instance is appropriate.

As regards the admissibility of documents (14) to (20) filed by the appellant with its grounds of appeal, the Board considers that the appellant could not have produced these documents relating to novelty before the appeal proceedings, as this was not a ground of opposition.

As to the other documents (21) to (29) filed with the grounds of appeal, the Board has no reason to doubt that they constitute an attempt to establish that the Opposition Division's decision does not hold good.

Accordingly, the appellant's new 16 documents are admitted into the proceedings.

As to the documents filed by the interveners, the Enlarged Board of Appeal's decision G 1/94 (OJ, 1994, 787, reasons 13) establishes that an intervener should be entitled to all available means to attack the patent, so the Board has no power to refuse to admit facts and arguments into appeal proceedings.

Accordingly, the intervener's new 22 documents are admitted.

Thus the respondent's case is now based on 38 new prior-art documents and evidence not considered by the Opposition Division, including 7 new documents cited against novelty - a ground not raised by opponent 01 during the opposition procedure - new closest prior art (i.e. document (14)), and an expert's opinion, i.e. document (50).

In these circumstances, the Board considers that there is considerable force in the respondent's argument for remittal.

It is true that, as the appellant and interveners have observed, it is in the interest of the public and of legal certainty to have a final decision as quickly as possible. However, it is clear that, as indicated above, essentially the fresh case was caused not by the respondent but by the new evidence filed by the appellant and the interveners. Thus, the responsibility for remittal lies primarily with the appellant and interveners who should have been well aware that the probability of remittal would increase with the number of facts and amount of evidence submitted.

Accordingly, in the exercise of its discretion, the Board considers that the case against the patent has now altered to such an extent that the respondent has a legitimate reason to have its full case considered at two instances. Therefore remittal of the case to the first instance is appropriate (Article 111(1) EPC).

The Board observes moreover that this will be prejudicial to the respondent as well as the appellant and interveners, since the respondent will be inhibited in any attempts to enforce the patent against alleged infringers.

3. As to the appellant's and interveners' request for examination of the formal aspect of the set of claims on file, the Board considers that, in the light of the numerous documents and evidence on file, the claims are likely to require amendment during the further prosecution, so any decision in that respect would be counter-productive.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar

The Chairman

N. Maslin

U. Oswald