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**Datasheet for the decision  
of 25 February 2009**

**Case Number:** T 0764/06 - 3.3.01

**Application Number:** 96924368.2

**Publication Number:** 0848705

**IPC:** C07D 207/34

**Language of the proceedings:** EN

**Title of invention:**

Crystalline R-(R\*,R\*)-2-(4-fluorophenyl)-beta, delta-dihydroxy-5-(1-methylethyl)-3-phenyl-4-(phenylamino)carbonyl-1H-pyrrole-1-heptanoic acid hemi calcium salt (atorvastatin)

**Patentee:**

Warner-Lambert Company LLC

**Opponent:**

Teva Pharmaceutical Industries Ltd.  
LEK Pharmaceutical and Chemical Company d.d.

**Headword:**

Crystalline form of atorvastatin/WARNER-LAMBERT COMPANY LLC

**Relevant legal provisions:**

EPC Art. 123(2), 114(2), 113(1), 100(c)  
RPBA Art. 13(1)(3)

**Relevant legal provisions (EPC 1973):**

EPC R. 55(c), 76(c)

**Keyword:**

"Admissibility of allegedly new ground of opposition (yes)"

"Added matter (yes) - Omission of an essential feature"

"Late-filed request (not admitted)"

**Decisions cited:**

G 0007/95, G 0001/95, G 0010/91, G 0009/91, T 0746/99,

T 0128/98, T 1180/97, T 0114/95, T 0926/93, T 0737/92

**Catchword:**

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Case Number: T 0764/06 - 3.3.01

**DECISION**  
of the Technical Board of Appeal 3.3.01  
of 25 February 2009

**Appellant:** LEK Pharmaceutical and Chemical Company d.d.  
(Opponent II) Verovskova 57  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
6 April 2006 concerning maintenance of European  
patent No. 0848705 in amended form.

**Composition of the Board:**

**Chairman:** P. Ranguis  
**Members:** J.-B. Ousset  
R. Menapace

## Summary of Facts and Submissions

- I. Opponent II and the patent proprietor both appealed against the decision of the opposition division that maintained the European patent No. 0 848 705 as amended according to the only auxiliary request filed on 20 January 2006 and the adapted description meeting the requirements of the EPC. The patent proprietor withdrew his appeal during the oral proceedings before the board.

Claim 1 according to that auxiliary request read as follows:

"1. Crystalline Form I atorvastatin (i.e. [R-(R\*,R\*)]-2-(4fluorophenyl)- $\beta$ , $\delta$ -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid hemi calcium salt) hydrate, having an X-ray powder diffraction pattern containing the following 2 $\theta$  values measured using CuK $\alpha$  radiation 9.150, 9.470, 10.266 10.560, 11.853, 12.195, 17.075, 19.485, 21.626, 21.960, 22.748, 23.335, 23.734, 24.438, 28.915, 29.234."

- II. Claims 1 and 4 as granted read as follows:

"1. Crystalline Form I atorvastatin (i.e. [R-(R\*,R\*)]-2-(4fluorophenyl)- $\beta$ , $\delta$ -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid hemi calcium salt) hydrate, having an X-ray powder diffraction pattern containing the following 2 $\theta$  values measured using CuK $\alpha$  radiation: 19.485 and 21.626."

"4. Crystalline Form I atorvastatin hydrate, having an X-ray powder diffraction pattern containing the

following  $2\theta$  values measured using  $\text{CuK}\alpha$  radiation:  
9.150, 9.470, 10.266, 10.560, 11.853, 12.195, 17.075,  
19.485, 21.626, 21.960, 22.748, 23.335, 23.734, 24.438,  
28.915, 29.234."

III. The oppositions filed by the three opponents I, II and III sought revocation of the patent in suit in its entirety. Opponents I and III had raised, in particular, an objection under Article 100 (c) EPC (the latter later withdrew his opposition). The opposition division held, however, that the subject-matter of the auxiliary request fulfilled the requirements of Article 123(2) EPC.

IV. The appellant argued *inter alia* that the subject-matter of claim 1 (see point 1 above) gave rise to an objection under Article 100 (c) EPC, because, the  $2\theta$  values mentioned in claim 1 were not associated with their relative intensity values as set out in the description as originally filed. Therefore, even very small intensities were encompassed within the claimed scope. However, the application as filed was limited to relative intensities of  $>20\%$  (see Tables on pages 4 and 13 and claim 1) so that these relative intensity values represented indispensable characteristics. Their omission led, thus, to a subject-matter extending beyond the disclosure of the application as originally filed.

Furthermore, the amended set of claims submitted during oral proceedings held on 25 February 2009 should not be admitted because late filed.

V. Opponent I (Respondent II), who neither filed an appeal nor intervened in writing, was present at the oral proceedings and declared that he did not have any specific request.

VI. Respondent I (patent proprietor, hereafter "Respondent") considered that the objection based on Article 100(c) EPC should not be admitted in view of Article 114(2) EPC and the constant jurisprudence of the boards of appeals, in particular decisions T 746/99; T 128/98; T 737/92; G 9/91 and G 10/91). Furthermore, before the opposition division no objection had been raised against claim 1 (identical to claim 4 as granted and found to meet the requirements of the EPC) and this claim was not examined by the opposition division on the basis of Article 100 (c) EPC.

Furthermore, the respondent contested the appellant's argument with respect to the relative intensity values, because these values could not be considered as structural parameters of the claimed compounds as admitted by the opponents in their written submissions before the opposition division and confirmed by the following documents:

- (3) US Pharmacopeia 23, pages 1843-1844
- (4) Pharmeuropa, vol. 14, No. 1, January 2002, pages 185-191
- (7) Jenkins R. and Snyder R.I., "Introduction to X-Ray Powder Diffractometry", (1996), John Wiley & Sons, Inc., pages 358,238,239.

The relative intensity of each peak is dependent on several parameters and the values can change as

illustrated by document (3) (see page 1843, right-hand column, third paragraph from the bottom) and document (7) (see first paragraph on page 358). Moreover, the relative intensity values are used to compare an unknown crystal with a known reference as shown in document (3) (see page 1844, beginning of the last paragraph) and document (4) (see pages 189-190 bridging paragraph). In contrast, in the patent in suit the structure of the compound has already been described.

The filing of a new set of claims during oral proceedings after the board had announced that claim 1 gave rise to an objection under Article 100 (c) EPC was justified by the fact that no hint had been given by the board during the written procedure that the admissibility of the ground of appeal pursuant Article 100(c) EPC would be discussed during the oral proceedings, this point not having been discussed in the opposition proceedings either.

Furthermore, up to then relative intensity values had not been considered an essential parameter to characterize the crystalline form claimed in claim 1.

VII. The appellant requested that the interlocutory decision of the opposition division be set aside and the patent in suit be revoked.

The respondent requested that the appeal be dismissed.

VIII. At the end of the oral proceedings, the decision of the board was announced.

## Reasons for the Decision

1. The appeal is admissible
2. Claim 1 found to be allowable in the decision under appeal corresponds to claim 4 as granted (see points I and II above).

### *Admissibility of the ground of opposition pursuant to Article 100(c)EPC*

3. The respondent maintained that this ground for opposition should be disregarded on the ground that it had not been raised by any of the opponents against the claims 4, 6 and 9 as granted, now claims 1, 6 and 9 and it had not been examined by the opposition division. As it had not been in dispute during the opposition proceedings said ground for opposition was not admissible on appeal.

In support of this position the respondent relied on decisions T 737/92, T 128/98, T 746/99, G 9/91 and 10/91, which he contended represented the relevant constant jurisprudence of the boards of appeal.

- 3.1 Rule 55(c) EPC 1973, now Rule 76(c) EPC, does not refer to claims but rather requires that the notice of opposition contains a statement of the extent to which the patent was opposed. Where an opponent - as in the present case - requested revocation of the patent in its entirety, for the requirements of said Rule, which include the grounds on which the opposition is based, to be met, it is sufficient to substantiate the ground(s) for opposition in respect of at least one



claim of the patent. If one claim of each request is found not to be allowable, the patent will be revoked. Thus an opponent is under no obligation to substantiate grounds of opposition against more than one claim of such request (decisions T 926/93, OJ EPO 447, T 114/95, and T 1180/97). Furthermore, it was held in decision T 114/95 that there was no limitation set by the EPC on allowing an opponent, whose opposition was considered admissible, to support and use grounds, evidence and arguments for revocation of the patent that were submitted by other opponents.

3.2 The decisions of the boards of appeal cited by the appellant are not relevant and, in any event, not in conflict with the jurisprudence set out above: Decision T 737/92 concerned the situation where the ground of opposition pursuant Article 100(c) was not substantiated at all. In the case underlying Decision T 128/98 an objection based on Article 100(c) EPC was raised for the first time in the statement setting out the grounds of appeal. In decision T 746/99 it was lack of novelty which had not been in dispute during opposition proceedings, which ground of opposition was then held not admissible on appeal.

3.3 The patent in suit was opposed in its entirety by all opponents, either explicitly or implicitly, as none of them had made a statement under Rule 55(c) EPC 1973 that the patent was opposed only to a certain extent (see Point 8 of the decision G 9/91, OJ EPO 1993,408 and G 10/91, both cited by the appellant, but equally of no relevance for the specific matter at issue, in that both deal in essence with the restriction of the

examination of an opposition to the grounds raised in the notice of opposition).

As to the substantiation of the ground of opposition in question, this requirement (see decisions G 1/95 and G 7/95, OJ EPO 1996, 615 and 626) was undisputedly also fulfilled at least by one opponent (e.g. "III. Unzulässige Erweiterung gemäss Artikel 123(2) EPÜ" on pages 5 - 8 of the notice of appeal of opponent I).

- 3.4 It follows, that in the present case the ground for opposition under Article 100(c) EPC did not constitute a fresh ground for opposition and, therefore, its consideration by the board of appeal did not require the appellant's (patentee's) approval (see decision G 10/91).
- 3.5 From the fact that none of the opponents objected to the allowability of auxiliary request 1 in view of the requirements of Article 123(2) EPC as mentioned in the decision of the opposition division, and no argument was put forward against claim 1 (claim 4 of the granted version) during opposition procedure, it cannot, contrary to the appellant's contention, be derived that the ground of opposition pursuant to Article 100(c) EPC was not in dispute during opposition procedure. The absence of any allegation of extension of the subject matter of the claims according to the auxiliary request during opposition procedure can very well be due to a deliberate choice of the opponents to dispute the patentability of the subject matter of this request on other grounds. Rather, a ground of opposition, once it has been validly raised, continues to belong to the

legal and factual framework of the opposition according to Rule 76(c) EPC (see point 3.3 above).

3.6 The ground of opposition based on Article 100(c) EPC is therefore admissible. Its consideration does not require the respondent's approval.

4. Article 100(c) EPC

4.1 In claim 1 as originally filed, each  $2\theta$  values of X-ray diffraction peaks for the crystalline form I of the atorvastatin is shown together with its relative intensity ( $> 20\%$ ) after two minutes of grinding of the different peaks. In present claim 1, the same  $2\theta$  values appear, however without the respective relative intensity value of each peak (see point I above). It should thus be investigated, whether the person skilled in the art using his **common general knowledge** would derive directly and unambiguously from the description as filed that the diffraction values are not necessarily disclosed in association with their respective relative intensity values as currently claimed in claim 1.

4.2 The table in claim 1 as originally filed is supported by the description as originally filed (see page 4). The paragraph introducing said table in the description reads as follows:

*"Accordingly, the present invention is directed to crystalline Form I atorvastatin and hydrates thereof characterized by the following X-ray powder diffraction pattern expressed in terms of the  $2\theta$ , d-spacings, and relative intensities with a relative intensity of  $> 20\%$*

*measured after 2 minutes of grinding and measured on a Siemens D-500 diffractometer with CuK<sub>α</sub> radiation:"*

4.3 Therefore, the person skilled in the art has to rely on the content of the description as originally filed in order to decide thereon. On page 3 of this description, under "Summary of the invention", the subject-matter to which the invention is directed is mentioned. In this definition the diffraction values (peaks or d-spacings) are disclosed together with the relative intensity values of each peak. Also in the other parts of the description these diffraction values are **always** disclosed together with their relative intensity values (see point 4.1). The person skilled in the art would thus conclude that the latter are essential to characterize the claimed subject-matter.

4.4 The board notes that opponent I himself pointed out in his statement setting out the grounds of opposition that the intensity varies depending on the orientation of the crystal under analysis (see page 10, paragraph 2). Opponent III maintained that the intensity of the peaks is not a parameter of the compound (see page 7 of the statement of grounds of opposition).

Those statements of two parties as such do not reflect necessarily the common general knowledge of the person skilled in the art if they are not supported by evidence. Furthermore, the argumentations of both opponents were presented to deny that the claimed compounds could be defined by the two most intense peaks of the table, since the intensity depended upon the orientation and grinding. Unless going beyond the

intention of the opponents, the board cannot accept in the absence of common general knowledge supporting those declarations that intensity can be totally disregarded.

- 4.5 Regarding the common general knowledge represented by the documents (3), (4) and (7), the board observes the following:

Document (7) primarily relied upon by the patent proprietor states: "**Sample-Sensitive Parameters.** These are the most important class of parameters that can affect both the absolute and relative intensity of diffraction lines. Preferred orientation... is the most serious effect and is present to some degree in most specimen mounts".

However, this fact is not relevant since it is well known in the art that the preferred orientation is minimized by the grinding of the specimen (see document (3), page 1844, right-hand column, "Test preparation"). This finding is also confirmed by the patent in suit (see page 5, line 15).

Furthermore, document (3) discloses that the intensity of the diffracted X-ray beam is dependent on several parameters like the intensity and wavelength of the incident radiation or the volume of the crystalline specimen or the absorption of the radiation by the specimen or the experimental arrangement to record the intensity data and concludes "Thus the experimental conditions are especially important for measurement of the diffraction intensities" (see page 1843, right-hand column, third paragraph from the end) emphasizing

- therefore the importance of these data. It is true that the intensity ratio and the d-spacing can be used to compare an unknown diffraction pattern with a known one (see document (3), page 1844, right-hand column, last paragraph and also document (4), bridging paragraph, pages 189-190). However, this does not necessarily mean that the intensity is not a meaningful parameter when the compound is known - all the more, as document (3) also mentions that "the spacings between and the relative intensities of the diffracted maxima can be used for qualitative and quantitative analysis of crystalline materials" (see page 1843, left-hand column, first paragraph of "X-ray diffraction").
- 4.6 From the common general knowledge as shown by the documents (3), (4), (7), it cannot be concluded without any doubt, that the relative intensity values are not essential to characterize a crystalline form.
- 4.7 That means, there is nothing in the description, which could allow the person skilled in the art to derive directly and unambiguously from the application as originally filed that the claimed crystalline form can be characterized by the diffraction values alone.
- 4.8 In conclusion, the omission of the relative intensity values in claim 1 defines a subject-matter, which has no basis in the description as originally filed.
- 4.9 The board would like to add that the respondent's contention that the intensity values are not a parameter of the structure of the crystal is incompatible with his response of 8 May 2003 (page 4) where, in order to justify the fact that only two peaks

were mentioned in claim 1 as granted, i.e. 19.485 and 21.626, it was stated that "...a man skilled in the crystallographic field is aware that one crystal modification of a known solid material can be sufficiently uniquely characterized by the two most intense  $2\theta$  values or by one unique  $2\theta$  value of the X-ray powder diffraction pattern measured for said solid material". If that is so, then the values of the relative intensity of each peak are not a parameter which is unrelated with the structure of the crystal.

- 4.10 It follows that the subject-matter of claim 1 extends beyond the content of the application as originally filed (Article 100(c) EPC).

*Late filing of requests*

5. Shortly before the end of the oral proceedings the respondent requested to be given the possibility to file auxiliary requests because, so he argued, he had been taken by surprise by the conclusion of the board that the ground of opposition pursuant Article 100(c) EPC was admissible.

- 5.1 The board refused this request in exercising its discretion conferred on it by Article 13(1) of the Rules of Procedure of the Boards of Appeal of the EPO ("RPBA") in respect of amendments to a party's - here the respondent's - case after it has filed its grounds of appeal or reply. That "*discretion shall be exercised in view of inter alia the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy.*" (Rule 13(1) RPBA). It was clear in the given circumstances, that amended

sets of claims, even if they were found to meet the requirements of Article 123(2) EPC (the same requirements as under Article 100(c) EPC), would have had to be examined in respect of all other formal and substantive requirements of the EPC, the board and the opponents not having had the opportunity to prepare themselves for the necessary discussion of all issues raised by amended claims, which were unknown to them and whose filing they didn't expect given the late stage of the proceedings and the respondent's behaviour up to then (cf. Article 13(3) RPBA: *"Amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings"*).

- 5.2 In contrast, the respondent could not reasonably exclude that the issue of the admissibility of an objection pursuant to Article 100(c) EPC would be decided against him, nor was there anything else preventing him from filing amendments in the form of modified or auxiliary requests in time for avoiding their refusal under Article 13(3) RPBA, cited above. The ground of opposition in question was already introduced and discussed before in the first instance proceedings. It was again invoked by the appellant in his statement setting out the grounds of appeal (of 6 August 2006, point 1) and the respondent actually took position on this ground during the written procedure (see letters of 5. March 2007, point 1, and of 29 December 2008, point I). So the respondent had the opportunity to - and actually did - present his comments within the meaning of Article 113(1) EPC on



the grounds for the board's decision based on Article 100(c) EPC.

- 5.3 Under these circumstances the respondent was objectively not taken by surprise and there was no reason exceptionally to admit late amendments in the form of auxiliary requests on that ground.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar

The Chairman

M. Schalow

P. Ranguis