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**Datasheet for the decision
of the Enlarged Board of Appeal
of 19 May 2010**

Case Number: R 0016/09
Appeal 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:

-

Relevant legal provisions:

EPC Art. 112a(2)(c)(d)
EPC R. 104, 106

Relevant legal provisions (EPC 1973):

RPBA Art. 12, 13

Keyword:

"Petition for review - clearly unallowable"

Decisions cited:

G 0009/92, R 0021/09

Catchword:

See paragraph 2.2.13



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Case Number: R 0016/09

D E C I S I O N
of the Enlarged Board of Appeal
of 19 May 2010

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Decision under review:

**Decision of the Technical Board of Appeal
3.3.01 of the European Patent Office of
25 February 2009.**

Composition of the Board:

Chairman: P. Messerli
Members: M-B. Tardo-Dino
R. Young

Summary of Facts and Submissions

- I. The petition for review filed on 23 September 2009 concerns the decision T 764/06 of Technical Board of Appeal 3.3.01, announced at the end of oral proceedings on 25 February 2009 and notified by post on 14 July 2009, to revoke European Patent No. 848705.

The petitioner, who is the patent proprietor, was one of the appellants in the appeal proceedings, but withdrew its appeal during oral proceedings before the Board of Appeal.

- II. The patent relates to "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)".

- III. The relevant facts for the present petition can be summarised as follows.

- (a) Three oppositions were filed on the grounds of Article 100(a), (b) and (c) EPC.
- (b) In a decision dated 6 April 2006 the Opposition Division found that the patent could be maintained in amended form on the basis of a first auxiliary request wherein the specific crystalline polymorphic form was characterized by all 2θ values shown in a list of the respective powder diffraction pattern disclosed in the application as originally filed.

- (c) The opponents had not objected to this particular feature under Article 123(2) EPC (page 7 of the decision, first line) and the Opposition Division found that the first auxiliary request met the requirements of this article (top of page 14 of the decision of the opposition division).
- (d) Opponent II filed a notice of appeal against this decision, and raised in its statement of grounds of appeal inter alia three objections to claim 1 in respect of Article 100(c) EPC, one of them directed in particular to the fact that the above mentioned feature of the 20 values was not associated with the corresponding relative intensity values as set out in claim 1 of the application as originally filed.
- (e) The patent proprietor then contended in a letter dated 5 March 2007 that this particular ground under Article 100(c) EPC should be disregarded according to Article 114(2) EPC because during the opposition proceedings, no objection on this ground had been raised by any opponent against claim 1 of the request found able to be maintained by the opposition division which corresponded to claim 4 as granted. This ground had been raised only in appeal proceedings and therefore had not been examined by the Opposition Division.
- (f) The patent proprietor further pointed out in its letter dated 29 December 2008 that the opponents themselves had argued during the opposition proceedings that the relative intensity values could not be considered to be structural

parameters of the compound claimed but would vary from sample to sample.

(g) The Board of Appeal in its decision T 764/06 refused to reject as inadmissible the objection in respect of Article 100(c) EPC. It declared that all the opponents had requested the revocation of the patent in its entirety, without any restriction, that there was no obligation to substantiate grounds of opposition against more than one claim, and that no limitation was set by the EPC on allowing an opponent to support and use grounds, evidence and arguments for revocation of a patent that had been submitted by other opponents (points 3.1 and 3.3 of the decision under review). In this particular case the Board of Appeal noted that the requirement in respect of the substantiation of the ground in question had been undisputedly fulfilled by at least one opponent, and concluded that the ground for opposition under Article 100(c) EPC was therefore not a fresh ground.

(h) The Board of Appeal furthermore decided that the subject-matter of claim 1 extended beyond the content of the application as filed and, after refusing to admit further auxiliary requests, revoked the patent.

IV. In parallel with its petition, the petitioner filed on 22 September 2009 a request under Rule 139 EPC for correction of the minutes of the oral proceedings held on 25 February 2009. The reason given in support of the request was that the minutes did not mention that the

Board of Appeal closed the oral proceedings [sic] already prior to the interval wherein it decided on the admissibility of filing an auxiliary request and did not re-open the debate prior to announcing the final decision.

- V. In support of this request for correction two affidavits were filed, one of the professional representative and one of an employee of the patent proprietor both of whom had attended the oral proceedings before the Board of Appeal. These affidavits also stated that the chairman of the Board of Appeal had interrupted the representative during his pleading on the admissibility of an auxiliary request to ask him whether he was aware of Rule 106 EPC.
- VI. The Board of Appeal issued, on 12 October 2009, a first communication giving its preliminary view on the order of events, which received approbation from opponent II in its letter dated 20 November 2009. Then after the respondent's reply dated 23 November 2009 the Board of Appeal rejected the request for correction of the minutes on 8 February 2010, for the following reasons:
- The request for correction and the affidavits were drawn up more than six months after the oral proceedings concerned and the receipt of the minutes.
 - The requested correction would affect a text which had been put down in the minutes during the oral proceedings and certified by the minute writer and the chairman who both signed the minutes immediately afterwards.

- No corroborating objective evidence had been presented or was otherwise available for what was purported to be "the very clear and identical recollection of both representative of the patentee and the employee of the patentee" (quotations marks from the Board of Appeal) six months later and in contrast to what the representative of the other party remembered.

The minutes thus definitively read: "After deliberation the Chairman - announced that no auxiliary requests of the patentee are admitted - and declared the debate closed. Then the following decision was given:

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

VII. In the petition it was alleged that the refusal to admit one single auxiliary request during the oral proceedings was both a fundamental procedural defect contradicting the highest order of judicial impartiality in appeal proceedings on the basis of Article 112a(2)(d) EPC and a fundamental violation of Article 113 EPC on the basis of Article 112a(2)(c) EPC.

The petitioner criticised the fact that the Board of Appeal, which had not given any preliminary opinion on the admissibility of the ground under Article 100(c) EPC, had refused to admit the auxiliary request because the amended set of claims would have raised issues which the Board or the other party could not reasonably be expected to deal with without adjournment of oral

proceedings (section IV of the petition). In the petitioner's view the arguments with respect to the grounds for opposition raised by the parties in this case could not reasonably be expected to be unknown or variable. It explained in its submissions that the specific crystalline modification of the one chemical compound, which was the subject-matter of the patent in suit, could only be claimed in an auxiliary request by additional physical measurement parameters, which had been known by the parties involved, at least from the date the opposition started (pages 5 and 6 of the petition).

It further submitted that the petition was admissible because the petitioner could not raise an objection in respect of the procedural defect during the oral proceedings of the appeal proceedings according to Rule 106 EPC.

- VIII. The Enlarged Board of Appeal issued, on 25 March 2010, a communication attached to a summons to oral proceedings informing the petitioner of its provisional view.
- IX. Oral proceedings took place before the Enlarged Board on 19 May 2010. The petitioner maintained its objection under Article 112a(2) (d) EPC which it defined as referring to a breach of the principle of impartiality. It contended that such a violation was to be read as a defect defined in Rule 104 EPC. It further explained in this respect that the Board of Appeal had deviated from the case law of the boards of appeal according to which in the same circumstances auxiliary requests are admitted.

X. In an additional argument to its written submissions supporting the alleged violation of its right to be heard the petitioner further argued at the oral proceedings that the Board of Appeal could not properly exercise its discretion on the basis of Article 13(1) and (3) RPBA when refusing to admit the filing of auxiliary requests in general without knowing the subject-matter of the future auxiliary request not yet presented in the form of a written text.

XI. The final requests of the petitioner were:

- to set aside the decision T 764/06 under review
- to re-open the procedure before the Technical Board 3301
- to reimburse the fee for the petition for review
- to replace the members of the technical Board who participated in the decision T 764/06.

XII. At the end of the oral proceedings the decision was announced.

Reasons for the Decision

1. *Admissibility of the petition for review*

- 1.1 The formal requirements for the petition for review according to Article 112a(4) and Rule 107 EPC are met.
- 1.2 Rule 106 EPC additionally requires as a prerequisite of admissibility of the petition for review that an objection in respect of the procedural defect be raised during the appeal proceedings and dismissed by the Board of Appeal except where such objection could not be raised during the appeal proceedings.
- 1.3 In this respect, the petitioner filed its request for correction of the minutes of oral proceedings held on 25 February 2009 before the Board of Appeal in order to establish what, in its view, had been the order of the procedural steps followed by the Board during the closing stages of the oral proceedings, namely that the Board of Appeal had closed the oral proceedings [sic] already prior to the interval when they decided on the admissibility of an auxiliary request and did not re-open the debate prior to announcing the final decision. According to the petitioner, this proved that it could not raise any objection in respect of the procedural defect during oral proceedings of the appeal proceedings.
- 1.4 The Enlarged Board of Appeal, considering the original minutes of the oral proceedings, the request and other documents related to the procedure for correction of the minutes and the evidence filed by the petitioner, comes to the conclusion that the lack of possibility

for the petitioner to raise an objection according to Rule 106 EPC cannot be excluded.

- 1.5 The upshot is that the petition at least cannot be found clearly inadmissible, and in view of the conclusion to which the Enlarged Board comes with regard to allowability (see below), the question ultimately needs not to be answered.

2. *Allowability of the petition for review*

- 2.1 The petitioner bases its petition on two alleged defects: a violation of the right to be heard (Articles 112a(2)(c) and 113 EPC) and a violation of the principle of impartiality, Article 112a(2)(d) and Rule 104 EPC.

The petitioner did not expand orally on its written argument about the admission by the Board of Appeal of the objection based on the ground of opposition under Article 100(c) EPC, in respect of the absence of characterization of the 2 θ values also by the respective associated intensity values, despite the fact that this objection had not been discussed by the opponents during the opposition proceedings nor examined by the opposition division.

Nor did the petitioner take up during the oral proceedings the argument that it had been taken by surprise, because, in the absence of any hint from the Board of Appeal prior to the oral proceedings, it could not have been foreseen that the Board would reverse the decision of the Opposition Division on this particular ground.

In its oral submissions the petitioner fastened on the fact that it had been heard only on admissibility issues in general and not on the subject-matter of the proposed auxiliary request, and could not comment on the substance; this amounted, in its view, to a violation of its right to be heard.

In addition, the fact that the Board of Appeal had refused the filing of auxiliary requests without knowing the subject-matter thereof amounted to an abuse or a misuse of discretion and also to a breach of the principle of impartiality because in such circumstances it was general case law of the Boards of Appeal to admit new requests.

2.2 The right to be heard

The petitioner focused on the allegation that the Board of Appeal misused its discretion because it decided in general without a proper set of claims in hand, leaving the petitioner no opportunity to comment on the subject-matter. In other words, if the Board of Appeal had let the petitioner expand on the technical issues of a precise set of claims, it would at least have stood a chance.

2.2.1 Considering the facts as reported in detail (paragraph III above), the petitioner had been aware of the new challenge under Article 100(c) EPC raised by the opponent II in the grounds of appeal three years prior to the oral proceedings before the Board of Appeal. It had objected in its written submissions of 5 March 2007 and 29 December 2008, to the admissibility

of this objection and also replied concerning its merits (paragraph III(e) and (f) above). The petitioner chose not to file an auxiliary request because it was sure that this new attack under Article 123(2) EPC was scientifically hopeless, as it argued during the oral proceedings before the Enlarged Board and had contended in its written submissions in appeal (see paragraph III(e) and (f) above).

2.2.2 It is thus important to note that it was only during the closing stages of oral proceedings before the Board of Appeal, when it became clear that its main and sole request would not be allowed, that the petitioner started to express its intention to present an auxiliary request, and this evidently in the absence of a prepared set of claims in text form. Consequently the request of the patent proprietor is to be understood as a request for authorisation to file at least a set of claims as an auxiliary request.

2.2.3 Under these circumstances, where there had been opportunities to file auxiliary requests far earlier as already seen in the paragraph 2.2.1, above, the Board of Appeal dealt with this last minute attempt by the petitioner to change the course of events, as an announced amendment to the case pursuant to Article 13 RPBA. This article leaves to the discretion of the Board of Appeal the question of the admissibility of amendments to a case.

2.2.4 Article 13 RPBA makes a distinction between any amendment to a party's case made after the filing of the grounds of appeal or the reply (Article 13(1)), and amendments sought to be made after oral proceedings

have been arranged (Article 13(3)). This article furthermore gives in paragraph (1) examples of criteria to be taken into consideration by the Board of Appeal when exercising its discretion: complexity of the new subject-matter, current state of the file and the need for procedural economy. In compliance with the wording of Article 13(1) RPBA which refers to the criteria as "inter alia" the boards of appeal have applied these criteria in different combinations depending on the circumstances of the case, considering them as exemplary and not cumulative. Therefore in the Enlarged Board's view a situation may arise where the importance of one of them may outweigh the others.

2.2.5 The question to be decided with respect to the alleged violation of the right to be heard, is whether the Board of Appeal decided not to admit auxiliary requests without giving the petitioner the opportunity to comment on the issues on which it based its decision.

2.2.6 According to the petitioner, there was a debate about the formal admissibility of new requests; as it appears from its written submissions and as acknowledged during the oral proceedings before the Enlarged Board, it was not limited in its pleading for the admissibility of auxiliary requests. It could explain the reasons why it intended to file this request, in particular the absence of a preliminary communication from the Board of Appeal informing it that the objection under Article 100c) EPC would be admitted.

2.2.7 It is evident from point 5.1 of the Reasons of the decision under review that the criteria which weighed with the Board of Appeal were as follows: "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 for the necessary discussion of all issues raised by the 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) EPC: '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 cannot reasonably be expected to deal with without adjournment of the oral proceedings')".

2.2.8 In other words, the Board of Appeal evidently exercised its discretion on the basis of all the exemplified criteria: the procedural stage which had been reached (terminally late), the subject-matter proposed to be admitted (an amended set of claims with the associated need for full examination) as well as the unexpectedness of the proposal (cf. paragraphs 2.2.1 and 2.2.7, above) which would militate against the need for procedural economy.

2.2.9 Consequently, the Enlarged Board is satisfied that the petitioner could submit its arguments about the procedural issues on which the Board of Appeal based its decision to refuse auxiliary requests, especially

the possible exceptional circumstances namely the reasons of a such late filing, put forward to justify the late filing.

2.2.10 Seen against this background, the main argument of the petitioner, that no opportunity was given to speak to the subject-matter of the proposed auxiliary request, i.e. to the text of any amended claims to be filed is not relevant.

2.2.11 It is the view of the Enlarged Board that it belongs to the discretion of the boards of appeal to decide which criteria are to have precedence according to the circumstances of the case.

2.2.12 Much speaks, in the view of the Enlarged Board, for the criterion of lateness, in appropriate circumstances, to outweigh the criterion of the subject-matter to be submitted, in the exercise of discretion on admissibility of amended claims.

2.2.13 In fact, the Enlarged Board sees no legal basis for an obligation incumbent on the Board of Appeal to hear the petitioner on substantive issues before deciding the issue of admissibility of a proposed auxiliary request if, given the particular circumstances of the case, these issues are found not to correspond to the relevant decisive criterion. A requirement for a party in any case to be invited to formulate and supply a text before any decision is taken as to the admissibility of a proposed auxiliary request, regardless of the relevant surrounding circumstances, would in the view of the Enlarged Board be to deprive

the boards of appeal of the discretion explicitly provided by Article 13 RPBA.

2.2.14 Equally irrelevant, and for the same reasons as set out above, is the petitioner's argument that the Board of Appeal could not exercise its discretion in an informed and therefore appropriate way, in the absence of a knowledge of the text of the claims to be submitted.

2.2.15 This argument on which the petitioner insisted at the oral proceedings before the Enlarged Board, is in any case weakened by the statements in its written submissions, according to which, firstly the specific crystalline modification of the compound which was the subject-matter of the patent in suit could only be claimed in an auxiliary request by additional physical measurement parameters (paragraph VII, above) and secondly, in view of the statements, appearing no less than three times in the petition for review, that it had been indicated by the Respondent to the Board of Appeal during the oral proceedings that the auxiliary request to be filed "will be based on the set of claims as originally filed" (petition for review, pages 4, 5 and 6).

2.2.16 These written statements, which contrast with the thrust of the petitioner's oral arguments before the Enlarged Board, tend to indicate that neither the Board of Appeal nor the other party could have been in any appreciable doubt as to what the text of the proposed auxiliary request would be.

2.2.17 Nor is it of any significance in the present case that the Board of Appeal had not issued a communication to

inform the patent proprietor of its provisional opinion prior to the oral proceedings. The critical issue had already been raised by the appellant in its statement of grounds of appeal (see paragraph III), three years before the oral proceedings before the Board of Appeal. As results from Article 12 RPBA and as already recalled in the decision R 21/09 of 19 March 2010, the framework of the appeal proceedings in inter partes cases as in any judicial procedure is also defined by the written submissions of the parties. This is also a particular consequence of the general procedural principle of party disposition as defined for example in paragraph 1 of G 9/92 (OJ 1994, 875). The communication of the Board of Appeal, if any, is a means at the Board's disposal to streamline the appeal proceedings and above all the oral proceedings.

2.2.18 Lastly the Enlarged Board does not see how the rejection of the objection of inadmissibility of the ground under Article 100(c) EPC regarding the feature of the absence of characterisation of the 20 values because it was raised for the first time before the Board of Appeal, for which the Board of Appeal gave reasons could be a fundamental violation of the right to be heard.

2.2.19 Consequently the Enlarged Board comes to the conclusion that the petitioner was fully able to explain its case as it stood at that time, when the only outstanding request, apart from the main request, was to be allowed to file an auxiliary request. Thus there was no violation of its right to be heard.

- 2.3 The refusal of the auxiliary request as a violation of the principle of impartiality
- 2.3.1 The petitioner contended at the oral proceedings before the Enlarged Board that a fundamental violation of any general procedural principle may be a procedural defect "defined" in Article 112a(2)(d) EPC and its implementing Rule 104 EPC. It deduced from the word "may" in Rule 104 EPC, "a fundamental procedural defect **may** have occurred ..." (emphasis by the Enlarged Board) that the two defects were to be understood as members of a list which is not exhaustive. It referred to J 7/83 (OJ 1984, 211) for the definition of a procedural violation and to G 9/91 (OJ 1993, 707) for the general principle of impartiality.
- 2.3.2 Under the heading of "violation of the principle of impartiality" the petitioner complained about a wrong exercise of its discretion by the Board of Appeal which refused to admit the proposed auxiliary request in circumstances where it was expected to be admitted according to the general practice and case law of the Boards of Appeal and the personal experience of the representative.
- 2.3.3 The Enlarged Board finds it necessary to make it clear that the principle of impartiality according to the EPC and, also in its natural and ordinary meaning, does not cover the currently alleged procedural defect. Under the EPC, this principle addresses the question of suspected partiality of the members of the Board of Appeal pursuant to Article 24 EPC. The violation of this principle is mentioned by Article 112a(2)(a) EPC which is clearly not applicable here.

2.3.4 Turning to what the petitioner is really complaining about, this appears in fact to be a criticism of the course of action taken, and of the merit of the decision made by the Board of Appeal on the admissibility issue, compared to the petitioner's understanding of the case law.

2.3.5 That having been said, the Enlarged Board firstly notes that the alleged violation is not included in the list of fundamental procedural defects of Rule 104 EPC. This rule implements Article 112a(2) (d) EPC which provides: "any other fundamental procedural defect as defined in the Implementing Regulations".

The wording of Article 112a(2) (d) EPC is quite clear:

- a petition for review can only be filed on the grounds it specifies
- it leaves it to the Implementing Regulations to define further procedural defects which may justify a petition for review. This implies that what is not defined by the Implementing Regulations does not qualify as a procedural defect in the sense of Article 112a(2) (d) EPC.

Among the Documents of the Travaux préparatoires relating to the discussion of Article 112a EPC, Document MR/21/00,d,e,f which relates to Article 112a EPC is especially illuminating: Under the reasons given to explain the proposed wording of the paragraph (d) of the said article, which became the final wording, it is commented that "the proposed Article 112a(2) lists the

possible reasons for a 'Petition for review by the Enlarged Board of Appeal'. Article 112a(2)(d) provides that further fundamental procedural defects on which a petition for review may be filed may be defined in the Implementing Regulations, if the need arises".

Rule 104 EPC is the implementing rule providing two additional fundamental procedural defects to wit, (a) the Board did not hold oral proceedings despite a request to this end; or (b) it omitted to decide upon a request. Consequently it is clear that the list of grounds specified in Article 112a EPC is exhaustive and if an alleged defect which is neither on the list of Article 112a EPC nor one defined by its implementing rule it cannot form a basis for a petition for review.

2.3.6 Since the list of grounds for review mentioned in Rule 104 EPC is exhaustive and since the Board decided on the request to file an auxiliary request Rule 104 EPC is of no relevance here, and the arguments of the petitioner based on this rule must fail.

2.3.7 Secondly, as already noted above (sub-paragraph 2.2.3), the Board of Appeal exercised the discretion provided by Article 13 RPBA; the petitioner admitted that it was a matter of discretion but criticised the way in which the Board of Appeal exercised it referring to particular decisions of the Boards of Appeal.

2.3.8 In the light of the above, the Enlarged Board sees no procedural violation in the present case. In fact the petition seeks no more than a review of the Board of Appeal's assessment of the circumstances and criteria it took into consideration in applying Article 13 RPBA. As is apparent from the case law of the Boards of Appeal, there is room for discretion of the boards of appeal when making the balance between the criteria and choosing to which precedence must be given with respect to the circumstances of each case. To find otherwise would require the Enlarged Board first to re-examine whether or not the Board of Appeal was right in its judgement, which is a substantive and not a procedural issue.

2.3.9 This review is thus outside the scope of Article 112a EPC which is an exceptional legal remedy limited to fundamental procedural defects in an individual case and not a means for further development of the EPO procedural practice or for ensuring a uniform application of the law, and under no circumstances can it be used to review the application of the substantive law.

3. Consequently the petition is clearly unallowable. In view of this result, there is no reimbursement of the fee for a petition for review (Rule 110 EPC).

Order

For these reasons it is unanimously decided that:

The petition for review is rejected as clearly unallowable.

The Registrar

The Chairman:

P. Cremona

P. Messerli