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**Datasheet for the decision
of the Enlarged Board of Appeal
of 23 March 2012**

Case Number: R 0016/11
Appeal Number: T 1710/09 - 3.3.02
Application Number: 01201913.9
Publication Number: 1175904
IPC: A61K 31/663
Language of the proceedings: EN

Title of invention:

Alendronate for use in the treatment of osteoporosis

Patentee:

Merck Sharp & Dohme Corp.

Opponents:

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Hexal AG + Sandoz AG
Arrow International Ltd.
betapharm Arzneimittel GmbH
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Gedeon Richter Plc.
Generics [UK] Ltd. et al
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Headword:

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Relevant legal provisions:

EPC Art. 112a(2), 113, 76, 123(2)

Keyword:

"New objection raised by the Board (no)- denial of the right to be heard (no)- petition for review clearly unallowable"

Decisions cited:

R 0012/09; R 0022/10; R 0006/11

Catchword:

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Case Number: R 0016/11

DECISION
of the Enlarged Board of Appeal
of 23 March 2012

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Decision under review: **Decision of the Technical Board of Appeal
3.3.02 of the European Patent Office of
12 April 2011.**

Composition of the Board:

Chairman: R. Menapace
Members: M.-B. Tardo-Dino
P. Gryczka

Summary of Facts and Submissions

- I. The petition for review concerns the decision T 1710/09 of the Board of Appeal 3302, announced on 12 April 2011 and posted on 28 July 2011 dismissing the petitioner's appeal against the decision of the opposition division to revoke the European patent No. 1175 904 entitled *Alendronate for use in the treatment of osteoporosis* was dismissed.
- II. The petition was filed on 7 October 2011 and the corresponding fee was paid on the same date. The petition relies on an alleged fundamental violation of the right to be heard (Articles 112a(2) (c), and 113(1) EPC).
- III. The patent in suit was granted on a divisional application of the European patent application No. 98 935 752.0. Seventeen oppositions were filed against it on the basis of Article 100(a), (b) and (c) EPC. The opposition division found that claims 1 of both the main and the auxiliary requests complied with Article 76 EPC, but revoked the patent for lack of inventive step.

The decision under review

- IV. Claim 1 of the main request underlying the decision of the Board of Appeal read:

"Use of alendronate in the manufacture of a medicament for treating osteoporosis in a human in need of such treatment, where said medicament is orally administered to said human in the form of a tablet as a unit dosage

comprising about 70 mg of the alendronate compound, on an alendronic acid active weight basis, according to a continuous schedule having a once-weekly dosing interval"

Claim 1 of auxiliary request I differed therefrom in that the alendronate compound was restricted to alendronate monosodium trihydrate.

Auxiliary request II further contained the insertion "for at least one year and" after the word "schedule".

The Board of Appeal dismissed the appeal on the ground that Article 76 EPC was infringed.

- (a) With respect to the main request it held in point 3 of the reasons for its decision that "a unit dosage of **70 mg** of alendronate **in the form of a tablet** for a **once-weekly** dosing interval for **treating** osteoporosis [in bold as in the original text of the decision] is not individualised in the description as originally filed in the earlier application and the subject-matter of claim 1 of the main request cannot be derived directly and unambiguously" (point 3.4 of the Reasons), not even by combining the claims and examples provided in the earlier application as originally filed (point 3.2 of the Reasons). In particular, "... reading these sources of disclosure [...] the skilled person is free in principle to combine different variations of the elements being suggested as features of the claim [...] with no recognisable preference for the features as

actually represented in this claim " (point 3.3(c) of the Reasons).

- (b) With respect to claim 1 of the first and second auxiliary requests, the Board of Appeal pointed out that the claims as originally filed in the earlier application disclosed alternatives concerning the dosage (35 mg for osteoporosis prevention; 70 mg for osteoporosis treatment), the dosing interval (once weekly, twice weekly, biweekly or twice-monthly) and the form of the formulation (tablets liquid formulations, capsules, elixirs, syrups, effervescent compositions, powders). The Board found that "[i]n all cases, the alternatives are of equal weight, no preference is indicated by specific words or in any other directly recognisable way and their singling out for reasons of original disclosure is not allowed" (last section of point 3.5.2). It concluded that the particular combination of features of claim 1 of the first and second auxiliary requests was not to be found in individualised form in the earlier application as originally filed.
- (c) The Board of Appeal went on to discuss in detail the several "additional arguments" of the petitioner, including the case law referred to by the latter (point 4 of the Reasons for the decision, see also point 2.5.2, below) and found that these arguments could not hold.

The petition

V. The petitioner alleged a violation of the right to be heard under Article 113 EPC, on the ground that the decision issued in writing was based on an objection - namely that the original application gave "*no recognisable preference*" (in italics in the petition) for a 70 mg tablet for once-weekly administration - which had never been raised by the opposition division or any of the 17 opponents, or by the Board of Appeal in its preliminary written opinion, and which had not been explained or implied by the Board at the oral proceedings.

VI. The petitioner's arguments in support of the alleged violation of its right to be heard (Article 113 EPC), as submitted in writing and expounded during the oral proceedings before the Enlarged Board of Appeal, may be summarised as follows:

The finding in the decision under appeal that none of the petitioner's requests met the requirements of Article 76 EPC was based on the absence of a preference (rather than the absence of a disclosure) for the combination of the relevant features. As was apparent from point 4.2 of the Reasons for the decision, the Board of Appeal did not see any basis for claim 1 of the first auxiliary request in the description of the original PCT application because claims 9-11 as originally filed disclosed alternative embodiments (different doses, different intervals) which were all of equal weight in that no preference was indicated by specific words or in any other recognisable way. The Board of Appeal was thus imposing an extra level on the

normal requirement for a written basis under Articles 76 and 123 EPC in that it was not merely demanding the usual direct and unambiguous disclosure of the claimed invention, but also required that it was disclosed in preference to other embodiments. However, the Board of Appeal had never explained its specific "no recognisable preference" objection, which had never been raised by the opposition division or the opponents, nor had it informed the petitioner of this new objection in a preliminary opinion or during the oral proceedings.

The minutes of the oral proceedings were materially incorrect in respect of the statement "[the Board of Appeal] invited the parties to comment on the combination of features of claim 1 of all requests in view of claim 8 of the earlier application being part of the group [of claims 6 to 11 of the earlier application]". According to the sworn statements of three professional representatives attending the oral proceedings before the Board of Appeal, none of them could remember any oral statement from the board about claim 8 of the PCT being "part of the group [of claims 6 to 11 of the earlier application]".

However, even assuming that the statement in the minutes was correct, this would not be sufficient to satisfy a party's right to be heard, which required more than merely ensuring that a party was permitted to speak at oral proceedings. The party had to know the objections it was facing (see R 22/10). It was only when reading the reasons for the decision that the petitioner had been able to understand what the Board had in mind.

According to the petitioner's explanations during the oral proceedings before the Enlarged Board, there were two different points to be considered in this petition case, one of which had been missed by the Enlarged Board in its communication referring to the submissions of opponent 06. Actually, the Article 76 EPC objection which the petitioner could expect and was prepared to counter was the objection raised by opponents 06 (and 09), which however related only to the unallowable generalisation of claim 1 of the main request with respect to the alendronate.

Under these circumstances the petitioner had believed that auxiliary request 1, where the active ingredient had been restricted to alendronate monosodium trihydrate, would overcome the unallowable generalisation objected to by the opponents and relied upon in paragraph point 3.2 of the decision under review. It had come as a surprise when this request was not allowed either. The petitioner could not have known that the Board would go further and apply, as well as the criterion of the unallowable generalisation, an additional requirement regarding Article 76 EPC which had never been foreseen, namely the disclosure of a "recognisable preference" for the subject-matter disclosed (point 3.3 Reasons for the decision).

In reply to questions by the Enlarged Board during the oral proceedings, the petitioner answered that the debate prior to the first interruption of the hearings before the Board of Appeal had been directed to all of the requests then pending and did not dispute that when the hearings were resumed, the Board of Appeal invited

the parties to present further comments. At that point in time, the petitioner contended, it had become aware that the Board of Appeal had another concern beyond the unallowable generalisation, and that was why it had referred to the case law. But it could not have expected that the problem was the "no recognisable preference" requirement for the disclosure of the claimed combination, which amounted to an extra hurdle for meeting the requirements of Article 76 EPC.

Even if the minutes of the oral proceedings accurately reflected what had happened, it was only when reading the reasons for the decision that the petitioner had been able to understand what the Board had in mind. That being so Rule 106 EPC was complied with.

- VII. On 29 February 2012, as an annex to the summons to oral proceedings, a communication was issued informing the petitioner of the provisional view of the Enlarged Board that the petition for review was clearly unallowable.
- VIII. Oral proceedings were held on 23 March 2012, at the end of which the Enlarged Board announced its decision.
- IX. The petitioner's final requests remained unchanged, namely that:
- decision T 1710/09 be set aside pursuant to Article 112a (5) and Rule 108(3) EPC and the proceedings concerning European patent No. 1175904 re-opened before the Technical Board of Appeal.

- the composition of the Technical Board be different in accordance with Rule 108(3) EPC.

- the petition fee be reimbursed under Rule 110 EPC.

Reasons for the Decision

1. *Admissibility of the petition for review*

- 1.1 The provisions of Article 112a(4) and Rule 107 EPC are complied with.

- 1.2 Pursuant to Rule 109(2) (a) EPC the Enlarged Board in its three-member composition rejects those petitions for review which are clearly inadmissible or clearly unallowable. In view of the finding on the allowability of the present petition for review (point 2 below), there was no need to further investigate the admissibility requirements laid down in Rule 106 EPC.

2. *Allowability of the petition for review*

- 2.1 The petitioner did not deny that the objection under Article 76 EPC had been discussed with respect to all three requests underlying the decision under review. Nor has he alleged that he was hindered by the Board of Appeal in any way during the oral proceedings or at any other time in bringing forward his arguments.

- 2.2 What the petitioner complains of is in essence that when considering Article 76 EPC the Board of Appeal did not merely demand the usual direct and unambiguous disclosure of the claimed invention, but also required

that it was disclosed in preference to other embodiments. As the petitioner could not be and was not made aware of this "extra hurdle" he was deprived of the opportunity to comment on it, in breach of Article 113(1)EPC.

2.3 However, the skilled reader of the decision under review as a whole (also insofar as it responds to the parties' arguments) will appreciate that wherever in the reasons for the decision under review the Board of Appeal referred to the absence of a (recognisable) preference (points 3.3. (c) and 3.5.2 of the decision, see point IV (a) and (b), above), it did so as part of the line of reasoning leading to its conclusion that the claimed combination of features could not be "derived directly and unambiguously" from the earlier application by a person skilled in the art - see in particular at the very end of point 3.4. of the reasons (point IV (a) above) where this is concluded in respect of claim 1 of the main request. The same considerations and conclusions also apply to the auxiliary requests, as set out in point 3.5 of the reasons. Rather in the given context the term in question is related to or merely an alternative expression for e.g. "not individualised" (point 3.4) and "all alternatives are of equal weight" (point 3.5.2 of the Reasons, see point IV, 3 (b) above). By no means can this line of reasoning be construed as being based on an additional criterion over and above "the usual direct and unambiguous disclosure of the claimed invention". Similarly, the expression "generalised in an unallowable manner" (point 3.2. of the reasons at the bottom of page 8, cf. point V above) or the *terminus technicus* "intermediate generalisation" as commonly

used do not stand for a different/independent concept of the disclosure within the meaning of Article 76 (and Article 123(2)) EPC.

2.4 That means that there is actually nothing in the reasons for the decision which could constitute a new and/or unforeseeable ground within the meaning of Article 113 (1) EPC. Rather, the Board of Appeal decided against the petitioner after having considered the parties' written and oral submissions on the decisive issue, which is simply whether or not the combination of the relevant subject-matter - a combination of the features of a 70 mg tablet of alendronate (monosodium trihydrate) once-weekly for the treatment of osteoporosis - was disclosed in the original application. This is enough for the purposes of Article 113 (1) EPC.

2.5 No provision of the EPC requires a board of appeal to provide the parties with each foreseeable argument given in the reasons of its decision. Parties are not entitled to advance indication of the reason or reasons for a decision before it is taken (R 22/10 cited by the petitioner, point 7 of the Reasons, and the several other decisions there referred to; R 006/11 point 5.3 for the definition of the right to be heard and point 8.2 regarding treatment by the board of an argument). So, when the petitioner contended that it had had "no indication of the Board's thinking", this goes beyond the right to be heard and would mean in the given circumstances a demand to be told the reasons why the Board of Appeal had not been convinced by the petitioner's arguments before it had taken its decision

and before it could start drafting the written reasons for it.

2.6 After all, it is and must remain up to a party how to make its case, whereas it is the board's duty to decide on the basis of the parties' submissions. A party has to put forward, on its own initiative and in due time, everything that could support its position and it should be routine for professional representatives to decide independently, i.e. without guidance by the board, how to pursue their cases (R 12/09, point 11 of the Reasons and the jurisprudence cited there).

2.7 What is to be deduced from

- point VIII of the decision under review, reporting the petitioner's position that the combination of features followed the principle that the person skilled in the art would seriously contemplate the resulting teaching as presented in the claims and its detailed arguments as to the disclosure of the critical features and the claimed combination of them in the application as originally filed;
- point IX of the facts and submissions where the respondent's arguments are summarised, in particular that, contrary to the opinion of the opposition division and the Petitioner's submissions, there were problems *inter alia* with respect to Article 76(1) EPC concerning the requests on file, because their teaching represented a combination of individually disclosed features which was not allowed in the

context as realised in the claims then pending,
and

- point 4 of the Reasons for the decision, in which the petitioner's arguments in defence of his position regarding the disclosure requirements - in particular on the criteria for determining the "disclosure status" of subject-matter individualised from a list and the jurisprudence invoked by the petitioner - are discussed in detail and held unfounded,

is that the petitioner had an opportunity (and made extensive use of it) to express his point of view on the disclosure issue, the Board's negative finding on it being (one of) the grounds on which the decision under review is based (Article 113(1) EPC).

- 2.8 The Enlarged Board cannot see anything in the written proceedings which could have - inadvertently on the part of the Board of Appeal - induced the petitioner to believe that the examination under Article 76 EPC would be restricted to the "unallowable generalisation objection" to claim 1 of the main request. As the Enlarged Board pointed out during the oral proceedings, there are standard patterns used by the boards of appeal in conducting the discussion on the grounds raised. In this respect there was nothing unusual or surprising in the conduct of the appeal proceedings. As to Article 76 EPC (and/or Article 123(2) EPC) it is normally up to the patent proprietor to indicate where in the (parent) application as originally filed a claimed combination of features is disclosed - which the petitioner did in a comprehensive manner in its

statement of the grounds of appeal as reported under point IV of the facts and submissions in the decision under review - and then to counter the opponents' objections and counter-arguments - which the petitioner also did, as evidenced *inter alia* by the filing of the decision T 783/09, (point 4.3 of the Reasons for the decision under review).

2.9 In view of the preceding considerations, the exact wording of the chairman's invitation to the parties to comment on the combination of claimed features in view of the claims of the earlier application (point VI, above) is immaterial. The Board observes in this context, that the petitioner did not request correction of the minutes.

3. From all this it follows that contrary to his contentions the petitioner actually has indeed had an opportunity to present its comments, within the meaning of Article 113(1) EPC, on the non-compliance with Article 76 EPC of claim 1 according to each of its requests, that being the ground on which its appeal was ultimately dismissed.

Order

For these reasons it is unanimously decided that:

The petition for review is rejected as clearly unallowable.

The Registrar

The Chairman

W. Crasborn

R. Menapace