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Datasheet for the decision of 22 May 2012

Case Number: T 0223/11 - 3.3.02

Application Number: 03722591.9

Publication Number: 1506041

IPC: A61P 19/10, A61K 31/663

Language of the proceedings: EN

Title of invention:
Ibandronic acid for the treatment and prevention of osteoporosis

Patentee:
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Opponents:
Laboratorios Liconsa, S.A.
Alfred E. Tiefenbacher GmbH & Co. KG
Teva Pharmaceutical Industries LTD.
Gedeon Richter Plc.
Generics [UK] Limited
Synthon BV

Intervener:
Sandoz Farmacêutica, Lda.

Headword:
Ibandronic acid/HOFFMANN - LA ROCHE

Relevant legal provisions:
EPC Art. 123(2), 115, 105(1)(a)

Relevant legal provisions (EPC 1973):
-

Keyword:
"All requests: added subject-matter (yes)"
"Admissibility of intervention (no)"
"Referral to the Enlarged Board of Appeal (no)"

Decisions cited:
T 0016/05

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0223/11 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 22 May 2012

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Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted 1 February 2011 concerning maintenance of European patent No. 1506041 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
R. Cramer

Summary of Facts and Submissions

I. European patent No. 1 506 041 was granted with 8 claims; it is based on the international application PCT/EP2003/004629 published as WO 2003/095029.

Claim 1 as granted read as follows:

"Use of ibandronic acid or pharmaceutically acceptable salt thereof for the manufacture of a medicament for the prevention or the treatment of disorders characterized by pathologically increased bone resorption wherein the medicament
a) comprises at least 120% of the expected efficacious daily dose, i.e. 50 - 250 mg, of ibandronic acid or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipients thereof; and
b) the medicament is orally administered on one day per month."

II. Opposition was filed against the granted patent under Article 100(a) EPC (novelty and inventive step), under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for added subject-matter. Problems under Article 53(c) were indicated as well.

III. The opposition division held that "account being taken of the amendments made by the patent proprietor during the opposition proceedings, the patent and the invention to which it related" met the requirements of the Convention.

IV. The appellants (opponents 02, 04, 05, 07 and 08) lodged an appeal against that decision and submitted grounds of appeal.

Opponent 03 is party to the proceedings as of right.

A notice of intervention was filed with letter of 16 February 2011. The intervention was based on the fact that the patent proprietor had applied to the Lisbon Administrative Circuit Court for a preliminary injunction against the National Authority of Medicines and Health Products and the Ministry of the Economy and Innovation in Portugal in order to have the marketing authorisation, granted to the intervener for the medicinal product "Acido Ibandronico Sandoz" in the dose of 150 mg, suspended while European patent No. 1 506 041 was valid. The intervener was summoned as a counter-interested party in these proceedings.

V. Dated 30 November 2011, together with the summons to the proceedings, a communication of the board was despatched, giving its preliminary opinion that the intervention was not admissible. If the board were indeed to decide that the intervention was inadmissible, the submissions made by the intervener with respect to the patentability of the invention to which the patent related were to be regarded as third-party observations under Article 115 EPC.

The intervener contested the arguments of the board.

VI. The respondent (patent proprietor) defined its main request as the set of claims as maintained by the opposition division (clean copy submitted on

2 November 2011 together with its comments on the appellants' grounds of appeal) and filed an auxiliary request with letter of 19 April 2012. Claim 1 of the main request reads (amendments with respect to claim 1 as granted marked by the board; a "clean copy" of the claim can be derived from the subsequently following presentation of claim 1 of the auxiliary request):

"Use of ibandronic acid or pharmaceutically acceptable salt thereof for the manufacture of a medicament for the prevention or the treatment of osteoporosis ~~disorders characterized by pathologically increased bone resorption~~ wherein the medicament
a) comprises ~~at least 120% of the expected~~ an efficacious ~~daily~~ dose of about 150 mg~~, i.e. 50 - 250 mg,~~ of ibandronic acid or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipients thereof; and
b) the medicament is orally administered on one day per month."

In claim 1 of the auxiliary request, at the end of the wording of claim 1 of the main request, the words "as a single dose" are added, and the claim's wording is as follows:

"Use of ibandronic acid or pharmaceutically acceptable salt thereof for the manufacture of a medicament for the prevention or the treatment of osteoporosis wherein the medicament
a) comprises an efficacious dose of about 150 mg of ibandronic acid or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipients thereof; and

b) the medicament is orally administered on one day per month as a single dose."

VII. On 22 May 2012, oral proceedings took place before the board.

Admissibility of the intervention was discussed and decided on.

During the proceedings, the respondent provided the board and the other parties with copies of the decision T 0016/05 of 17 July 2007 (not published in the OJ EPO) and suggested that the board consult the Enlarged Board of Appeal on the basis of its proposal as submitted (see minutes of these proceedings) if the current proceedings were to give rise to a decision contradicting T 0016/05.

VIII. The appellants' submissions can be summarised as follows:

Notwithstanding all concerns that the disease and the active substance in claim 1 of the main request were the result of inadmissible selections and that the specified efficacious dose with regard to the disclosure in the originally filed set of claims could not be 150 mg because 120% of 150 mg resulted in 180 mg, there was at least a selection from two lists to arrive at the subject-matter of this claim as far as the dose to be administered and the frequency of administration were concerned.

The dose was not presented in the form of a preferred embodiment throughout the application as originally

filed and, as far as the frequency of administration was concerned, even in the cases where it was characterised as preferred there followed contradictory information in the form of "killing remarks". For the same reasons, the decision T 0016/05 was not comparable; in that decision, only features supported by a clear statement of preference were introduced into the claims as requested, which would be the minimum provision for such introduction to be allowable. Assessment of further differences as might exist was not necessary under these conditions.

Claim 1 of the auxiliary request containing the same features was not allowable under Article 123(2) EPC for the same reasons. In addition, it contained further information that *per se* was to be chosen from alternatives.

IX. The respondent's arguments may be summarised as follows:

Claim 1 of the main request was not to be objected under Article 123(2) EPC since it resulted from claim 6 as originally filed, including the claims it depended on, and since all the features of this claim 1 were additionally prioritised in the description.

The skilled person could not be caught by surprise by this teaching, which had obviously been present from the beginning and had always been seriously contemplated; additionally there was no "unwarranted advantage" as cited in T 0016/05, a decision very close to the present situation. Classifying the features of claim 1 of the main request as contravening Article 123(2) EPC, despite being supported by clear

prioritisation in the description, would result in a decision contradicting T 0016/05. In this case, the respondent would encourage the present board to refer a question to the Enlarged Board of Appeal.

As for the auxiliary request, the respondent argued that the introduction of the feature "as a single dose" from original claim 9 into claim 1 of the main request clarified that administration on one day per month was mandatory and did not result from a selection out of the alternatives "on one, two or three consecutive days per month" as contained in original claim 1.

X. The intervener essentially argued as follows:

The proceedings in Portugal were to be regarded as infringement proceedings, as the sole objective of the patent proprietor when instigating these proceedings had been to prevent the intervener from entering the market. The patent proprietor had based its suit on its existing patent rights.

XI. The patent proprietor argued that the proceedings in question were administrative proceedings against the national authorities in Portugal and not infringement proceedings. The intervener was not directly involved in these proceedings.

XII. The intervener requested that the intervention be declared admissible.

XIII. The appellants (opponents 02, 04, 05, 07 and 08) requested that the decision under appeal be set aside and that patent No. 1 506 041 be revoked.

XIV. The respondent (patent proprietor) requested that the intervention be declared inadmissible.

Further it requested that the appeals be dismissed, or alternatively that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims filed as auxiliary request with the letter of 19 April 2012.

It further requested the referral of a question to the Enlarged Board of Appeal.

Reasons for the Decision

1. The appeals are admissible.

2. *Admissibility of the intervention*

Under Article 105(1)(a) EPC any third party may intervene in opposition proceedings (and in opposition appeal proceedings) if it proves that proceedings for infringement of the patent in question have been instituted against it. It is thus essential for the application of Article 105(1)(a) EPC that the proceedings concerned can be considered to be infringement proceedings. The EPC does not define what proceedings constitute infringement proceedings; this is a matter of national law in the state concerned.

Both the patent proprietor (respondent) and the intervener agree that the competent court for establishing patent infringement in Portugal is the

Commercial Court. The patent proprietor has however instituted proceedings before the Administrative Circuit Court. The patent proprietor essentially claims before this court that a marketing authorisation should not have been granted for the intervener's product while its patent is in force.

Although the present board appreciates that these proceedings can obstruct the intervener's possibilities of (future) market entry with an allegedly infringing product, it is neither the patent proprietor's claim nor the court's assessment that the intervener is in fact infringing the patent. The court is rather assessing that the granting of the marketing authorisation opens up the possibility for a future infringement.

It is internationally a widely accepted principle that the submission of a request for a marketing authorisation for a pharmaceutical product by a generic company does not constitute patent infringement (the so-called Bolar exemption). The EU Council and the EU Commission have for instance adopted the following common position: "The Council and the Commission consider that the submission and subsequent evaluation of an application for a marketing authorisation as well as the granting of an authorisation are considered as administrative acts and as such do not infringe patent protection" (Official Journal of the European Union 2003, C 297 E/66, footnote 1).

The principle behind the Bolar exemption is that generic companies should be in a position to take the necessary preparatory measures in order to be able to

enter the market without delay once patent protection expires.

The Portuguese legislator has in the meantime codified this principle in law No. 62/2011 of 12 December 2011. This law entered into force after the judgement of the Administrative Court was rendered. However, this circumstance does not mean that prior to the promulgation of the new law the proceedings instigated by the patent proprietor, no matter how obstructive these may have been to a future market entry of the intervener's product, can be considered as equivalent to infringement proceedings.

The present board thereby notes that according to the judgement of the Administrative Court, one of the intervener's arguments, in line with the Bolar exemption, was that it "has the right to undertake the preliminary and preparatory steps so as to be in a position to sell the medicinal products the day after the industrial property rights held by the Plaintiff lapse". It can therefore not even be established by the board that the intervener had the actual intention of bringing its product onto the market while the patent was still in force.

Thus, as the proceedings before the Lisbon Administrative Circuit Court cannot be considered to be infringement proceedings, the intervention is inadmissible.

Under these circumstances, the question whether the proceedings were instituted "against" the intervener within the meaning of Article 105(1)(a) EPC, the

intervener not having been summoned as the principal defendant but as a counter-interested party, does not need to be answered.

3. *Claim 1 of the main request; Article 123(2) EPC*

3.1 This claim 1 relates to the

- use of ibandronic acid … for the manufacture …
- for the prevention or the treatment of osteoporosis …

wherein the medicament

- comprises an efficacious dose of about 150 mg of ibandronic acid … and
- is orally administered on one day per month.

3.2 A combination of the features of claim 6 as originally filed, including the claims it depends on, relates to (differences with respect to the wording in paragraph 3.1 are marked in bold; text in square brackets introduced by the board) the

- use of ibandronic acid … for the manufacture …
- for the prevention or the treatment of osteoporosis …

wherein the medicament

- comprises **at least 120% of the expected efficacious daily dose** [namely] **an efficacious dose of about 100 mg to about 150 mg, [in particular] about 100 or 150 mg** of ibandronic acid … and
- is orally administered on one**, two or three consecutive** day(s) per month.

The alternative of a dose of 100 mg is to be considered since it is the subject-matter of claim 5 and relates to claim 3 which cannot be disregarded when choosing claim 6 together with the claims it refers to as starting point for consideration under Article 123(2) EPC. Claim 3 discloses a range of 100 to 150 mg which obviously contains two particular values as the end points of the range and not only 150 mg.

Thus, there is no information in the claims that a dose of 150 mg was specifically to be linked to exactly one of the three alternatives of the administration scheme, namely "on one day per month" as claimed in claim 1 of the main request.

Accordingly, the subject-matter of claim 1 of the main request contains a combination of features that is not individualised **in the claims** as originally filed.

3.3 Looking at the description as originally filed in order to find support for such individualisation reveals that the alternative doses of 100 mg and 150 mg are always treated with equal weight.

As far as the alternative in administration frequency of "on one day per month" is emphasised as being "preferred", there are single sentences with this meaning (for instance on page 5, lines 9 and 15). However, in the directly following text it is equally emphasised that "the scope of the present invention includes medicaments administered as multiple sub-doses such as on two consecutive day per month or on three consecutive days per month" (page 5, lines 16 to 18),

immediately invalidating the statement of preference for "on one day per month".

Moreover, in case of an efficacious dose of 100 mg even administration on two consecutive days is preferred (page 5, lines 29 to 32).

Thus, from the overall content of the application as originally filed, no emphasis concerning any of the alternatives with respect to dose or administration frequency can be deduced and - even if such deduction was possible - it would be additionally necessary in the current case that it was disclosed that such preferential features had to be linked to arrive at a teaching disclosed in complete, individualised form. This is not the case either.

Therefore, even if only the features dose and administration frequency are considered with regard to the claims as originally filed, and including support from any disclosure in the original description, the subject-matter of claim 1 of the main request represents added subject-matter under Article 123(2) EPC.

3.4 However, there is also a further problem:

3.4.1 If a particular efficacious dose, namely "the expected efficacious daily dose", is mentioned in claim 1 of the original set of claims and dependent claims refer to "the efficacious dose" (original claims 3, 5 and 6), in the absence of any other "efficacious dose" being mentioned in the context, the normal understanding of a skilled person is that the term "the efficacious dose"

in original claims 3, 5 and 6 is a mere short-cut description of the only "efficacious dose" mentioned before, i.e. "the expected efficacious daily dose". Under these circumstances a dose resulting from the combination of these claims must contain - as defined in original claim 1 - "at least 120% of the expected efficacious daily dose", i.e. at least 180 mg. In conclusion, as a result of this combination of claims, a dose of 150 mg was not disclosed at all.

3.4.2 On the other hand, it is true that original claim 6 does not contain "the expected efficacious daily dose" in unequivocal definition, because the adjectives "expected" and "daily" are not repeated. There is a real probability that a totally different "efficacious dose" is meant, based on the sole provision that its value fits into the range defined by "at least 120% of the expected efficacious daily dose" because claim 6 depends on original claim 1. Realising in this way the existence of another possibility which deviates from the conclusion of the resulting 180 mg (see above), and therefore consulting the original description, the skilled person would at least find indicators pointing in this direction. On page 5, lines 27 to 32, where there are instructions how to put the teaching into practice, an "efficacious dose" of 150 mg for instance is assembled from two 75 mg sub-doses or three 50 mg sub-doses, no sub-doses being mentioned that could result in a 180 mg "efficacious dose".

3.4.3 The definitions in the description as originally filed of "expected dose" (see page 3, lines 31 to 32) and "efficacious dose" (see page 5, lines 23 to 32) cannot provide information making it possible to conclude

unequivocally which of the two possibilities would apply. These attempts at a clear definition suffer from the same problem of missing adjectives to define one and the same particular subject-matter.

While a literal definition of the wording "expected efficacious daily dose" as contained in claim 1 of the main request is missing, the definition of an "expected dose" (meaning "expected efficacious daily dose"?) on page 3 states only that it "corresponds to the cumulated efficacious daily doses", whatever such cumulated daily doses may be.

In addition, in lines 23 and 24 of page 5 an **efficacious dose** "referring" to a range from about 100 to about 150 mg is mentioned, but the paragraph preceding this text relates to the medicament preferably comprising "… preferably 120% to 200% … of the **efficacious dose** (emphasis by the board).

3.4.4 The only conclusion the skilled person can draw from such inconsistent accumulation of terms in the description is that no valid clear-cut definition can be deduced at all.

As a result of these considerations, there are at least two possibilities for giving a minimum of technical sense to the imprecise correlation of original claims 1 and 6. This situation leads to the conclusion that on the basis of these claims a further choice is necessary to arrive at the 150 mg-feature of claim 1 as requested: The potential alternative 180 mg dosage resulting from application of the 120%-multiplier is to be disregarded

and an "efficacious dose" of 150 mg has to be chosen as the relevant feature.

3.4.5 Under these conditions and taking into account the claims as originally filed as the basis for considerations with respect to the original disclosure, the subject-matter of claim 1 of the main request even contains a combination of three features (dose, administration frequency and disregard of the multiplier) without individualisation in the application as originally filed and is not directly and unambiguously derivable; it contravenes Article 123(2) EPC.

3.5 An alternative attempt to find a disclosure of the combination of features of claim 1 of the main request could be started from parts of the description as originally filed; the most promising are set out in sections a) and b) below:

a) In accordance with the first line of point 4 of the decision of the opposition division and the mention in line 7 of the third paragraph under point 1.4 in the respondent's letter of 2 November 2011, the teaching set out on page 4, lines 11 to 17 of the original description is to be considered. With the differences with respect to the points characterising current claim 1 under paragraph 3.1 in this decision marked in bold, it relates to the

- use of ibandronic acid … for the manufacture …
- for the prevention or the treatment of **disorders characterized by pathologically increased bone resorption** …

wherein the medicament

- comprises **about 100 to about 150 mg** of ibandronic acid … and
- is orally administered on one**, two or three consecutive** day(s) per month.

Again, there is at least no information that a dose of 150 mg was specifically to be linked to an administration scheme of "on one day per month".

b) The same is valid for page 3, lines 20 to 28, another promising part of the original description (differences with respect to the points characterising current claim 1 under paragraph 3.1 of this decision marked in bold) relating to the

- use of **a bisphosphonic acid or a pharmaceutical acceptable salt thereof, especially** … the use of ibandronic acid … for the manufacture …
- for the prevention or the treatment of **disorders characterized by pathologically increased bone resorption** …

wherein the medicament

- comprises **about 50 to 250 mg, preferably about 100 to 150 mg** of **a bisphosphonic acid** … and …
- is orally administered on one**, two or three consecutive** days per month.

Again, there is at least no information that a dose of 150 mg was specifically to be linked to an administration scheme of "on one day per month".

c) Thus, reading these sources of disclosure relevant for the subject-matter as requested in claim 1 of the main request, the skilled person is free to combine different variations of the elements being suggested as features of the claim at least with respect to

– dosage (e.g. **150 mg**) and

– dosing frequency (e.g. **on one day per month**)

with no recognisable preference for the combination of these features as actually presented in the claim 1 of the main request (indicated in bold).

3.6 As a consequence, a dosage of **150 mg** of ibandronate for oral administration on **one day** per month related to prevention or treatment of osteoporosis is not individualised in the application as originally filed, and the subject-matter of claim 1 of the main request cannot be derived directly and unambiguously.

4. *Auxiliary request; Article 123(2) EPC*

4.1 The considerations and conclusions under paragraph 3 above apply *mutatis mutandis* to claim 1 of the auxiliary request, as the only differing amendment is the added term "as a single dose". Regarding this amendment, the possibility is to be considered that "as a single dose" referring to original claim 1 means that each single one of the doses to be taken on one, two or three consecutive days is to be taken as a single dose and not as an assembly of multiple sub-doses.

4.2 In addition, claims 9 and 10 represent equally weighted alternatives and combining exactly and only one of them (claim 9) with features of original claim 6 together with referenced claims represents an additional choice

to be performed in order to arrive at the combination of features in claim 1 of the auxiliary request.

4.3 Therefore, the particular combination of features in claim 1 of the auxiliary request is also not to be found in individualised form in the application as originally filed; it is not directly and unambiguously derivable and the provisions of Article 123(2) EPC are not fulfilled.

5. Under these circumstances, the further arguments of the respondent cannot succeed either.

5.1 Applying the principle of direct and unambiguous derivability gives rise to a clear and unequivocal conclusion in the present case. There is no room for complementary considerations such as what the skilled person would seriously contemplate or if there was an "unwarranted advantage".

5.2 In coming to its conclusion, the present board duly considered decision T 0016/05 of 17 July 2007 cited by the respondent in support of its line of argumentation concerning the combination of features as currently claimed to be disclosed in its originally filed application.

The respondent referred in particular to section 1.4 of the cited decision requiring that features which were allowed to be introduced in order to produce an amended claim 1 be presented as preferred. Irrespective of other circumstances which influenced the decision on the case of T 0016/05, the considerations and conclusions presented in the current case show that at

least the features concerning the dose and the frequency of administration were not even presented as preferred in the application as originally filed, representing the basis of the patent in suit, and **in addition** there were no pointers to the particular combination of features comprised in the amended claims 1 as requested (see for comparison the first six lines of section 1.4 of decision T 0016/05 confirming the outcome of another decision of the boards where conformity with Article 123(2) EPC was denied).

Therefore, the present decision does not contradict T 0016/05 and there is no reason for a referral to the Enlarged Board of Appeal.

Order

For these reasons it is decided that:

1. The intervention is inadmissible.

2. The decision under appeal is set aside.

3. The patent is revoked.

4. The request for a referral to the Enlarged Board of Appeal is refused.

The Registrar: The Chairman:

N. Maslin U. Oswald