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Datasheet for the decision of 25 May 2011

Case Number: T 0610/06 - 3.3.04

Application Number: 99942350.2

Publication Number: 1059933

IPC: A61K 38/29

Language of the proceedings: EN

Title of invention:
Use of parathyroide hormone consisting of aminoacid sequence 1-34 of human parythyroide hormone for reducing the risk of both vertebral and non-vertebral bone fracture

Patentee:
Eli Lilly & Company

Opponent:
Daiichi Sankyo Company, Limited
Chugai Seiyaku Kabushiki Kaisha

Headword:
h PTH 1-34/ELI LILLY

Relevant legal provisions:
EPC Art. 100(c), 123(2)
RPBA Art. 12, 13

Keyword:
"Request - added matter (yes)"
"Admissibility of auxiliary requests (no)"

Decisions cited:
-

Catchword:
-

Case Number: T 0610/06 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 25 May 2011

Appellant: (Opponent 01)
Daiichi Sankyo Company, Limited
3-5-1, Nihonbashi Honcho
Chuo-ku
Tokyo 103-8426 (JP)

Representative:
Stoner, Gerard Patrick
Mewburn Ellis LLP
33 Gutter Lane
London EC2V 8AS (GB)

Respondent: (Patent Proprietor)
Eli Lilly & Company
Lilly Corporate Center
Indianapolis, IN 46285 (US)

Representative:
Fisher, Adrian John
Carpmaels & Ransford
One Southampton Row
London WC1B 5HA (GB)

Party as of right: (Opponent 02)
Chugai Seiyaku Kabushiki Kaisha
5-1 Ukima 5-Chome
Kita-Ku, Tokyo 115-8543 (JP)

Representative:
Maschio, Antonio
D Young & Co LLP
120 Holborn
London EC1N 2DY (GB)

Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 17 February 2006 concerning maintenance of European patent No. 1059933 in amended form.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: B. Claes
R. Gramaglia

Summary of Facts and Submissions

I. The subject of the appeal is the decision of the opposition division of 17 February 2006 to maintain the European patent No. 1059933, which was based on the international patent application published with the No. WO 00/10596, entitled "*Use of parathyroide hormone consisting of aminoacid sequence 1-34 of human parythyroide hormone for reducing the risk of both vertebral and non-vertebral bone fracture*", in amended form on the basis of the patent proprietor's auxiliary request then before it.

II. Claim 1 of the auxiliary request before the opposition division read:

"1. Use of a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid hormone for the manufacture of a medicament for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a postmenopausal woman at risk of or having osteoporosis, wherein said medicament is to be administered by subcutaneous injection to said woman without concurrent administration of an antiresorptive agent other than vitamin D or calcium, in a daily dose of 20 µg for at least about 12 months up to 3 years."

III. Appeals had been filed by the proprietor and opponent 01 (the latter is referred to hereinafter as "appellant"). Opponent 02 was a party as of right in the appeal of opponent 01.

IV. After the appealing parties had filed their statements of grounds of appeal both these parties also filed responses thereto.

V. The patent proprietor filed further submissions in response to the board's communication summoning oral proceedings.

Oral proceedings were held in the absence of the party as of right. During the oral proceedings the proprietor (referred to hereinafter as "respondent") withdrew its appeal and filed a first and second auxiliary request. Claim 1 of these requests differed from claim 1 of the auxiliary request before the opposition division in that the dosage regimen contained in the wording of the claim was amended to "in a daily dose of 20 µg for at least about 12 months up to **24 months**" and "in a daily dose of 20 µg for at least about **18** months up to **24 months**", respectively.

VI. The appellant (opponent 01) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed or alternatively that the decision under appeal be set aside and that the patent be maintained on the basis of the first or second auxiliary request filed during the oral proceedings.

VII. The appellant's arguments as far as they are relevant for the present decision can be summarised as follows:

Article 100(c) EPC - Claim 1 of the auxiliary request before the opposition division

– The dosage regimen "in a daily dose of 20 µg for at least about 12 months up to 3 years" found no basis in the application as published.

– The paragraph on page 13, lines 12 to 24, of the general description related to length of treatment by the dosage regimen. The allegedly supporting sentence in lines 15 and 16 referred to cyclic administration of the hormone and furthermore qualified the administration as to be "once daily for 1-7 days". Those two aspects of the administration were however not a feature of the claim. The sentence could therefore not constitute a basis for the upper length of 3 years on the claimed dosage regimen which thus represented a new teaching.

Admissibility of the auxiliary requests filed during the oral proceedings before the board

– The auxiliary requests were late filed.

– Objections in relation to the length of the administration had always been a part of the case of the opponent. A last explicit reference to it had been made in the appellant's reply to the proprietor's statement of appeal.

– The amendments contained in the auxiliary requests introduced new difficulties and were anyhow not *prima facie* allowable. In particular the support

claimed for the amendments in example 3 on page 47, lines 6 to 8, combined with figure 10 of the application as published, referred to experimental conditions which included the supplementation of vitamin D and calcium, contrary to the optional feature in claim 1 of the auxiliary requests.

VIII. The respondent's arguments as far as they are relevant for the present decision can be summarised as follows:

Article 100(c) EPC - Claim 1 of the auxiliary request before the opposition division

– The dosage regimen "in a daily dose of 20 µg for at least about 12 months up to 3 years" was based on example 3 in the application as published.

– Support for the "up to three years" feature was contained in the general part of the description, in particular on page 13, lines 15 to 16. The reference in this passage to "once daily for 1-7 days" should be read in the context of the previous sentence in the same paragraph which referred to a period of days or weeks. Thus "once daily for 7 days" then meant "once daily".

– Support for the "at least 12 months" feature was to be found in the summary of example 3 on page 51, lines 15 to 17 which specifically referred to a period of "12 months of therapy".

Admissibility of the auxiliary requests filed during the oral proceedings before the board

– An objection to the length of the administration per se had never been dealt with before in the proceedings before the oral proceedings.

– The amendments were simple and easy to deal with. There was clear support for the amendments in claim 1 of both auxiliary requests in example 3 on page 47, lines 6 to 8, combined with figure 10 of the application as published.

Reasons for the Decision

1. The appeal is admissible.

Article 100(c) EPC - Claim 1 of the auxiliary request before the opposition division

2. It needs to be decided pursuant to Article 100(c) EPC whether or not the dosage regimen "in a daily dose of 20 µg for at least about 12 months up to 3 years" constitutes an amendment which introduces subject-matter which extends beyond the content of the application as filed pursuant to Article 123(2) EPC.

3. Reference has been made by the respondent in particular to page 13, lines 12 to 16 of the application as published for supporting the amendment in the aspect of "3 years". This passage reads: "*The hormone can be administered regularly (e.g., once or more each day or week), intermittently (e.g., irregularly during a day*

*or **week**), or cyclically (e.g., regularly for a period of days or **weeks** followed by a period without administration). **Preferably PTH is administered once daily for 1-7 days for a period ranging from 3 months for up to 3 years in osteoporotic patients**.*" (emphasis added by the board to highlight, in particular, the sentence contained in lines 15 to 16)

4. The sentence emphasised in bold in the passage just cited provides a literal basis for a regimen of up to "3 years", however, in the context of the disclosure, this regimen is actually qualified by a mode of administration which is said to be "once daily for 1-7 days". The respondent has argued that the reference to 7 days in this expression should be interpreted as referring to a week and that therefore in one aspect at least it referred to continuous daily administration for up to three years, hence supporting the contentious amendment.

5. The board notes however that even if the respondent's argument that the sentence on page 13, lines 15 to 16, referred to a continuous administration of the PTH for up to three years was accepted, this sentence still qualifies the dose to be administered "once daily" contrary to the more general reference in the amendment in claim 1 to "a daily dose of 20 µg".

6. In accordance with established case law of the boards of appeal, the relevant question to be decided in assessing whether an amendment adds subject-matter extending beyond the content of the application as filed is whether the proposed amendment is "**directly and unambiguously**" derivable from the application as

filed (see Case Law of the Boards of Appeal of the European Patent Office, 6th Edition 2010, III.A.7).

7. In view of the above considerations, the board is satisfied that a skilled person reading the application as filed cannot derive the feature "in a daily dose of 20 µg for at least about 12 months up to 3 years" from the passage relied on. Accordingly, claim 1 fails to comply with the requirements of Article 123(2) EPC.

Admissibility of the auxiliary requests filed during the oral proceedings before the board

8. During the written phase before the board the respondent has not filed any requests other than those which had been already the subject of the opposition proceedings.

9. After the board had announced its decision at the oral proceedings that claim 1 of the auxiliary request before the opposition division failed to comply with the requirements of Article 123(2) EPC, the respondent filed two completely new auxiliary requests (see section V, above). The dosage regimen contained in the wording of claim 1 was amended to "in a daily dose of 20 µg for at least about 12 months up to **24 months**" and "in a daily dose of 20 µg for at least about **18** months up to **24 months**", respectively for the first and second auxiliary request.

10. The respondent has referred in particular to example 3 on page 47, lines 6 to 8, and combined with figure 10 of the application as published in support of the amendments. This passage reads: "*Data from this*

clinical trial including a total of 1637 women treated with recombinant parathyroid hormone (1-34), rhPTH(1-34) 0, 20, or 40 µg/kg/day, ***and supplemented with vitamin D and calcium****, for 18-24 months, showed results reported in Tables 15-19*" (emphasis added by the board).

11. The board notes that the passage referred to, contrary to the wording of claim 1 of the auxiliary requests (see sections II and V), describes data of an experiment in which the rhPTH(1-34) administration was **concurrent** with the administration of vitamin D and calcium. Indeed, the feature "wherein said medicament is to be administered by subcutaneous injection to said woman without concurrent administration of an antiresorptive agent other than vitamin D or calcium" as part of these claims appears to merely constitute an optional feature for the claimed use in relation to vitamin D and calcium whereas in example 3 it is a characterising feature. It was therefore highly unlikely that either of these auxiliary requests would be allowable.

12. Further, these auxiliary requests were filed extremely late, i.e. at the end of the oral proceedings in the appeal stage. It had been clear since the appellant filed its appeal on 29 June 2006, and even clearer since it filed its reply to the patent proprietor's appeal on 20 November 2006, that the issue of the combination of the dosage values with the length of the treatment would be a disputed issue in the appeal. Accordingly, the patent proprietor could have filed these and/or other auxiliary requests to anticipate various possible decisions on the issue with its reply to the appellant's appeal (see Article 12(2) RPBA).

Having failed to do so, it then waited until the last possible moment to amend its case. In the circumstances of the case, the board cannot see how its discretion can be exercised in the respondent's favour in view of "the current state of the proceedings" (see Article 13(1) RPBA).

13. In view of the above considerations, the board decides that the two auxiliary requests filed by the respondent during the oral proceedings are not admissible.

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

P.Cremona C. Rennie-Smith