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**Datasheet for the decision
of 5 March 2009**

Case Number: T 0373/06 - 3.3.02

Application Number: 99955918.0

Publication Number: 1137419

IPC: A61K 31/663

Language of the proceedings: EN

Title of invention:

Uses of 1-amino-3-(N,N-dimethylamino)-propylidene
-1,1-bisphosphonic acid

Applicant:

GADOR S.A., et al

Opponent:

-

Headword:

Uses of NH₂-ODP/GADOR S.A., et al

Relevant legal provisions:

EPC Art. 111

Relevant legal provisions (EPC 1973):

-

Keyword:

"Remittal - yes: unexamined subject-matter"

Decisions cited:

-

Catchword:

-



Case Number: T 0373/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 5 March 2009

Appellant: GADOR S.A.
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Buenos Aires 1414 (AR)

Representative: Winkler, Andreas Fritz Ernst
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 14 October 2005
refusing European application No. 99955918.0
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 99 955 918.0 was refused by a decision of the Examining Division dated 19 September 2005 under Article 97(1) EPC 1973 in conjunction with Articles 54 and 56 EPC 1973.

II. The decision was based on the main request and auxiliary requests 1 to 5 received on 19 August 2005.

The three independent use claims 1, 4 and 5 of the main request read as follows:

"1. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention of osteopathies in a subject in whom a selective modulation of osteoblasts is indicated.

4. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the post-treatment of osteopathies in a subject in whom a selective modulation of osteoblasts is indicated.

5. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the treatment of osteopathies in a child in whom a selective modulation of osteoblasts is indicated."

The three independent use claims 1, 4 and 5 of first auxiliary request read as follows:

"1. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention of osteopathies in a subject in whom a selective stimulation of the cellular activities of osteoblasts is indicated.

4. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the post-treatment of osteopathies in a subject in whom a selective stimulation of the cellular activities of osteoblasts is indicated.

5. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the treatment of osteopathies in a child in whom a selective stimulation of the activities of osteoblasts is indicated."

The three independent use claims 1, 4 and 5 of second auxiliary request read as follows:

"1. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention of osteopathies in a subject by selective modulation of osteoblasts, wherein the subject has or is at risk of unfit mineralized bone structures.

4. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the post-treatment of osteopathies in a subject by selective modulation of osteoblasts, wherein the subject has or is at risk of unfit mineralized bone structures.

5. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the treatment of osteopathies in children by selective modulation of osteoblasts, wherein the child has or is at risk of unfit mineralized bone structures."

The three independent use claims 1, 4 and 5 of third auxiliary request read as follows:

"1. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention of osteopathies in a subject by selective stimulation of the cellular activities of osteoblasts, wherein the subject has or is at risk of unfit mineralized bone structures.

4. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the post-treatment of osteopathies in a subject by selective stimulation of the cellular activities of osteoblasts, wherein the subject has or is at risk of unfit mineralized bone structures.

5. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the treatment of osteopathies in children by selective stimulation of the cellular activities of osteoblasts, wherein the child has or is at risk of unfit mineralized bone structures."

The three independent use claims 1, 2 and 3 of fourth auxiliary request read as follows:

"1. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention of osteopathies in a subject by selective modulation of osteoblasts, wherein the subject is a human being at or above the age of 40 years.

2. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the post-treatment of osteopathies in a subject by selective modulation of osteoblasts.

3. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention and/or treatment of osteopathies in children by selective modulation of osteoblasts."

The three independent use claims 1, 2 and 3 of fifth auxiliary request read as follows:

"1. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention of osteopathies in subject by selective stimulation of the cellular activities of osteoblasts, wherein the subject is a human being at or above the age of 40 years.

2. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the post-treatment of osteopathies in a subject by selective stimulation of the cellular activities of osteoblasts.

3. Use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid, any of its soluble salts or any of its hydrates, for the manufacture of a medicament for the prevention and/or treatment of osteopathies in children by selective stimulation of the cellular activities of osteoblasts."

III. The reasons for the decision can be summarised as follows:

The Examining Division considered that the subject-matter of use claim 1 of the main request and auxiliary requests 1 to 3 was anticipated by the disclosure, in document WO-A-9702827, of the same use of a compound according to claim 1, i.e. NH₂-ODP (1-amino-3-

(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid) as in the application.

It also held that the subject-matter of use claim 1 of auxiliary requests 4 and 5 was not inventive vis-à-vis this document, which, in its view, suggested the treatment of people being at/or above the age of 40 years.

IV. The appellant (applicant) lodged an appeal against the said decision.

With its grounds of appeal, it filed a main and an auxiliary request which correspond respectively to the fourth and fifth auxiliary requests filed on 19 August 2005.

V. In its written submissions, it mainly argued that the problem to be solved vis-à-vis document WO-A-9702827 was to provide an improved therapeutic or pharmaceutical effectiveness of NH₂-ODP and that this problem was solved by the selection of patients at the age of 40 or above. In its view, as document WO-A-9702827 neither disclosed nor suggested that the effectiveness of NH₂-ODP could be improved by selecting certain patient, the subject-matter of claim 1 was inventive.

VI. Oral proceedings were held on 5 March 2009.

At the beginning of the oral proceedings, the appellant filed a new set of claims as a single request replacing the main and auxiliary requests filed with its grounds of appeal.

This set of claims is identical to the set of claims of auxiliary requests 4 and 5 before the Examining Division, wherein the subject-matter of independent use claim 1, relating to the treatment of human beings at/or above the age of 40, was deleted.

- VII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution.

Reasons for the Decision

1. The appeal is admissible.
2. The Board notes that the set of claims of the sole request is identical to the set of claims of auxiliary requests 4 and 5 before the Examining Division, wherein the subject-matter of independent use claim 1, relating to the treatment of human beings at/or above the age of 40, has been deleted.

The Board observes that, as a consequence of this deletion, the subject-matter of the claim relating to the treatment of human beings at/or above the age of 40, is no longer at issue.

Under these circumstances, the decision of the Examining Division, which was strictly confined to the subject-matter of independent use claim 1, relating to the treatment of human being at/or above the age of 40, no longer holds good and the decision under appeal has to be set aside.

3. *Remittal to the department of first instance*

3.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party based solely upon one particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111 EPC).

3.2 The observations made above apply fully to the present case. The Examining Division decided that the subject-matter of independent use claim 1, relating to the treatment of human beings at or above the age of 40, was not patentable on the grounds of lack of inventive step (Article 56 EPC), but disregarded the patentability of the subject-matter of independent use claims 2 and 3, relating respectively to the post-

treatment of osteopathies and to the treatment of children. These issues, however, form the basis for the request that a patent be granted and must therefore be considered as essential substantive issues in the present case.

- 3.3 Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.

The Registrar

The Chairman

N. Maslin

U. Oswald