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**Datasheet for the decision
of 22 August 2013**

Case Number: T 0778/11 - 3.3.10

Application Number: 04018057.2

Publication Number: 1481962

IPC: C07C 59/125, C07C 51/41

Language of the proceedings: EN

Title of invention:
New cholesterolemia-lowering carboxyalkylether compound

Applicant:
Warner-Lambert Company LLC

Headword:
-

Relevant legal provisions:
EPC Art. 76(1), 54

Keyword:
"Main request: added subject-matter (yes)"
"Auxiliary request: novelty (no)"

Decisions cited:
T 0823/96, T 0730/01

Catchword:
-



Case Number: T 0778/11 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 22 August 2013

Appellant: Warner-Lambert Company LLC
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 3 December 2010
refusing European patent application
No. 04018057.2 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
C. Schmidt

Summary of Facts and Submissions

I. The present appeal lies from the decision of the Examining Division refusing European patent application No. 04 018 057.2, which is a divisional application of the European patent application No. 98 960 278.4. The only claim of the main request underlying the contested decision read as follows:

"The compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid monocalcium salt."

The single claim of the auxiliary request underlying the contested decision read as follows:

"The compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid calcium salt."

II. The Examining Division found that the subject-matter of the single claim of the then pending main request contained added subject-matter extending beyond the content of the parent application as filed and thus did not comply with the requirement of Article 76(1) EPC. The subject-matter of the claim of the then pending auxiliary request fulfilled the requirement of Article 76(1) EPC, was novel but not inventive over the teaching of document

(1) WO-A-96 303 28.

III. The Appellant (Applicant) argued that the subject-matter of the claim of the main request found a basis in the parent application as filed. Although there was no explicit textual disclosure of the monocalcium salt

of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid in the parent application, said compound was nevertheless implicitly disclosed therein. More particularly, 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid, which was a preferred carboxyalkylether for use in the pharmaceutical compositions according to the invention, was disclosed on page 3, lines 13 to 14, and pharmaceutically acceptable salts of carboxyalkylethers were disclosed on page 3, lines 15 to 16. On page 6, lines 15 to 19 it was disclosed that pharmaceutically acceptable salts, albeit of the statins for use in combination with the carboxyalkylethers in the pharmaceutical compositions according to the invention, could be prepared by reacting the free acid form of the statin with an appropriate base, usually one equivalent thereof, calcium hydroxide being listed as a typical base. Said teaching was of general applicability such that the skilled person would therefore react 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid with one equivalent of calcium hydroxide and thereby inevitably produce the monocalcium salt. The reference to "one equivalent" of an appropriate base meant one equivalent of the base itself and not one equivalent of hydroxide anions, such that reaction of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid with one equivalent of the dibasic base calcium hydroxide would inevitably result in the monocalcium salt.

IV. In a communication annexed to the summons to oral proceedings dated 4 April 2013, the Board indicated that it saw no reason for departing from the conclusions of the first instance with regard to the requirements of Article 76(1) EPC of the subject-matter

of the claim of the main request. With regard to the claim of the auxiliary request, it indicated that the subject-matter thereof would appear to lack novelty over the disclosure of document (1), citing claims 1 and 9 and page 11, line 1 of said document in this respect.

- V. With letter dated 28 June 2013, the Appellant informed the Board that it did not intend to attend oral proceedings. The Appellant did not provide any comments on the communication of the Board.
- VI. The Appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main or auxiliary request underlying the appealed decision.
- VII. At the oral proceedings held on 22 August 2013 in the absence of the Appellant, the Board gave its decision.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Amendments (Article 76(1) EPC)*

- 2.1 The patent application in suit is a divisional application of the earlier (parent) European patent application No. 98 960 278.4. For the requirements of Article 76(1) EPC to be fulfilled, it is thus necessary

that the content of the application in suit does not go beyond the content of the parent application as filed.

2.2 In order to determine whether or not an amendment adds subject-matter extending beyond the content of the application as filed, it has to be examined whether technical information has been introduced which a skilled person would not have directly and unambiguously derived from the application as filed, either explicitly or implicitly, implicit disclosure meaning no more than the clear and unambiguous consequence of what is explicitly disclosed.

2.2.1 The claim of the main request is directed to the compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid monocalcium salt. Said compound is a carboxyalkylether, the application in suit concerning the combination of such a carboxyalkylether with a statin for use in a method of treatment (see page 1, lines 3 to 7 of the parent application as filed).

2.3 The Appellant did not dispute that there was no explicit disclosure of the claimed compound in the parent application, but instead submitted that said compound was implicitly disclosed, since it would be inevitably prepared when the skilled person reproduced the teaching of said earlier application. More particularly, support for this compound was to be found in the following passages of the parent application as filed:

- 2.3.1 the compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid of Formula III was disclosed on page 3, lines 13 to 14;
- 2.3.2 pharmaceutically acceptable salts of such carboxyalkylethers of Formula I were disclosed on page 3, lines 15 to 16;
- 2.3.3 the calcium salt of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid was disclosed on page 8, lines 2 to 3;
- 2.3.4 the reaction of the free acid form of a statin with an appropriate base, usually one equivalent, such as calcium hydroxide, resulting in a pharmaceutically acceptable salt of the statin was disclosed on page 6, lines 15 to 19.
- 2.4 The Board accepts that the calcium salt of the compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid is disclosed on page 8, lines 2 to 3. However, the compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid may form a monocalcium or a hemicalcium salt, as acknowledged by the Appellant in its letter before the Examining Division dated 10 April 2008 (see second paragraph on page 1). Hence, the mere reference to the "calcium salt" of this compound does not unambiguously disclose the monocalcium salt thereof.
- 2.5 The Board also accepts that pharmaceutically acceptable salts of carboxyalkylethers of Formula I are disclosed on page 3, lines 15 to 16, the compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid of

Formula III disclosed on page 3, lines 13 to 14 being such a carboxyalkylether of Formula I. However, the passage with which the Appellant combines this disclosure in order to arrive at the specific monocalcium salt thereof, namely that on page 6, lines 15 to 19, concerns the pharmaceutically acceptable salts of **statins** and not of carboxyalkylethers. Thus, this passage on page 6 cannot form a basis for a particular salt of a carboxyalkylether compound, let alone of the specific compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid.

2.6 The Appellant argued that although the teaching on page 6, lines 15 to 19 was in connection with the statin component of the combination, it was of general applicability. The skilled person, wishing to prepare a pharmaceutically acceptable salt of a carboxylalkylether, would proceed by analogy and would therefore have reacted 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid with one equivalent of calcium hydroxide and thereby have inevitably produced the monocalcium salt thereof. The claimed monocalcium salt was thus implicitly disclosed in the parent application.

In this respect, the Board observes that the term "implicit disclosure" should not be construed to mean matter that does not belong to the content of the technical information provided by a document but may be rendered obvious on the basis of that content (see T 823/96, point 4.5 of the reasons, not published in OJ EPO). Thus, even if it were to be accepted that the skilled person on reading "pharmaceutically acceptable salts of Formula I" on page 3, lines 15 to 16 may have

recognised that it was desirable to employ one equivalent of a base such as calcium hydroxide in order to prepare a salt of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid, this does not imply directly and ambiguously that a monocalcium salt was an **inevitable** product of the processes disclosed in the parent application as filed. This argument of the Appellant must therefore be rejected.

2.7 Since the Board holds that the passage on page 6, lines 15 to 19 cannot be combined with that at page 3, lines 15 to 16, it is not necessary for the Board to comment on whether the reaction of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid with one equivalent of calcium hydroxide would result in the monocalcium or hemicalcium salt thereof. Hence, the Appellant's arguments in this respect are redundant.

2.8 There being neither an explicit nor an implicit disclosure in the parent application as filed for the **monocalcium** salt of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid, the Board concludes that the claim of the main request is amended in such a way that its subject-matter extends beyond the content of the parent application as filed, contrary to the requirement of Article 76(1) EPC.

Auxiliary request

3. *Amendments (Article 76(1) and 123(2) EPC)*

3.1 The claim of the auxiliary request is directed to the compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid calcium salt.

3.2 Said compound is disclosed on page 8, lines 2 to 3 of both the parent application (see point 2.5 above) and the present application as filed.

3.3 For these reasons, the Board concludes that the subject-matter of the claim does not extend beyond the content of either the application in suit or the parent application as filed, such that the requirements of Articles 76(1) and 123(2) EPC are satisfied.

4. *Novelty*

4.1 Document (1) discloses pharmaceutically acceptable salts of the compound 6,6'-oxybis(2,2-dimethylhexanoic acid) (see claim 9 in combination with claim 1, or alternatively page 4, lines 8 to 15), 6,6'-oxybis(2,2-dimethylhexanoic acid) being another name for the compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid. Document (1) further discloses that the preferred salts of these carboxylic acids are those made with bases such as calcium hydroxide (see page 10, line 33 to page 11, line 1). Therefore, in order to arrive at the claimed calcium salt of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid, only a selection within a single list in document (1), namely from the list of bases given at page 10, line 36 to page 11, line 3, is necessary.

Document (1) thus unambiguously discloses the calcium salt of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid as defined in the claim of the auxiliary request, with the consequence that said

document is detrimental to the novelty of the subject-matter of this claim.

- 4.2 The Examining Division found that the subject-matter of the claim of the auxiliary request was novel over the disclosure of document (1), since a selection had to be made from within two lists therein.

The two lists presumably meant by the Examining Division are the acid compound and the base compound necessary for making the calcium salt of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid. However, since document (1) already discloses pharmaceutically acceptable salts of the particular acid compound 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid (see claim 9 of document (1), which is indirectly dependent on claim 1), only the base compound, namely calcium hydroxide, has to be selected from the list of bases described at page 10, line 36 to page 11, line 3 of document (1) to arrive at the calcium salt of present claim 1 (see point 4.1 above). Therefore, the calcium salt of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid results from a selection within only a single list in document (1), options disclosed in a single list each being regarded as directly and unambiguously disclosed (see, for example, T 730/01, not published in OJ EPO).

- 4.3 The Appellant did not provide any comments in response to the communication of the Board, wherein it was indicated that the subject-matter of the auxiliary request would appear to lack novelty over the disclosure of document (1) (see point IV above), such that no arguments in support of the novelty of the

subject-matter of the claim of the auxiliary request were filed during the appeal proceedings.

4.4 As a result, the auxiliary request is not allowable as the subject-matter of the single claim thereof lacks novelty within the meaning of Articles 52(1) and 54(1) and (2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

P. Gryczka