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Datasheet for the decision of 27 July 2012

Case Number: T 2108/08 - 3.3.02

Application Number: 01975405.0

Publication Number: 1322335

IPC: A61K 47/00, A61K 31/195, A61K 9/20

Language of the proceedings: EN

Title of invention:
Stable solid dosage forms of amino acids and processes for producing same

Applicant:
Sigmapharm, Inc.

Headword:
Pharmaceutical formulation comprising amino acids/SIGMAPHARM

Relevant legal provisions:
EPC R. 137
RPBA Art. 13
EPC Art. 113

Relevant legal provisions (EPC 1973):
-

Keyword:
"Admissibility of the requests: no"

Decisions cited:
G 0004/92

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2108/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 27 July 2012

Appellant: (Applicant)
Sigmapharm, Inc.
15 Eagleton Farms Road
Newtown, PA 18940 (US)

Representative:
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 16 June 2008 refusing European patent application No. 01975405.0 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
R. Cramer

Summary of Facts and Submissions

I. European patent application No. 01975405.0, based on international application PCT/US01/30095, published as WO 02/26263, was filed with 73 claims.

II. The present appeal lies from a decision of the examining division refusing the application (Article 97(2) EPC).

III. The following documents *inter alia* were cited in the examination and appeal proceedings:

D1 WO 01/97782
D2 WO 01/97612
D3 EP-A-0414263
D5 US 4087544
D6 US 6054482
D7 WO 00/07568

IV. The examining division's decision was based on the main request filed with the letter of 22 March 2006, which was filed a second time with the letter of 5 March 2008, and on the first auxiliary request filed with the letter of 5 March 2008.

The examining division considered that both sets of claims did not meet the requirements of Article 123(2) EPC. Moreover, the examining division also pointed to deficiencies under Article 84 EPC. Additionally, it reasoned that the subject-matter claimed in the auxiliary request lacked novelty vis-à-vis documents D1 to D3.

V. The applicant (appellant) filed an appeal and filed grounds thereto. With the grounds of appeal the appellant withdrew the main request and first auxiliary request serving as basis for the first-instance decision and filed a new main request and two auxiliary requests (first and second auxiliary requests).

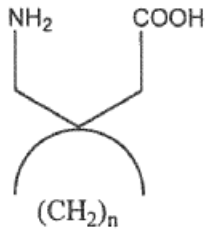
VI. A communication by the board within the meaning of Rule 100(2) EPC was sent on 15 December 2011. In said communication the board expressed its preliminary opinion in relation to the three sets of claims on file and gave detailed reasons thereto. In particular, the board considered that none of the sets of claims on file met the requirements of Articles 123(2) and 84 EPC. The board sent as an annex to said communication a copy of three documents cited in the description of the application in suit.

VII. The appellant filed a letter dated 16 April 2012 as a reply to the board's communication. With said letter it filed a new main request and a new auxiliary request in order to replace the requests previously on file. It also filed amended pages of the description for each of the two requests.

Claim 1 of the main request read as follows:

1. A stable pharmaceutical formulation comprising: one or more amino acids which is susceptible to formation of a lactam; one or more stabilizers to inhibit the formation of said lactam, said stabilizer comprising a composition that is known to reduce ionic activity; and an anion;

wherein the amino acid is an amino acid of formula:



wherein n is 4, 5 or 6; and

wherein the stabilizer is selected from ethanol, acetone, glycerine, propylene glycol and polysorbates.

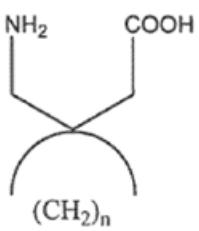
Claim 16 of the main request read as follows:

16. A process for forming a stable pharmaceutical formulation containing an amino acid susceptible to formation of a lactam and an anion, comprising the steps of treating the amino acid with a

stabilizer to inhibit the formation of said lactam, wherein the amino acid, stabilizer and anion are a defined in any preceding claim.

Claim 1 of the auxiliary request read as follows:

1. A process for forming a stable pharmaceutical formulation comprising an amino acid of formula:



wherein n is 4, 5 or 6;

comprising:

- treating crude amino acid with an alcoholic mineral acid solution to convert any lactam present into the free amino acid form, isolating the thereby purified amino acid, and formulating into a dosage form; or

- treating crude amino acid with a mineral acid solution to convert any lactam present into the free amino acid form, isolating the thereby purified amino acid, and formulating into a dosage form using an alcohol or acetone as a granulating liquid; or

- treating crude amino acid with an alcoholic mineral acid solution to convert any lactam present into the free amino acid form, isolating the thereby purified amino acid, and formulating into a dosage form using an alcohol or acetone as a granulating liquid.

Claims 12 and 13 of the auxiliary request read as follows:

12. A pharmaceutical composition obtainable by the process of any preceding claim.

13. Tablet, coated tablet, caplet, beads or capsule comprising the composition of claim 12.

VIII. The board sent a communication pursuant to Article 15(1) RPBA as an annex to the summons to oral proceedings.

The board informed the appellant that the two requests filed with the letter of 16 April 2012 could not be considered to be admissible under Article 13(1) RPBA and gave reasons thereto.

The board also expressed a preliminary negative opinion in relation to the assessment of novelty of the subject-matter claimed in the new main request (D3, D5, D7) and also in relation to Article 84 EPC.

IX. With a letter dated 26 July 2012, filed by fax, the appellant informed the board that it would not be attending the oral proceedings scheduled for 27 July 2012. However, the appellant did not file any substantive reply to the board's communication sent as an annex to the summons to oral proceedings.

X. Oral proceedings took place on 27 July 2012 in the absence of the appellant.

XI. The following requests are on file:

The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request, or alternatively on the basis of the auxiliary request, both filed with the letter of 16 April 2012.

Reasons for the Decision

1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of the appellant, who was duly summoned but decided not to attend, as announced in its letter of 26 July 2012.

The present decision is based on facts and evidence put forward during the written proceedings and on which the appellant had an opportunity to comment. Therefore, the conditions set forth in decision G 4/92, OJ EPO 1994, 149, are met.

3. *Admissibility of the requests filed with the letter of 16 April 2012*

3.1 Claim 1 of the main request filed with the letter of 16 April 2012 has been completely redrafted when compared to any of the independent claims previously on file. The specification in the nature of the amino acid and the specification in the list of options for the stabilizer are a clear and direct response to the board's communication dated 15 December 2012. However, there is no justification for the suppression in claim 1 of the characteristics concerning the anion as being from a mineral acid, the anion being present in an amount of at least 20 ppm, and the amino acid being in crystalline form, which are essential characteristics of the subject-matter claimed, present in the independent claims of the sets of claims previously on file. These characteristics (some of them already present in claim 1 of the application as filed) appear now, without any justification, in new dependent claims (claims 2, 10, 12). Thus, claim 1 of the main request now encompasses subject-matter not prosecuted in the sets of claims filed previously during examination and appeal proceedings.

The suppression of the essential characteristics mentioned above for the product claimed in claim 1 results at such a late stage in the proceedings in a fresh case which has not been justified by the appellant. In fact, the subject-matter now claimed manifestly lacks novelty for very different reasons to those given in the examining division's decision. In particular, apart from document D3, documents D5 and D7

now become relevant against novelty, as explained in detail in the board's communication sent as an annex to the summons to oral proceedings. Additionally, new problems in relation to Article 84 EPC arise.

Similar considerations to those given above in relation to the redrafting of product claim 1 also apply to the redrafted process claim 16 and the introduction of new dependent process claims in the main request.

Therefore, the main request cannot be admitted into the proceedings (Article 13(1) RPBA).

4. The auxiliary request filed with the letter dated 16 April 2012 is not admissible (Article 13(1) RPBA). The amendments made in this set of claims do not constitute a clear and direct response to the board's communication dated 15 December 2011 and open new and complex issues in relation to the allowability of the claimed subject-matter. In particular, claim 1 in the auxiliary request is directed to a process (comprising three separate alternatives) for forming a pharmaceutical formulation defined in a broader manner than that of the pharmaceutical formulation in claim 1 of the main request (the presence of an anion and the particular stabilizer are not compulsory in the product) and two product claims, namely claim 12 which is directed to a pharmaceutical composition "obtainable by the process of any preceding claim" (i.e. a formulation broader than the formulation in claim 1 of the main request) and claim 13 which is directed to a tablet, coated tablet, etc. comprising the composition of claim 12. The two independent product claims, which do not require the presence of a stabilizer or of an anion,

are even broader than the product claims in the set of claims of the application as filed. Thus, the subject-matter claimed in the auxiliary request might not be covered by the search report. Such a request cannot be admitted either under Rule 137 EPC.

4.1 Consequently, the requests filed with the letter of 16 April 2012 are not admissible.

5. Under Article 113(2) EPC, the European Patent Office shall examine and decide upon the European patent application or the European patent only in the text submitted to it, or agreed by the applicant or the proprietor of the patent.

5.1 With its letter of 16 April 2012 the appellant had filed a new main request and a new auxiliary request in order to replace the sets of claims previously on file. The appellant had also requested a patent to be granted on the basis of either of these two requests filed with its letter of 16 April 2012. The board informed the appellant with the communication sent as an annex to the summons to oral proceedings that none of these two requests was admissible and gave detailed reasons thereto. The appellant did not file any substantive reply contesting the board's findings or modify its requests.

5.2 Under these circumstances, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald