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**Datasheet for the decision
of 1 July 2013**

Case Number: T 0367/09 - 3.3.02
Application Number: 03773743.4
Publication Number: 1579860
IPC: A61K 31/4045, A61K 7/16,
A61K 38/22, A23K 1/165
Language of the proceedings: EN

Title of invention:

Bone regeneration product for human and veterinary use,
containing melatonin as active principle

Applicants:

Cutando Soriano, Antonio
Gomez Moreno, Gerardo
Arana Molina, Carlos
Galindo Moreno, Pablo Antonio

Headword:

Bone regeneration product/CUTANDO ET AL

Relevant legal provisions:

EPC Art. 113(2)
EPC R. 137
RPBA Art. 12, 13, 15

Keyword:

"Admission of claims request (no)"
"No set of claims left"

Decisions cited:

G 0004/92, G 0010/93

Catchword:

-



Case Number: T 0367/09 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 1 July 2013

Appellants:
(Applicants)

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Representative:

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted 21 November 2008
refusing European patent application
No. 03773743.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
D. Prietzel-Funk

Summary of Facts and Submissions

- I. European patent application No. 03773743.4, published as EP 1 579 860, was filed with five claims.

Claim 1 as originally filed read as follows:

"1. A bone regeneration product for human and veterinary use containing melatonin as an active principle, characterised in that the melatonin is incorporated in toothpastes, gels, mouthwashes, bone reabsorption membranes and animal feeds at a ratio ranging from 0.1% to 5%, with the addition of an antioxidant and a preservative, using for the toothpaste preparation both hydrophilic and hydrophobic bases or excipients susceptible of being used in the preparation of toothpastes, gels, mouthwashes, and bone reabsorption membranes."

- II. The present appeal lies from a decision of the examining division, posted on 21 November 2008, refusing the application under Article 97(2) EPC.
- III. The following documents were cited *inter alia* in the examination and appeal proceedings:

D3 WO 98/05298

D5 Roth et al., The Journal of Biological Chemistry 274(31), 22041-22047, 1999

D6 Koyama et al., Journal of Bone and Mineral Research, 17(7), 1219-1229, July 2002

D7 Nakade et al., Journal of Pineal Research, 27(2), 106-110, 1999.

IV. The examining division considered that the subject-matter of claim 1 of the main request filed with the letter of 5 August 2008 (sole request) did not involve an inventive step (Article 56 EPC), and cited documents D3 and D5 to D7. In fact, the examining division also questioned the wording of claim 1 as appropriate for a medical use claim (see point 1.1 of the examining division's decision).

Claim 1 of the main request filed with the letter of 5 August 2008 read as follows:

"1. A bone regeneration product for human and veterinary use containing melatonin as an active principle, characterised in that the melatonin is incorporated in toothpastes, gels, mouthwashes, bone reabsorption membranes and animal feeds at a ratio ranging from 0.1% to 5%, with the addition of an antioxidant and a preservative, using for the toothpaste preparation both hydrophilic and hydrophobic bases or excipients susceptible of being used in the preparation of toothpastes, gels, mouthwashes, bone reabsorption membranes and animal feed for local and general use both in human beings and animals acting as specific odontological elements on the bone for its regeneration, osseointegration, anti-inflammatory actions, capturing free radicals and antioxidants."

V. The appellants (applicants) lodged an appeal against said decision and filed grounds thereto with their letter dated 21 January 2009. They also filed as an annex to said letter an amended set of claims and pages 1 to 9 of the description.

Claim 1 of the set of claims filed with the letter dated 21 January 2009 read as follows:

"1. A bone regeneration product for human and veterinary use containing melatonin as an active principle of the type incorporating melatonin at a ratio ranging from 0.1% to 5%, with the addition of an antioxidant and a preservative, characterised in that the melatonin is incorporated in toothpastes, gels, mouthwashes, bone reabsorption membranes and animal feeds, using for the toothpaste preparation both hydrophilic and hydrophobic bases or excipients susceptible of being used in the preparation of toothpastes, gels, mouthwashes and bone reabsorption membranes; and by the use of said toothpastes, gels, mouthwashes, bone reabsorption membranes and animal feed for local and general use both in human beings and animals acting as specific odontological elements on the bone for its regeneration, osseointegration, anti-inflammatory actions, capturing free radicals and antioxidants."

VI. On 19 October 2012 the board issued a communication pursuant to Rule 100(2) EPC and Article 12(1)(c) RPBA. In said communication the board stated that although the appellants had not explicitly said so, it had to be assumed that the set of claims filed with the letter dated 21 January 2009 replaced the set of claims serving as the basis for the decision under appeal, and that the appellants requested as their main request the grant of a patent on the basis of the set of claims filed with the letter dated 21 January 2009.

Moreover, the board expressed a detailed negative opinion about the amended claims and description filed with the grounds of appeal, which concerned *inter alia* observations in relation to Articles 54(4) and (5) and 53(c) EPC 2000, Articles 84 and 123(2) EPC, and Rule 42(1) (b) EPC 2000.

The appellants were reminded in said board's communication that the admissibility of any requests filed thereafter would have to be considered (Rule 137 EPC 2000 and Articles 12 and 13 RPBA).

VII. The appellants filed a reply dated 18 December 2012 to the board's communication of 19 October 2012.

The request filed with the letter of 18 December 2012 replaced the previous request on file, as stated by the appellants: "*in light of the findings in the communication of the Examining Division [sic], the appellant has decided to amend claim 1 of the application again and **to replace it** with a newly worded claim 1 which overcomes the defects concerning the lack of clarity in the object claimed and prevents the attempt to protect a therapeutic treatment. Claiming specific dental use is also prevented so as to not introduce subject matter which goes beyond the content of the initially filed application"* (emphasis added).

Claim 1 of the main request filed with the letter of 18 December 2012 read as follows:

"1. A bone regeneration product for human and veterinary use containing melatonin as an active principle, of the type incorporating melatonin in a

ratio ranging from 0.1% to 5%, with the addition of an oxidant and a preservative, being applicable for specific dental use in a localized manner both in human beings and animals, acting on the bone for its regeneration, osseointegration, anti-inflammatory action, free radical scavenging action, and antioxidant action, characterised in that it consists of a preparation configured as a toothpaste, gel, mouthwash, bone reabsorption membranes and animal feeds; and in that said preparation incorporates both hydrophilic and hydrophobic bases or excipients susceptible of being used in the preparation of toothpastes, gels, mouthwashes, as well as bone reabsorption membranes."

VIII. On 12 April 2013, as an annex to the summons to oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA.

In said communication the board made a summary of the situation and cited Enlarged Board of Appeal decision G 10/93, OJ EPO, 1995, 172. Furthermore, the board questioned the admissibility of the claims request filed with the letter of 18 December 2012, since it was not a clear and direct reply to the board's communication sent on 19 October 2012 (Article 12(1)(c) RPBA) and the claims were not clearly allowable.

IX. The appellants did not file any reply to the board's communication sent as an annex to the summons to oral proceedings.

X. Oral proceedings took place on 1 July 2013 in the absence of the appellants.

XI. The appellants requested with their letter dated 18 December 2012 that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with said letter.

Reasons for the Decision

1. The oral proceedings before the board took place in the absence of the appellants who were duly summoned but decided not to attend.

The present decision is based on facts and evidence put forward during the written proceedings and on which the appellants have had an opportunity to comment.

Therefore, the conditions set forth in Enlarged Board of Appeal opinion G 4/92, OJ EPO 1994, 149, are met.

Moreover, as stipulated by Article 15(3) of the RPBA the board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

2. *Admissibility*

2.1 The appeal is admissible.

2.2 *Admissibility of the claims request filed with the letter of 18 December 2012*

2.2.1 While Article 12(1)(c) RPBA provides that appeal proceedings shall be based on, in addition to the grounds of appeal and reply, any communication sent by

the board and any answer thereto, this does not mean that appellants have an unlimited right to file amended sets of claims as a reply to a board's communication, or that any set of claims filed after a board's communication expressing a preliminary opinion has been issued will automatically be admitted into the proceedings.

2.2.2 As stated in the board's communication sent as an annex to the summons to oral proceedings, a board's communication had been sent pursuant to Rule 100(2) EPC and Article 12(1)(c) RPBA on 19 October 2012. In said communication the board had dealt with the appellants' amended set of claims and amended description filed with their grounds of appeal. Moreover, the board had expressed a negative preliminary opinion in the communication sent on 19 October 2012 in relation to Articles 84 and 123(2) EPC for the filed request and amended description, and had given detailed reasons thereto.

2.3 It can be inferred from the appellants' letter dated 18 December 2012 (see passage quoted in point VIII above) that the appellants seek the admission of the amended request filed with the letter of 18 December 2012 on the basis that it represents a reply to the board's communication sent on 19 October 2012 (Article 12(1)(c) RPBA).

2.3.1 However, as expressed in the board's communication sent as an annex to the summons to oral proceedings, the appellants had not provided any specific reasons in support of their statement that the "*newly worded claim 1 overcomes the defects concerning the lack of*

clarity in the object claimed and prevents the attempt to protect a therapeutic treatment". A mere assertion cannot be considered a valid substantive reply. Additionally, the board's communication sent as an annex to the summons to oral proceedings gave reasons why the new main request could not be considered to be *prima facie* allowable within the meaning of Articles 84 and 123(2) EPC. In particular, in view of the wording of amended claim 1, which *inter alia* contains the following passages: "**a bone regeneration product for human and veterinary use** containing melatonin as an active principle (of the type incorporating melatonin in a ratio ranging from 0.1% to 5%,...) **"being applicable for specific dental use in a localised manner both in humans and animals, acting on the bone for its regeneration, osseointegration, anti-inflammatory action, free radical scavenging action, and antioxidant action"**. Such wording does not overcome the objections raised in the board's communication dated 19 October 2012 in relation to Articles 84 and 123(2) EPC. The fact that the wording quoted above is part of the preamble in a claim which addresses a medical purpose and at the same time is formulated in a two-part form does not render the claimed subject-matter clear, but opens a new discussion in relation to the requirements of Article 84 EPC.

2.3.2 Additionally, as mentioned in the board's communication sent as an annex to the summons to oral proceedings, expressions such as "of the type" and "configured as" are vague and obscure in the context in which they have been employed.

2.3.3 Therefore, there is *prima facie* a major lack of clarity (Article 84 EPC) of the subject-matter for which protection is sought in the set of claims filed with the letter of 18 December 2012.

2.3.4 Moreover, in the board's communication sent as an annex to the summons to oral proceedings the board also informed the appellants that it was not apparent where amended claim 1 should find an allowable basis in the application as filed (Article 123(2) EPC) and that the appellants had not stated where the basis was to be found. The appellants' statement "*claiming specific dental use is also prevented so as not to introduce subject matter which goes beyond the content of the initially filed application*" in their letter of 19 October 2012 is clearly insufficient in this respect.

2.4 Therefore, the new main request filed with the letter dated 18 December 2012 is not admissible since it cannot be considered as a clear and direct reply to the board's communication sent on 19 October 2012 and it opens new and complex issues for discussion in relation to Articles 84 and 123(2) EPC. In particular, amended claim 1 is *prima facie* non-allowable for the reasons mentioned in points 2.3.1 to 2.3.4 above.

2.4.1 Although the board expressed a negative opinion in relation to the admissibility of the new main request in the communication sent as an annex to the summons to oral proceedings and gave detailed reasons, the appellants did not file any counter-arguments.

Consequently, the main (sole) request filed with the letter of 18 December 2012 is not admitted into the

proceedings (Rule 137(3) EPC and Articles 12 and 13 RPBA).

2.5 Article 113(2) stipulates that the instances of the EPO shall examine and decide upon the European patent application only in the text submitted to it, or agreed, by the applicant. Since the appellants' claims request has not been admitted into the proceedings there is no basis for a patent to be granted and thus 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