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Datasheet for the decision of 13 September 2016

Case Number: T 2498/12 - 3.3.04

Application Number: 05254263.6

Publication Number: 1754489

IPC: A61K38/18

Language of the proceedings: EN

Title of invention:
A method of treating vitiligo using synergistic formation

Applicant:
Ramaiah, Abburi, Prof.

Headword:
Vitiligo/RAMAIAH

Relevant legal provisions:
EPC Art. 123(2), 133(2)
EPC R. 115(2)
RPBA Art. 15(3)

Keyword:
Amendments - allowable (no)

Decisions cited:
T 0689/90

Catchword:

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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2498/12 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 13 September 2016

Appellant: (Applicant)	Ramaiah, Abburi, Prof. 137, Charak Sadan, Vikas Puri New Delhi (IN)
Representative:	Green, Mark Charles Urquhart-Dykes & Lord LLP The Podium 1 Eversholt Street London NW1 2DN (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 12 July 2012 refusing European patent application No. 05254263.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	B. Claes
Members:	R. Morawetz
	M.-B. Tardo-Dino

Summary of Facts and Submissions

I. The appeal of the applicant ("appellant") lies against the decision of the examining division refusing European patent application No. 05254263.6.

II. The title of the application at issue is "*A method of treating vitiligo using synergistic formation*", and it was published as EP 1 754 489.

III. The examining division informed the applicant in a communication pursuant to Article 94(3) EPC that "*the present application documents contain neither the required sequence listing according to Rule 30 EPC, nor any other information about the exact amino acid sequence of the bFGF peptides of SEQ ID NO: 1-3, 5 and 6. Consequently, claims 1-4 lack disclosure with respect to SEQ ID:2, SEQ ID:3 (Art. 83 EPC*)".

IV. The applicant reacted by filing amended description pages and a sequence listing and submitting that the specific bFGF sequences were implicitly disclosed in the application as filed by reference to a series of patents including US 6,143,723 and AU 722,626.

V. The examining division issued a summons to oral proceedings and notified the applicant that the application as filed did not contain a clear indication that the sequences defined by SEQ ID NO: 1 to 6 in the application corresponded to the sequences disclosed in US 6,143,723 or AU 722,626.

VI. The applicant replied with a letter dated 21 May 2012, submitting a new page 20 of the description containing amino acid sequence information on the "*peptides used*

in accordance with the claimed invention."

VII. In the decision under appeal (see point 1.2.4) the examining division held that new page 20 of the description met the requirements of Article 123(2) EPC because the four criteria set out in decision T 689/90 for introducing features which were only disclosed in a cross-referenced document were fulfilled. The application was refused for lack of compliance with the requirements of Article 83 EPC.

VIII. With the statement of grounds of appeal the appellant maintained the main request as underlying the decision under appeal and filed an auxiliary request 1 and arguments with regard to sufficiency of disclosure.

Claim 1 of the main request reads:

"1. A peptide composition comprising 0.02 to 5% w/w of a peptide selected from the group consisting of bFGF amino acids 106-115 (SEQ ID NO: 1), bFGF amino acids 106-120 (SEQ ID NO: 5), bFGF amino acids 1-24 (SEQ ID NO: 6), SEQ ID: 2, cyclic bFGF amino acids 106-115 (SEQ ID NO: 1), cyclic bFGF amino acids 106-120 (SEQ ID NO: 5), cyclic bFGF amino acids 1-24 (SEQ ID NO: 6) and cyclic SEQ ID: 2 for use in the treatment of generalized stable vitiligo and segmental vitiligo in a combinatorial synergistic therapy with psoralens and UV-A (PUV-A) therapy, wherein use comprises local application of an effective amount of the composition."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that it specifies that synergy is observed at 3 months of treatment.

IX. The appellant was summoned to oral proceedings and was subsequently informed of the board's preliminary opinion in a communication according to Article 15(1) RPBA. In particular, the board indicated that it was inclined to consider that new page 20 of the description violated the requirements of Article 123(2) EPC.

X. With letter dated 5 September 2016 the appellant's representative informed the board that he would not be present at the oral proceedings and requested that the oral proceedings be cancelled and that the matter be decided on the basis of the state of the file.

XI. The board's registrar informed the appellant's representative by telephone on 5 September 2016 that the oral proceedings would take place as scheduled.

XII. On 6 September 2016 the appellant filed further arguments by fax.

XIII. In a communication dated 7 September 2016 the board informed the appellant's representative that it would not take the submission of 6 September 2016 into account (Article 133(2) EPC).

XIV. The appellant was neither present nor represented at the oral proceedings before the board on 13 September 2016, which were held in accordance with Rule 115(2) EPC and Article 15(3) RPBA. At the end of the oral proceedings the chairman announced the board's decision.

XV. The following document is referred to in this decision:

D5 US 6,143,723

XVI. The appellant requested in writing that the decision under appeal be set aside *"based on either"* a main request corresponding to the request filed with the letter of 21 May 2012 or the first auxiliary request filed with the statement of grounds of appeal.

Reasons for the Decision

1. The duly summoned appellant was neither present nor represented at the oral proceedings. The board considered it expedient to hold the scheduled oral proceedings in the appellant's absence in order to reach a final decision in this appeal case. The appellant was treated as relying on its written case in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

Article 133(2) EPC

2. According to Article 133(2) EPC, natural or legal persons not having their residence or principal place of business in a contracting state must be represented by a professional representative and act through him in all proceedings established by the EPC, with the exception of filing a European patent application.

3. The appealing applicant's address is in India, and thus not within the territory of a contracting state. From the evidence on file it is also not apparent that its principal place of business lies in a contracting state.

4. Therefore, filing arguments such as those contained in the appellant's fax received on 6 September 2016 required professional representation. As these submissions were neither made nor endorsed by the representative, the board cannot take them into account in the appeal proceedings.

Main request

Article 123(2) EPC

5. According to Article 123(2) EPC the European patent application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

6. In order to overcome an objection under Article 83 EPC raised by the examining division, the appellant had amended the description as originally filed by filing a new page 20 of the description incorporating amino acid sequence information disclosed in cross-referenced document D5 (see sections IV to VI).

7. The examining division held that new page 20 did not contravene Article 123(2) EPC. It considered that the amino acid sequences provided on new page 20 were implicitly disclosed in the application as filed by cross-reference to document D5 and could be incorporated into the application, as this disclosure fulfilled the criteria established by decision T 689/90 (OJ EPO 1993, 616).

8. The present main request corresponds to the application in the form refused by the examining division and encompasses new page 20 of the description as amended before the examining division, containing amino acid

sequence information on the "*peptides used in accordance with the claimed invention.*"

9. It was not disputed by the appellant that the application as filed did not contain any explicit amino acid sequence information. Therefore, what needs to be decided is whether the amino acid sequence information disclosed in the cross-referenced document D5 is within the content of the present application as filed.

10. In decision T 689/90 (*supra*) the board decided that features which were only disclosed in a cross-referenced document which was identified in the application as filed were *prima facie* not within the content of the application as filed. Only under particular circumstances would adding them to a claim not infringe Article 123(2) EPC, namely if the description of the invention as filed left the skilled reader in no doubt: "*(a) that protection is or may be sought for features which are only disclosed in the reference document; (b) that the features which are only disclosed in the reference document contribute to achieving the technical aim of the invention and are thus comprised in the solution of the technical problem underlying the invention which is the subject of the application; (c) that the features which are only disclosed in the reference document implicitly clearly belong to the description of the invention contained in the application (Article 78(1)(b) EPC) and thus to the content of the application as filed (Article 123(2) EPC); and (d) that such features are precisely defined and identifiable within the total technical information within the reference document.*" (*supra*, reasons 2.2). The criteria developed by the board in decision T 689/90 have been applied in several cases by the boards of appeal (see Case Law of the Boards of Appeal

of the European Patent Office, 8th edition 2016, section II.E.1.1.6). This board also adheres to these criteria when considering whether or not the amino acid sequences of the peptides disclosed in document D5 fall within the content of the application as filed.

11. The first question to be addressed is thus whether the application as filed leaves the skilled reader in no doubt that protection is or may be sought for the amino acid sequences of the peptides disclosed in document D5.

12. The cross-referenced document D5 is first mentioned in the application as filed in the section headed "*Background of the invention*" as follows: "*Patents of interest describing bFGF or agonist peptides and the formulation for their penetrations through intact skin include US patent 6,143,723* [document D5]*, Australian patent 722626, Indian patents 185613, 186437.*"

13. Page 3, last paragraph, to page 4, first paragraph, discloses that: "*According to this invention there is provided a method for combinatorial synergistic therapy (...)*" which comprises at least one peptide selected from a group consisting of bFGF amino acids 106-115 (SEQ ID NO 1), etc. Document D5 is not mentioned in this context.

14. Document D5 is again mentioned on page 5, second paragraph, of the application as filed as follows: "*The local application of bFGF peptide(s) in the formulation described in US patent 6,143,723* [document D5] *is effective in more than 80% of cases of stable generalised vitiligo (...)*"; and in the following paragraph on the same page: "*synergistic combinatorial therapy for treatment of fast spreading vitiligo cases*

comprising bFGF peptide(s) in the formulation described in the US patent 6,143,723 [document D5] *and steroid therapy.*"

15. On page 8, second paragraph, and page 9, first paragraph, the application as filed states: "*patents of interest describing bFGF or agonist peptides derived from it for use as pigmentary agents include US patent 6,143,723* [document D5]*, Australian patent 722626, Indian patents 185613, 186437*" and repeats in the following paragraph that: "*The local application of bFGF peptide(s) in the formulation described in US patent 6,143,723* [document D5] *is effective in more than 80% of cases of stable generalised vitiligo (...)*".

16. Finally, on page 12, third paragraph, the application as filed discloses that: "*The combinatorial therapy with local application of bFGF peptide(s) in the formulation described in the US patent 6,143,723* [document D5] *can be applied to almost any other therapy that are now in the market for the treatment of various types of vitiligo (...)*"; and on page 13, first paragraph, that: "*the local application of the bFGF peptide(s) in the formulation described in the US patent 6,143,723* [document D5] *was done for 3 months".*

17. The board concludes from the above that the application as filed refers to document D5 as a "*patent of interest*" disclosing bFGF or agonist peptides derived from it but not specifically bFGF peptides for use in the present invention. The peptides for use in the present invention are disclosed in the paragraph bridging pages 3 and 4 (see point 13 above). The application as filed further discloses repeatedly that these peptides are used in the formulation disclosed in

document D5 (see points 14 to 16). It is thus the understanding of the board that whenever the application as filed refers to document D5 in the context of the bFGF peptides of the invention it is for the use of the formulation disclosed in document D5, which allows for penetration of the bFGF peptides through intact skin, but not for the use of the bFGF peptides disclosed in document D5.

18. Therefore, the application as filed does not disclose to the skilled person that protection is or may be sought for the amino acid sequences of the peptides disclosed in document D5. Accordingly, criterion (a) as set out in decision T 689/90 (*supra,* reasons 2.2) is not met.

19. As regards criterion (b) set out in decision T 689/90 (*supra,* reasons 2.2), the board notes that the technical aim of the claimed invention is the synergistic treatment of specific forms of vitiligo.

20. The appellant had argued in the context of its submission under Article 83 EPC that the data provided in Tables 1 and 5 of the application demonstrated the synergistic interaction between the bFGF peptide and PUV-A in treating generalised stable vitiligo and segmental vitiligo (see grounds of appeal, paragraph 4.6).

21. However, the board notes that the application as filed fails to identify the peptide contained in the bFGF lotion tested in the examples. Thus, in Tables 1 to 5 the peptide is not identified structurally but merely referred to as "*Active Peptide*". From the disclosure in the application as filed the skilled person cannot understand the nature of the tested "*Active Peptide*".

Moreover, the skilled person can also not infer from the application as filed that the peptides disclosed in document D5 achieve the claimed combinatorial synergy. Accordingly, the skilled person cannot conclude that the peptides disclosed in document D5 "*would contribute to achieving the technical aim of the invention and are thus comprised in the solution of the technical problem underlying the invention which is the subject of the application.*" Therefore, criterion (b) as set out in decision T 689/90 (*supra,* reasons 2.2) is likewise not met.

22. Only if all four criteria (a) through (d) set out in decision T 689/90 (*supra,* reasons 2.2) were fulfilled would the amino acid sequences of the peptides disclosed in document D5 be within the content of the application as filed. Since criteria (a) and (b) are not met, the board concludes that it does need not to consider whether or not the remaining criteria, *i.e.* criteria (c) and (d), are fulfilled.

23. The board concludes from the above that new page 20 of the description, and thus the main request which comprises that page of the description, fails to meet the requirements of Article 123(2) EPC.

Auxiliary request 1

Article 123(2) EPC

24. Since the description of this request is identical to the description according to the main request, the reasoning set out above (see points 8 to 23) applies accordingly.

25. Therefore auxiliary request 1 likewise fails to meet the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Cremona B. Claes

Decision electronically authenticated