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Datasheet for the decision of 24 October 2019

Case Number: T 1413/16 - 3.3.04

Application Number: 08788347.6

Publication Number: 2190473

IPC: A61K39/35, C07K14/415, C07K14/435

Language of the proceedings: EN

Title of invention:
Peptide with reduced dimer formation

Patent Proprietor:
Circassia Limited

Opponents:
D Young & Co LLP
Strawman Limited

Headword:
Peptide with reduced dimer formation/CIRCASSIA

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 115(2)
RPBA Art. 12(2), 12(4), 15(3)

Keyword:
Main request: amendments - allowable (no)
Auxiliary requests 1 to 6: taken into account by the board (no)

Decisions cited:
T 0407/10

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 1413/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 24 October 2019

Appellant: (Opponent 1)	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Patent Proprietor)	Circassia Limited Magdalen Centre The Oxford Science Park Oxford OX4 4GA (GB)
Representative:	J A Kemp LLP 14 South Square Gray's Inn London WC1R 5JJ (GB)
Party as of right: (Opponent 2)	Strawman Limited 34 Lovedon Lane Winchester, Hampshire, SO23 7NU (GB)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 March 2016 concerning maintenance of the European Patent No. 2190473 in amended form**

Composition of the Board:

Chair	A. Chakravarty
Members:	R. Morawetz
	M. Blasi

Summary of Facts and Submissions

I. The appeal of opponent 1 (appellant) lies from the opposition division's interlocutory decision according to which European patent No. 2 190 473 as amended in the form of the main request, and the invention to which it relates, were found to meet the requirements of the EPC.

II. The patent, entitled "*Peptide with reduced dimer formation*", derives from European patent application No. 08788347.6 which was filed as international application under the PCT with the International application number PCT/GB2008/002779 ("application as filed" or "application"), published as WO 2009/022155.

III. Two oppositions were filed against the patent. The grounds for opposition were Article 100(a) EPC (lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC)) and Article 100(b) and 100(c) EPC.

IV. In the statement of grounds of appeal, the appellant *inter alia,* contested the opposition division's decision that the subject-matter of claim 1 of the main request found a basis in the application as filed.

V. In reply, the patent proprietor (respondent) maintained the main request dealt with in the decision under appeal and the sets of claims of auxiliary requests 1 to 6 filed with letter dated 19 November 2015. In reply to the objections raised, the respondent referred to the corresponding sections of the minutes of the oral proceedings before the opposition division and to the decision under appeal.

Claim 1 of the main request reads as follows:

"1. A pharmaceutical composition comprising:
i) at least a first and a second peptide, each of 9 to 25 amino acids in length, wherein the first and second peptide each comprise or consist of a different sequence selected from the sequences of SEQ ID NO: 37 (MLA01), SEQ ID NO: 38 (MLA04), SEQ ID NO: 39 (MLA05), or SEQ ID NO: 40 (MLA12); and
ii) as agent which inhibits peptide dimer formation, thioglycerol;
wherein the proportion of said peptides (i) present in solution as a dimer is 1% or less after storage of the solution for 72 hours at 25°C and 60% relative humidity."

VI. Opponent 2, a party as of right to the appeal proceedings, did not submit any arguments or requests.

VII. The board appointed oral proceedings, as requested by both the appellant and the respondent and issued a communication pursuant to Article 15(1) RPBA, in which it indicated, *inter alia*, that it considered that the application as filed provided no pointer to the combination of features of claim 1 of the main request. Further, the board noted that the respondent had not provided any substantiation for auxiliary requests 1 to 6.

VIII. In response, all parties informed the board in writing that they would not attend the oral proceedings.

IX. Oral proceedings took place as scheduled. At the end of the proceedings, the Chair announced the board's decision.

X. The appellant's arguments, submitted in writing, are summarised as follows:

Main request

Amendments (Article 123(2) EPC) - claim 1

The application as filed did not directly and unambiguously disclose to the person skilled in the art, the specific combination of features of claim 1.

None of the claims of the application as filed referred to a dimer formation of "*1% or less*". The "singling out" of the particular combination of features in claim 1 insofar as "*1% or less*" dimer formation was concerned led to a selection of features which, even if conceivably covered by the application as filed, was not specifically disclosed therein.

XI. The respondent's arguments, submitted in writing, are summarised as follows:

Main request

Amendments (Article 123(2) EPC) - claim 1

The subject-matter of claim 1 found a basis in claims 1 to 3, 8, 25 and 27 and on page 18, lines 12 to 18, page 24, lines 4 to 5 and page 10, line 17. Claim 1 corresponded to the most preferred embodiment disclosed on pages 14 and 15 of the application and illustrated in example 4, together with tables 4 to 6.

Auxiliary requests 1 to 6

No arguments were submitted.

XII. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

XIII. The respondent requested that the appeal be dismissed (amounting to a request that the patent be maintained in amended form on the basis of the main request considered allowable by the opposition division) or, alternatively, that the patent be maintained on the basis of one of the set of claims of auxiliary requests 1 to 6 as filed on 19 November 2015.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.

2. The duly summoned parties were neither present nor represented at the oral proceedings. The board continued the proceedings in their absence, in accordance with Rule 115(2) EPC. They were treated as relying on their written case in accordance with Article 15(3) RPBA.

Main request

Amendments (Article 123(2) EPC) - claim 1

3. In the decision under appeal the opposition division considered that the subject-matter of the claim found a basis in claims 1, 3, 25 and 27 as filed in combination

with the disclosure on page 24, lines 4 to 5, and page 15, lines 3 to 4, of the application as filed (see decision under appeal, point 4.3).

4. The appellant contested this part of the decision and submitted that the "singling out" of the particular combination of features in claim 1 insofar as "*1% or less*" dimer formation was concerned represented a selection of features which, even if conceivably covered by the application as filed, was not specifically disclosed in the application as filed.

5. It is undisputed that the features of claim 1 can be found separately, but not in combination with each other in the application as filed.

6. According to the established jurisprudence of the boards of appeal a combined selection of features does not, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed, in the absence of any pointer to that particular combination. The fact that features in question have been mentioned in the description as "preferred" may act as a pointer. However, the combination of a feature not originally disclosed as preferred with a plurality of further restrictions based on preferred features is not an amendment in accordance with Article 123(2) EPC (see Case Law of the Boards of Appeal, 9th edition 2019, sections II.E.1.6.1 and II.E.1.6.2 and decision T 407/10 cited therein).

7. The peptides recited in feature i) of claim 1 and thioglycerol as the agent that inhibits dimer formation (feature ii of claim 1) are disclosed in the

application as filed as being particularly preferred, see page 18, lines 14 to 18 and page 14, lines 22 to 23, respectively.

8. In the decision under appeal, the further feature of claim 1 "*wherein the proportion of said peptides ... present in solution as a dimer is 1% or less after storage of the solution for 72 hours at 25°C and 60% relative humidity*" was held to be directly and unambiguously derivable from the disclosure on page 15, lines 3 to 4 of the application as filed in combination with claim 3 as filed (see decision under appeal, point 4.3).

9. On page 15, lines 3 to 4 the application as filed discloses proportions of peptide present in solution as a dimer following a suitable period of time as follows *"By a minimal proportion of peptide present in solution as a dimer it is meant that a maximum of 5%, 4%, 3%, 2% or 1% is present in solution as a dimer."*

10. On page 15, none of the proportions of peptide present as a dimer in solution is explicitly mentioned as being preferred (see preceding point). Rather, they are presented as equivalent alternatives. Page 15 therefore provides no pointer to the selection of "*1% or less*" dimer formation from any other proportion of peptide present as a dimer in solution.

11. Claim 1 as filed discloses two alternative compositions as follows "*a composition comprising: a) i) at least one peptide of 9 to 25 amino acids in length wherein the peptide comprises a region comprising at least one T cell epitope; and ii) at least one agent which inhibits peptide dimer formation; or b) i) at least one peptide as defined in a)i) wherein the amino acid*

sequence of the region has additionally been engineered to reduce dimer formation; and optionally ii) at least one agent which inhibits dimer formation, wherein a minimal proportion of the peptide of the composition is present in solution as a dimer."

12. Dependent claim 2 as filed further defines the composition according to claim 1 as follows "*wherein the proportion of peptide as defined in a)i) that is present as a dimer in solution in the absence of the agent is at least 0.5%; and /or wherein the epitope is an MHC Class II-binding T cell epitope*" (emphasis added by the board).

13. Claim 3 as filed further defines the composition according to claim 2 as filed as follows "*wherein the proportion of peptide present as a dimer in solution is measured after the peptide has been in solution for at least 72 hours at about 25°C and about 60% relative humidity.*" However, claim 3 does not define the proportion of the peptide that is present in solution as a dimer in the presence of an agent which inhibits peptide dimer formation and hence also provides no pointer to the selection of "*1% or less*" dimer formation.

14. The claimed "*1% or less*" dimer formation is thus not explicitly disclosed as a preferred embodiment, and the application as filed (in particular, page 15, lines 3 to 4 and claims 1 to 3) does not provide a pointer to it. In fact, claim 4 as filed, which depends on all of the preceding claims and thus also on claim 3 as filed, leads in a different direction by specifying that "*less than 5% of the peptide is present in dimeric form in solution*".

15. The respondent's argument that the subject-matter of claim 1 corresponded to the "most preferred embodiment" disclosed on pages 14 and 15 of the application as filed is not found persuasive. It has already been established above that none of the minimal proportions of peptide present in solution is disclosed on page 15 as being particularly preferred (see above, point 10). Likewise, the periods of time are presented as equivalent alternatives as follows "*about 24 hours, about 48 hours, or about 72 hours*" (page 15, lines 8 to 9) and none is particularly preferred.

16. The respondent additionally referred to Example 4 and Tables 4 to 6 of the application as filed.

17. In example 4 (see pages 67 to 73), the ability of various agents to reduce or inhibit the formation of peptide dimers in compositions of peptides derived from the major cat allergen Fel d1 was studied. Table 4 lists five peptides, including the four peptides recited in claim 1. Table 5 discloses the agents added to the universal matrix, including Cysteine hydrochloride, L-Methionine hydrochloride and 1-Thioglycerol. Table 6 discloses the percentage dimer formation after 72 hours, 1 week, 2 weeks and 5 weeks but without identifying the peptides tested. The results of the example are summarised as follows "[*t*]*he data generated ... on samples ... stored for up to one week identified two agents, 1-Thioglycerol and Cysteine hydrochloride, as being effective at preventing peptide dimer formation*." (see page 72, lines 1 to 3). In the board's view, no pointer to "*1% or less*" dimer formation is recognisable from example 4 or the tables.

18. Finally, in the board's view, the selection of thioglycerol as the agent inhibiting peptide dimer

formation does not necessarily imply that "*less than 1% of the peptide is present in dimeric form in solution*". Indeed, the opposition division held that "*the low percentage of dimers (1% or less) defined in claim 1 cannot be regarded as an inherent feature of any composition comprising at least two of the peptides MLA01, MLA04, MLA05 and MLA12 and thioglycerol as, for instance, the combination of peptides used might have an effect on dimer formation*" (see decision under appeal, point 7.3).

19. The board concludes from the above that the subject-matter of claim 1 which results from the combination of the feature "*1% or less*" dimer formation, not originally disclosed as preferred, with a plurality of further restrictions based on preferred features, extends beyond the content of the application as filed.

20. Thus, the subject-matter of claim 1 does not meet the requirements of Article 123(2) EPC.

Auxiliary requests 1 to 6

Article 12(2) and 12(4) RPBA

21. Article 12(2) RPBA provides that the statement of grounds of appeal and the reply shall contain a party's complete case. In particular, it must be set out why it is requested that the decision under appeal be reversed, amended or upheld and should specify expressly all the facts, arguments and evidence relied on.

22. Article 12(4) RPBA requires the board to take into account everything presented by the parties pursuant to Article 12(1) RPBA, if and to the extent it relates to

the case under appeal and meets the requirements in Article 12(2) RPBA. It follows that claim requests failing to meet the requirements of Article 12(2) RPBA need not be taken into account by the board.

23. In the present case, the respondent has not provided any reasons in their reply to the statement of grounds of appeal why the decision under appeal should be amended or the patent be maintained on the basis of any of auxiliary requests 1 to 6.

24. Although the board drew the respondent's attention to this lack of substantiation well in advance of the oral proceedings the respondent did not provide any reasons in support of any of these claim requests which could have been considered by the board pursuant to Article 13(1) RPBA.

25. Accordingly, the board decided to not take auxiliary requests 1 to 6 into account (Article 12(4) RPBA).

Conclusion

26. The board concludes that the main request request, representing the sole request to be considered by the board, does not meet the requirements of Article 123(2) EPC. Accordingly, the patent cannot be maintained in amended form based on this request and, in the absence of another, allowable claim request, the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

S. Lichtenvort A. Chakravarty

Decision electronically authenticated