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Datasheet for the decision of 18 February 2020

Case Number: T 1850/16 - 3.3.04

Application Number: 05784064.7

Publication Number: 1797126

IPC: C07K16/28, A61K39/395, A61P37/06

Language of the proceedings: EN

Title of invention:
Compositions monovalent for CD40L binding and methods of use

Patent Proprietor:
Domantis Limited

Opponents:
Ablynx NV
Merck Patent GmbH

Headword:
An antibody which is monovalent for CD40L/DOMANTIS

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 115(2)
RPBA Art. 15(1)
RPBA 2020 Art. 15(3)

Keyword:
Main request, auxiliary requests I to VI - extension of subject-matter (yes)

Decisions cited:
T 0873/94, T 0010/97, T 0910/06, T 1041/07, T 0783/09

Catchword:

Europäisches Patentamt
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Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1850/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 18 February 2020

Appellant: (Patent Proprietor)	Domantis Limited 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Respondent I: (Opponent 01)	Ablynx NV Technologiepark 21 9052 Zwijnaarde (BE)
Representative:	Sanofi 54, rue La Boétie 75008 Paris (FR)
Respondent II: (Opponent 02)	Merck Patent GmbH Frankfurter Strasse 250 64293 Darmstadt (DE)
Representative:	Alt, Michael Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 June 2016 revoking European patent No. 1797126 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	B. Claes
Members:	R. Morawetz
	P. de Heij

Summary of Facts and Submissions

I. The appeal by the patent proprietor (appellant) lies from the opposition division's decision revoking European patent No. 1 797 126. The patent, entitled "*Compositions monovalent for CD40L binding and methods of use*", was granted for European patent application No. 05 784 064.7, which was filed as an international application under the PCT with the international application number PCT/GB2005/003562 ("application as filed" or "application"). The application was published as WO 2006/030220.

II. Two oppositions were filed to the patent under Article 100(a) EPC, on the grounds of exception to patentability (Article 53(c) EPC), lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and 100(c) EPC. Opponents 01 and 02 are respondents I and II (or "respondents") in these appeal proceedings.

III. The opposition division decided that the subject-matter of claim 1 of the main request did not comply with the requirements of Article 123(2) EPC; that the claims of auxiliary requests 1 to 5 did not comply with the requirements of Article 123(2) EPC for the same reasons as the main request; and, in addition, that claim 1 of auxiliary request 6 did not meet the requirements of Article 123(3) EPC. Auxiliary request 7 was not admitted into the opposition proceedings.

IV. With the statement of grounds of appeal, the appellant filed sets of claims of a main request and of auxiliary requests I to VI. The main request and auxiliary requests III and IV correspond to the main request and

auxiliary requests 2 and 3, respectively, filed by letter dated 10 March 2016 and dealt with in the decision under appeal. Auxiliary requests I, II, V and VI are newly filed requests.

Claim 1 of the main request reads as follows (emphases below added by the board for ease of understanding):

"1. Use of an antibody polypeptide comprising an antibody single variable domain polypeptide in the preparation of a medicament for treating or preventing a symptom of autoimmune disease, wherein said single variable domain polypeptide is monovalent for binding to CD40L (gp39) and antagonizes an activity of CD40 or CD40L or both, and **wherein said antibody polypeptide inhibits the binding of an antibody single variable domain comprising the amino acid sequence of SEQ ID NO: 26 to CD40L.**"

Claim 1 of auxiliary request I reads as follows (amendments *vis-à-vis* claim 1 of the main request indicated by underlining):

"1. Use of an antibody polypeptide <u>monovalent for binding to CD40L</u> comprising an antibody single variable domain polypeptide in the preparation of a medicament for treating or preventing a symptom of autoimmune disease, wherein said single variable domain polypeptide is monovalent for binding to CD40L (gp39) and antagonizes an activity of CD40 or CD40L or both, and **wherein said antibody polypeptide inhibits the binding of an antibody single variable domain comprising the amino acid sequence of SEQ ID NO: 26 to CD40L.**"

Claim 1 of auxiliary request II reads as follows (amendments *vis-à-vis* claim 1 of the main request indicated by underlining and strikethrough):

"1. Use of an antibody polypeptide monovalent for binding to CD40L comprising an antibody single variable domain polypeptide in the preparation of a medicament for treating or preventing a symptom of autoimmune disease, wherein said single variable domain polypeptide is monovalent for binding to CD40L (gp39) and antagonizes an activity of CD40 or CD40L or both, and **wherein said antibody polypeptide inhibits the binding of an antibody single variable domain consisting of ~~comprising~~ the amino acid sequence of SEQ ID NO: 26 to CD40L.**"

Claim 1 of auxiliary request III reads as follows (amendments *vis-à-vis* claim 1 of the main request indicated by underlining and strikethrough):

"1. Use of an antibody polypeptide comprising an antibody single variable domain polypeptide in the preparation of a medicament for treating or preventing a symptom of autoimmune disease, wherein said single variable domain polypeptide is monovalent for binding to CD40L (gp39) and antagonizes an activity of CD40 or CD40L or both, ~~and~~ **wherein said antibody polypeptide inhibits the binding of an antibody single variable domain comprising the amino acid sequence of SEQ ID NO: 26 to CD40L**, and wherein said antibody polypeptide comprises an antibody Fc region comprising one or both of C_H2 and C_H3 domains."

Claim 1 of auxiliary request IV reads as follows (amendments *vis-à-vis* claim 1 of the main request indicated by underlining and strikethrough):

"1. Use of an antibody polypeptide comprising an antibody single variable domain polypeptide in the preparation of a medicament for treating or preventing a symptom of autoimmune disease, wherein said single variable domain polypeptide is monovalent for binding to CD40L (gp39) and antagonizes an activity of CD40 or CD40L or both, ~~and~~ **wherein said antibody polypeptide inhibits the binding of an antibody single variable domain comprising the amino acid sequence of SEQ ID NO: 26 to CD40L,** and wherein the antibody polypeptide has a dissociation constant (K_d) of 10 nM to 50 pM."

Claim 1 of auxiliary requests V and VI read as follows (amendments vis-à-vis claim 1 of the main request indicated by underlining and strikethrough):

"1. Use of an antibody polypeptide monovalent for binding to CD40L comprising an antibody single variable domain polypeptide in the preparation of a medicament for treating or preventing a symptom of autoimmune disease, wherein said single variable domain polypeptide is monovalent for binding to CD40L (gp39) and antagonizes an activity of CD40 or CD40L or both, **~~and~~ wherein said antibody polypeptide inhibits the binding of an antibody single variable domain consisting of ~~comprising~~ the amino acid sequence of SEQ ID NO: 26 to CD40L,** wherein said antibody polypeptide comprises an antibody Fc region comprising one or both of C_H2 and C_H3 domains and wherein the antibody polypeptide has a dissociation constant (K_d) of 10 nM to 50 pM."

V. Both respondents submitted replies to the statement of grounds of appeal in which they maintained *inter alia*

objections as regards added subject-matter in claim 1 of the main request.

VI. The board scheduled oral proceedings and issued a communication pursuant to Article 15(1) RPBA 2007, in which it indicated that it was of the preliminary opinion in relation to the main request "*that the passages relied on by the appellant as providing a basis for the subject-matter of claim 1 do not provide a basis for the combination of the claimed features*" (see point 10). The board furthermore indicated that it would "*appear that the problem noted in point 10 above in relation to claim 1 of the main request applies also to the subject-matter of claim 1 of auxiliary requests I to VI*" (see point 11).

VII. Shortly before the oral proceedings, the appellant and the respondents informed the board in writing that they would not attend.

VIII. The oral proceedings took place as scheduled. At the end of them, the Chair announced the board's decision.

IX. The appellant's arguments are summarised as follows:

Main request

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

"*Literal basis for the wording of claim 1 can be found in the Application as filed at page 14, lines 1 to 5*". Further bases for antibody polypeptides which are monovalent for binding to CD40L were page 8, lines 28 to 29; page 36, lines 1 to 10; and page 88, lines 7 to 14.

There was also a basis for the combination with the other features, as explained in the letter dated 2 April 2015.

Further relevant disclosure regarding the utility of the antibody polypeptides of the invention in the treatment of autoimmune diseases could be found in the passage in the application from page 19, line 18 to page 20, line 4.

Finally, as regards the inhibition of binding to CD40L of the reference antibody single variable domain polypeptide of SEQ ID NO:26 (i.e. "DOM 8-24"; see page 155, line 29 to page 156, line 10 and Example 8), reference was made to page 28, lines 12 to 14.

The absence of an individualised disclosure of a claimed combination did not inevitably lead to addition of subject-matter (see decision T 783/09, Reasons, points 5.5 to 5.7).

In the present case, the claimed combination of features did not involve selection from lists as such but merely arose from "*reading related but separate disclosures together*".

The disclosure of the application had to be read as a whole and the disclosures in each individual paragraph of the application had not to be read in artificial isolation.

Decisions T 873/94, T 10/97, T 910/06 and T 1041/07 "*may also be of assistance to the Board when considering Article 123(2) EPC*".

Auxiliary requests I to VI

Admission

All auxiliary requests should be admitted into the appeal proceedings because, during the oral proceedings before the opposition division, the appellant had been deprived of an adequate opportunity to present claim requests to overcome objections raised by the opposition division for the first time during those proceedings.

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

The further features introduced *vis-à-vis* claim 1 of the main request had a basis in the application as filed.

X. The respondents' arguments are summarised as follows:

Main request

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

The application failed to disclose a literal basis for the wording of claim 1 and a basis for the specific combination of features of claim 1. The claim was an "*amalgamation of features scattered around in the description, taken out of context and combined in a new and inventive manner*". The aspects of combining features and the context in which these features were disclosed were disregarded by the appellant.

Auxiliary requests I to VI

Admission

Auxiliary requests I, II, V and VI comprised new features which were derived from the description and had not been examined in the opposition proceedings. The appellant could and should have already presented auxiliary requests I, II, V and VI during the opposition proceedings.

Auxiliary requests III and IV corresponded to auxiliary requests 2 and 3 filed late in the opposition proceedings. These requests introduced new features from the description and should not be admitted into the appeal proceedings.

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

The objections set out for claim 1 of the main request applied to the subject-matter of claim 1 of these requests too. The introduction of additional features did not remedy the unallowable combination of features.

XI. The appellant and the respondents made their requests in writing.

The appellant's requests, as far as relevant to the present decision, were:
-that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims of the main request, or, alternatively, that the patent be maintained on the basis of one of the sets of claims of auxiliary requests I to VI;
-that these auxiliary requests be admitted into the

proceedings and that the case be remitted to the opposition division for consideration of novelty, inventive step and sufficiency of disclosure if the board was of the opinion that the above requests could not be granted.

Respondent I's requests, as far as relevant to the present decision, were that the appeal be dismissed and that auxiliary requests I to VI not be admitted into the appeal proceedings.

Respondent II's requests, as far as relevant to the present decision, were that the appeal be dismissed and that auxiliary requests I to VI be dismissed as late-filed.

Reasons for the Decision

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

2. An amended version of the Rules of Procedure of the Boards of Appeal (RPBA 2020) came into force on 1 January 2020. The previous version of the Rules of Procedure of the Boards of Appeal is referred to as RPBA 2007. The transitional provisions are set out in Article 25 RPBA 2020.

3. The duly summoned parties were, as announced in advance, 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 cases, in accordance with Article 15(3) RPBA 2020.

Main request

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

4. The subject-matter of the claim relates to a second medical use of an antibody polypeptide and comprises the combination of the following features:

(A) an antibody polypeptide comprising an antibody single variable domain polypeptide;

(B) its use in the preparation of a medicament for treating or preventing a symptom of autoimmune disease;

(C) the single variable domain polypeptide is monovalent for binding to CD40L (gp39) and antagonises an activity of CD40 or CD40L or both; and

(D) the antibody polypeptide inhibits the binding to CD40L of an antibody single variable domain comprising the amino acid sequence of SEQ ID NO: 26.

5. On appeal, respondent I maintained that the subject-matter of the claim extended beyond the content of the application as filed because the claimed combination of features was not disclosed in the application as filed.

6. The appellant submitted that a basis for the individual features recited in claim 1 could be found in the application as filed and that the claimed combination of features "*merely arose from reading related but separate disclosures together*" (see section IX).

7. It is, however, established case law of the Boards of Appeal that the content of an application must not be considered to be a reservoir from which features

pertaining to separate sections of the application can be combined in order to artificially create a particular combination. In the absence of any pointer to that particular combination, this 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 (see e.g. decision T 686/99, Reasons, point 4.3.3).

8. Thus, when assessing whether the subject-matter of claim 1 is disclosed in the application, the relevant question is whether a skilled person reading the application as a whole would contemplate combining the individual features because of a clear prompt or indication in the application providing a motivation to do so. It has been held, for example, that the fact that features in question have been mentioned in the description as "preferred" may act as a pointer (see Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, section II.E.1.6.1).

9. The passages relied on by the appellant on page 14, lines 1 to 5; page 19, line 18 to page 20, line 4; page 36, lines 1 to 10; and page 88, lines 7 to 14 relate to antibody polypeptides that monovalently bind to CD40L and which comprise a single immunoglobulin variable domain that specifically binds to and antagonises the activity of CD40L for the treatment of autoimmune diseases or disorders. These passages thus relate to features (A), (B) and (C) of claim 1 but are silent about feature (D). By referring to the letter dated 2 April 2015 (see appellant's letter dated 5 July 2017, page 6, lines 41 and 42) the appellant appears to rely in addition on the passage on page 8, line 27 to page 9, line 20 for the combination of all the features of the claim. However, the same conclusion applies to

this passage. Besides, Article 12(2) RPBA 2007 requires a party to present its complete case on appeal, i.e. not make general reference to submissions at first instance.

10. The passage on page 28, lines 12 to 14, of the application relied on by the appellant states "[t]*he invention also includes an antibody polypeptide that antagonizes or inhibits the binding of DOM8-24 to CD40L, or an antibody polypeptide that binds to the same epitope of CD40L bound by DOM8-24*". From page 155, line 29 to page 156, line 10 and Example 8 it can be derived that DOM8-24 is an antibody single variable domain polypeptide having the amino acid sequence depicted in SEQ ID NO: 26.

11. The passage on page 28 thus discloses to the skilled person that the invention also includes an antibody polypeptide that inhibits the binding to CD40L of an antibody single variable domain polypeptide having the amino acid sequence depicted in SEQ ID NO: 26, i.e. the passage relates to an antibody polypeptide as described in feature (D).

12. However, the passage on page 28 of the application does not disclose that the antibody polypeptide that inhibits the binding of DOM8-24 to CD40L is an embodiment of an antibody polypeptide that monovalently binds to CD40L and is silent about any use of the described antibody polypeptide, let alone that such an antibody polypeptide would be preferred in the context of the claimed medical use characterised by features (A), (B) and (C).

13. Thus, none of the passages relied on by the appellant hints that an antibody polypeptide that inhibits the

binding to CD40L of an antibody single variable domain comprising the amino acid sequence of SEQ ID NO: 26 would be suitable, let alone preferred, in the context of the claimed use. In other words, none of the passages motivates the skilled person to combine features (A), (B) and (C) with feature (D).

14. Moreover, the board notes that in the sections immediately preceding and following the passage on page 28, lines 12 to 14, the application discusses various dual-specific ligands but is silent on any medical use of any antibody polypeptide.

15. In the board's judgement therefore, the skilled person would not clearly and unambiguously derive from the passage on page 28, lines 12 to 14, and its context that feature (D) disclosed in this section could be combined with the features (A), (B) and (C) disclosed in separate sections of the application. The appellant's argument that the claimed combination of features results from reading separate but related disclosures together therefore fails.

16. As regards the appellant's reliance on the case law, the board considers that the factual basis of decisions T 10/97, T 910/06 and T 783/09 is not comparable to the factual basis of the present case. In decision T 10/97 the amendments related to the deletion of some members from a list of individualised, equally useful compounds (see Reasons, point 2). Likewise, in decision T 910/06, the amendments made to the claim concerned deletions of possible alternatives, thus restricting the group of permissible alternatives for certain features of the claim (see Reasons, points 4.5 and 4.6). In decision T 783/09, the board held that, from a list of 44 qualitatively equal elements, 41 elements could be

deleted (see Reasons, points 5.7 to 6.2).

17. In the present case, the claimed combination does not result from the deletion of possible alternatives from a list of individualised, equally useful elements but from the combination of features cited in separate sections of the application in the absence of any incentive or pointer to combine exactly these features.

18. Further, in decision T 873/94 (OJ EPO 1997, 456, Reasons, point 2.2) the board held that where the amendment involved the addition of a limiting feature to a claim, applying the "novelty test" was not appropriate for determining whether or not the amendment complied with the requirements of Article 123(2) EPC. By contrast, the board assessed whether the claimed combination of features was properly supported by the application as filed. As the present decision is in line with this approach, the board fails to see how it supports the appellant's case.

19. Finally, the board observes that its approach (see points 8 to 13 above) is also in line with the approach taken in decision T 1041/07, where the board held that "*when assessing whether a particular combination of features is disclosed in a document, the relevant question is whether the skilled person seriously contemplates combining those features cited in isolation in that document, i.e. if those features are directly and unambiguously disclosed in combination, e.g. by way of a direct pointer linking the two features together*" (see Reasons, point 3.5).

20. The board concludes from the above that the subject-matter of claim 1, which results from the combination

of the feature "*wherein said antibody polypeptide inhibits the binding of an antibody single variable domain comprising the amino acid sequence of SEQ ID NO: 26 to CD40L*", not originally disclosed as a preferred embodiment of an antibody polypeptide in the context of the claimed use, with the features (A), (B) and (C), based on different embodiments of the antibody polypeptide, provides the skilled person with new technical information which they cannot directly and unambiguously derive from the application as filed.

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

Auxiliary requests I to VI

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

22. Whereas the respondents challenged the admission of auxiliary requests I to VI into the appeal proceedings, the board admitted them. There is no need to give reasons for their admission, since they could not be allowed (see below).

23. In claim 1 of auxiliary request I feature (A) has been amended; in claim 1 of auxiliary request II features (A) and (D) have been amended; and in claim 1 of auxiliary requests III and IV further features have been added. Finally, in claim 1 of auxiliary requests V and VI, the amendments made in claim 1 of auxiliary requests II, III and IV have been combined (see section IV). These amendments, in particular the replacement of the term "*comprising*" with the term "*consisting*" in feature (D), do not remedy the lack of a basis in the application as filed for the combination of feature (D) - be it in the wording as in claim 1 of the main

request or with "*consisting*" in place of "*comprising*" - with the remaining features of claim 1.

24. Therefore, the subject-matter of claim 1 of these requests fails to meet the requirements of Article 123(2) EPC for the same reasons as set out above for the subject-matter of claim 1 of the main request.

Request for remittal

25. All claim requests on file are not allowable because they fail to meet the requirements of Article 123(2) EPC. The appellant's request for remittal is thus devoid of purpose.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay B. Claes

Decision electronically authenticated