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Datasheet for the decision of 10 October 2012

Case Number: T 0230/08 - 3.3.04

Application Number: 00909970.6

Publication Number: 1146892

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Language of the proceedings: EN

Title of invention:
BAFF, inhibitors thereof and their use in the modulation of the B-cell response

Patentees:
Biogen, Inc.
Apoxis SA

Opponents:
01 - Human Genome Sciences, Inc.
02 - Merck Serono SA

Headword:
BAFF-inhibitors/BIOGEN

Relevant legal provisions:
EPC Art. 54

Keyword:
"Main request - novelty (no)"

Decisions cited:
T 0019/90

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0230/08 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 10 October 2012

Appellant: (Opponent 02)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 27 November 2007 concerning maintenance of European patent No. 1146892 in amended form.

Composition of the Board:

Chair: G. Alt
Members: B. Claes
D. S. Rogers

Summary of Facts and Submissions

I. The appeal was lodged by opponent 02 (appellant) against the interlocutory decision of the opposition division according to which European patent No. 1 146 892 (entitled "*BAFF, inhibitors thereof and their use in the modulation of the B-cell response*" which was granted for European patent application 00909970.6 and was published as WO 00/43032) could be maintained in amended form.

II. Opponent 01 (Human Genome Sciences, Inc.) also filed an appeal against the decision. With a letter dated 19 November 2008 opponent 01 withdrew its opposition and is therefore no longer a party to the appeal proceedings.

III. The respondents (patentees) filed *inter alia* six auxiliary requests with a letter dated 7 August 2012.

IV. With a letter dated 9 August 2012 the firm Eli Lilly and Company filed third party observations pursuant to Article 115 EPC including documentary evidence. The observations related to the issue of sufficiency of disclosure of the invention in the patent in suit.

V. With a letter dated 14 September 2012, the appellant commented on the third party observations and the respondents' auxiliary requests. With a letter dated the same day the respondents requested that the third party observations be not admitted into the proceedings and commented on them.

VI. The appellant filed further submissions with a letter dated 26 September 2012.

VII. Oral proceedings before the board took place on 9 and 10 October 2012. During the oral proceedings, the respondents filed a new main request. This request replaced all previous requests on file. The sole claim of this request read:

"1. Use of an antibody specific for soluble BAFF for the preparation of a pharmaceutical composition for the treatment of an autoimmune disease."

VIII. The appellant (opponent 02) requested that the decision under appeal be set aside and that the patent be revoked.

The respondents (patentees) requested that the decision under appeal be set aside and the patent be maintained upon the basis of the main request submitted at the oral proceedings before the board; and that the third party observations of the firm Eli Lilly dated 9 August 2012 be not admitted into the proceedings.

IX. The appellant's arguments, as far as they are relevant for the present decision, can be summarised as follows:

Main request - Novelty (Article 54 EPC)

- The opposition division had correctly found that there was *verbatim* disclosure of the subject-matter of claim 1 in document (C1), i.e. the international patent application WO 98/18921. Any argument that a prior art disclosure lacked

sufficiency of disclosure had to be based on serious doubts, substantiated by verifiable facts. The decision under appeal merely referred to numerous contradictions in the document. The skilled person was however put in a position by document (C1) to work the claimed invention when judged at the effective date of the patent in suit and the respondents had not brought forward any technical argument why the claimed subject-matter should not be enabled by the disclosure in document (C1). Document (C1) was therefore novelty destroying for the subject-matter of claim 1.

– The disclosure in a prior art document should be assessed on its own merits. The disclosure of the patent in suit was irrelevant for this assessment.

– For the generation of the antibodies, as disclosed in document (C1), the receptor for BAFF was not necessary. Document (C1) disclosed on pages 54 and 55 various assays for testing the isolated antibodies for their BAFF-antagonistic function. Furthermore, any such assays would be based on T cell assays which were part of the general knowledge of the skilled person.

X. The respondents' arguments, as far as they are relevant for the present decision, can be summarised as follows:

Main request - Novelty (Article 54 EPC)

– Document (C1) was not focussed on identifying new medical uses for BAFF and its antagonists. It contained a very broad and generic disclosure with

respect to the functions of BAFF and its antagonists and did not specifically disclose the claimed subject-matter. Deriving all the features of the subject-matter of claim 1 from document (C1) required mosaicing of various parts of the description therein and this did not support a clear and unambiguous disclosure.

– In view of the statement on page 2 of document (C1) that "[s]*oluble forms of the TNF ligand superfamily have only been identified so far for TNF, LT ß, and Fas ligand ...*" the disclosure could not be taken to disclose the concept of "soluble BAFF" as disclosed in paragraphs [0068] and [0069] of the patent in suit.

– It was the patent in suit which disclosed experimental evidence relating to the activity of BAFF and therefore proof of concept data supporting the medical use of claim 1. A technical elucidation of the functions of BAFF was not contained in document (C1) nor did it contain a teaching how to select the antibodies of claim 1. Therefore document (C1) did not disclose the claimed subject-matter in an enabling manner. On the other hand the patent in suit was entitled to claim the second medical use for BAFF as subject-matter of claim 1.

– Accordingly, document (C1) could not be held detrimental to the novelty of the subject-matter of claim 1.

Reasons for the Decision

1. The appeal is admissible.

Main request - Novelty (Article 54 EPC)

2. In the decision under appeal the opposition division considered document (C1), i.e. international patent application WO 98/18921, not to be detrimental to the novelty of the claimed subject-matter under Article 54(1),(2) EPC. It held that "[a]*lthough Cl mentions a method of treating an individual in need (...) of decreased (e.g. autoimmune diseases) level of Neutrokine alpha activity, using BAFF or anti-BAFF antibodies, it contains numerous contradictions in the following passages: p56-57, p 49 lines 16, 25-28, p11 lines 3-7, p 57 lines 4-5, p 50 line 8 and p 12 lines 8-11. These contradictions do not enable the skilled person to conclude that it is indeed an antibody to BAFF which should be used to treat autoimmune diseases (...). Cl does not present an enabling disclosure which anticipates the subject matter of the main request*."

3. It has not been in dispute that Neutrokine α, the member of the TNF ligand superfamily as disclosed in document (C1), is identical to BAFF, the pivotal compound of the patent in suit.

3.1 Document (C1) discloses that Neutrokine α is expressed *inter alia* in activated T cells (see page 12, lines 12 to 15).

3.2 On page 13, in lines 8 to 13 the document discloses "*a method for treating an individual in need of a*

decreased level of Neutrokine α activity in the body comprising, administering to such an individual a composition comprising a therapeutically effective amount of an Neutrokine α antagonist. Preferred antagonists for use in the present invention are Neutrokine α-specific antibodies.", thereby emphasising as antagonists for use in the invention Neutrokine α-specific antibodies. Definitions of Neutrokine α antagonist are given on page 54, line 5 to 7, page 55, lines 16 to 18 and page 57, lines 24 to 25 of document (C1), i.e. such compounds which decrease or eliminate the natural biological functions of Neutrokine α, including antibodies.

3.3 On page 44, in lines 5 to 10, document (C1) discloses that the invention is useful for the treatment of *inter alia* autoimmune diseases and on page 56, lines 15 to 20, that in particular, the *"antagonists may be employed for instance to inhibit Neutrokine α (...) in certain auto-immune (...) diseases"* whereby "[e]*xamples of auto-immune diseases include multiple sclerosis, and insulin-dependent diabetes*". Document (C1) discloses furthermore "*an isolated antibody that binds specifically to an* [sic] *polypeptide having an amino acid sequence*" (page 10, lines 25 to 27) "*of the predicted extracellular domain of the Neutrokine α polypeptide having the amino acid sequence at positions 73 to 285 in SEQ ID NO:2*" (aspect (b) on page 9, line 21 to 28) and defines such a polypeptide as a soluble form of Neutrokine α on page 8, lines 8 to 13 ("... *soluble forms of Neutrokine α include all or a portion of the extracellular domain cleaved from the transmembrane domain* ..."). Accordingly, such antibodies correspond to an antibody specifically

binding to "soluble BAFF" as defined in the patent in suit, e.g. see paragraphs [0040] and [0067], and in particular as disclosed in the latter paragraph which defines the extracellular domain of BAFF to have a length of 218 amino acids, thereby starting at position 67 (= 285-218) of mature membrane-bound BAFF.

3.4 In addition, document (C1) discloses antibodies against various epitope-bearing peptides and polypeptides of BAFF (see on page 40, lines 26 to 30) including such peptides and polypeptides based on the extracellular domain, which would hence result in antibodies as defined in claim 1 (see page 40, lines 3 to 18).

3.5 The board is therefore satisfied that all the features of the subject-matter of claim 1 are disclosed in document (C1).

4. The respondents have not disputed the above finding, but have argued in a first line of argument that the subject-matter of claim 1 can only be derived from the disclosure in document (C1) when mosaicing passages of various parts of the description of document (C1). The need for such mosaicing should result in a finding that the claimed subject-matter was not disclosed in a clear and unambiguous manner.

5. The board does not agree with this point of view. The board is satisfied that there is a clear and unambiguous disclosure of the subject-matter of claim 1 in document (C1). The board's conclusion is based, in particular, on the disclosure on page 56, lines 15 to 20 (see above, point 4) relating to the use of BAFF antagonists to inhibit Neutrokine α in auto-immune

diseases and the specific disclosure of antibodies against soluble form of Neutrokine α, including all or a portion of the extracellular domain cleaved from the transmembrane domain.

6. In a second line of argument, the respondents have argued that the skilled person reading document (C1) was taught that soluble forms of the TNF ligand superfamily had up till then only been identified for TNF, LT ß, and Fas ligand. The disclosure of document (C1) could therefore not be taken to disclose the concept of "soluble BAFF" as disclosed in paragraphs [0068] and [0069] of the patent in suit.

7. The board considers, however, that it is of no relevance in this context whether or not document (C1) discloses "soluble" BAFF in the sense of "naturally occurring" soluble BAFF, which, as suggested by the respondents was only disclosed in the patent in suit. Given the definition of the antibody in the claim it suffices that document (C1) discloses, in the context of the medical use as claimed, antagonistic antibodies which are specific for "soluble BAFF" as such. These antibodies are disclosed in document (C1) (see point 3.3, above). Accordingly this argument must fail.

8. In a third line of argument the respondents submitted that it was only the patent in suit which disclosed experimental evidence relating to the activity of BAFF and therefore provided "proof of concept data" supporting the claimed medical use. The specific medical application of the subject-matter of claim 1 was therefore not enabled by the disclosure in document (C1) and, hence, document (C1) could not be held

detrimental to the novelty of the subject-matter of claim 1.

9. The board agrees with the respondents that for a document to be novelty destroying, this document must contain a disclosure of the claimed invention which is sufficient within the meaning of Article 83 EPC. It is established case law of the Boards of Appeal in respect of Article 83 EPC that an objection for lack of sufficiency of disclosure must be supported by the formulation of serious doubts, substantiated by verifiable facts (see decision T 19/90, OJ EPO 1990, 476). The board notes however that, neither during the written proceedings nor during the oral proceedings before the board, have such doubts been formulated by the respondents for carrying out the invention in relation to the antibodies specific for soluble BAFF in the treatment of autoimmune diseases. Based on the arguments as submitted by the respondents therefore, the board concludes that the document sufficiently discloses the claimed invention.

10. In a last line of argument, the respondents have argued that the disclosure in document (C1) did not enable the selection of the antibodies as recited in claim 1, i.e. the document did not technically elucidate the functions of BAFF, and did not disclose the BAFF-receptor and a method for the selection of the antibodies of claim 1, i.e. which are useful in the treatment of autoimmune diseases.

11. In this respect the appellant has argued that for the generation and selection of the antibodies recited in claim 1 the knowledge of the related receptor is not

necessary and the board can concur with this finding. In fact document (C1) discloses to the skilled person in the paragraphs on page 54, line 1 to page 55, line 15, a variety of designs of assays for identifying, *inter alia*, a receptor protein or other ligand binding protein which binds specifically to BAFF as well as assays for *inter alia* functional antagonists of BAFF. The board therefore considers that the skilled person was taught by the disclosure in document (C1) how to identify antibodies specific for (soluble) BAFF that additionally also interfere with the function or activity of BAFF, and can hence be applied in a treatment of, *inter alia*, autoimmune diseases.

12. In view of the above considerations, the board concludes that document (C1) discloses the subject-matter of claim 1 in an enabling manner and is therefore prejudicial to the novelty of claim 1.

Procedural issue

13. In view of the finding in point 12 above, and in view of the fact that there is only a main request on file, the board considers it not necessary to deal in this written decision with the request of the respondents on the admissibility of the Third Party observations of the firm Eli Lilly dated 9 August 2012 (see Sections IV and VIII, above).

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

P. Cremona G. Alt