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# Datasheet for the decision of 10 March 2022

**Case Number:** T 1589/19 - 3.3.04

**Application Number:** 15168899.1

**Publication Number:** 2990420

**IPC:** C07K16/28, A61P19/02, A61P31/04, C07K14/715

**Language of the proceedings:** EN

**Title of invention:**
Use of interleukin-4 receptor antibodies and compositions thereof

**Patent Proprietor:**
Immunex Corporation

**Opponents:**
Regeneron Pharmaceuticals, Inc.
Sanofi

**Headword:**
Competing antibodies/IMMUNEX

**Relevant legal provisions:**
EPC Art. 76(1), 84
RPBA 2020 Art. 13(2), 12(1)(a)

**Keyword:**
Divisional application - subject-matter extends beyond content of earlier application - main request and auxiliary request 1 (yes)
Clarity - auxiliary requests 2 and 3 (no)
Basis of proceedings - decision under appeal

**Decisions cited:**
G 0001/06, G 0003/14

**Catchword:**
-

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**Case Number: T 1589/19 - 3.3.04**

# D E C I S I O N
# of Technical Board of Appeal 3.3.04
# of 10 March 2022

| | |
|---|---|
| **Appellant:**<br>(Patent Proprietor) | Immunex Corporation<br>One Amgen Center Drive<br>Thousand Oaks, CA 91320-1799 (US) |
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| **Representative:** | Carpmaels & Ransford LLP<br>One Southampton Row<br>London WC1B 5HA (GB) |
| **Respondent II:**<br>(Opponent 2) | Sanofi<br>54 Rue La Boétie<br>75008 Paris (FR) |
| **Representative:** | Zwicker, Jörk<br>ZSP Patentanwälte PartG mbB<br>Hansastraße 32<br>80686 München (DE) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 22 March 2019 revoking European patent No. 2990420 pursuant to Article 101(3)(b) EPC** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | B. Claes |
| **Members:** | D. Luis Alves |
| | M. Blasi |

## Summary of Facts and Submissions

I. The patent proprietor (appellant) filed an appeal against the decision of the opposition division to revoke European patent No. 2 990 420, entitled "*Use of interleukin-4 receptor antibodies and compositions thereof*". The patent was granted on European patent application No. 15 168 899.1, a divisional application of European patent application No. 10 185 626.8, in turn a divisional application of European patent application No. 01 952 133.5. The latter had been filed as an international application published as WO 01/92340 ("earlier application as filed").

II. Two oppositions had been filed against the granted patent. The opposition proceedings were based on the grounds under Article 100(a) EPC, lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), as well as the grounds under Article 100(b) and (c) EPC.

III. The decision under appeal dealt with sets of claims of a main request and of auxiliary requests 1 to 3, all filed with the letter dated 6 March 2018. As concerns the main request, the opposition division held that the claims were clear (Article 84 EPC) and did not relate to subject-matter extending beyond the content of the application as filed (Article 123(2) EPC) and of the earlier application as filed (Article 76(1) EPC). However, the invention defined in the claims was not sufficiently disclosed (Article 83 EPC). The conclusions relating to Article 83 EPC applied equally to the sets of claims of auxiliary requests 1 to 3.

IV. With the statement setting out the grounds of appeal, the appellant filed four documents in relation to issues that the board ultimately did not decide on in this appeal. Accordingly these documents are not addressed further in this decision. The appellant also filed arguments to the effect that the invention defined in the claims of each of the requests considered by the opposition division was sufficiently disclosed.

V. Both opponents submitted replies to the appeal, including arguments *inter alia* to the effect that the claims were not clear (Article 84 EPC) and related to subject-matter extending beyond the content of the earlier application as filed (Article 76(1) EPC). Opponent 1 (respondent I) filed three further documents and opponent 2 (respondent II) filed two further documents.

VI. The board summoned the parties to oral proceedings in line with the parties' requests.

VII. Respondents I and II each made a further written submission on the merits of the case.

VIII. In a subsequent communication under Article 15(1) RPBA 2020, the board informed the parties of its preliminary opinion on various matters concerning the appeal, *inter alia* that claim 1 of the main request and auxiliary request 1 related to subject-matter extending beyond the content of the earlier application as filed and claim 1 of auxiliary requests 2 and 3 lacked clarity.

IX. At the end of the oral proceedings the chair announced the board's decision.

X. The sets of claims of the main request and auxiliary requests 1 to 3 are identical to those considered by the opposition division. Claim 1 of each request reads as follows.

Claim 1 of the main request reads:

"1. A fully human monoclonal antibody capable of inhibiting an IL-4 induced biological activity and capable of inhibiting an IL-13-induced biological activity that competes with a fully human reference IgM antibody for binding to a cell that expresses human IL-4 receptor (IL-4R), wherein:
a) the light chain of the reference IgM antibody is a kappa light chain and the variable region sequence of the light chain is the sequence of SEQ ID NO:6 and the variable region sequence of the heavy chain of the reference IgM antibody is the sequence of SEQ ID NO:8; or
b) the light chain of the reference IgM antibody is a kappa light chain and the variable region sequence of the light chain is the sequence of SEQ ID NO:26 and the variable region sequence of the heavy chain of the reference IgM antibody is the sequence of SEQ ID NO:24."

Claim 1 of auxiliary request 1 reads (differences relative to claim 1 of the main request highlighted by the board):

"1. A fully human monoclonal antibody capable of inhibiting an IL-4 induced biological activity and capable of inhibiting an IL-13-induced biological activity that competes with a fully human ~~reference~~ IgM antibody for binding to a cell that expresses human

IL-4 receptor (IL-4R) for use in a method of treating dermatitis, atopic dermatitis, contact dermatitis, or asthma, wherein:
a) the light chain of the ~~reference~~ IgM antibody is a kappa light chain and the variable region sequence of the light chain is the sequence of SEQ ID NO:6 and the variable region sequence of the heavy chain of the ~~reference~~ IgM antibody is the sequence of SEQ ID NO:8; or
b) the light chain of the ~~reference~~ IgM antibody is a kappa light chain and the variable region sequence of the light chain is the sequence of SEQ ID NO:26 and the variable region sequence of the heavy chain of the ~~reference~~ IgM antibody is the sequence of SEQ ID NO:24."

Claim 1 of auxiliary request 2 and claim 1 of auxiliary request 3 read as claim 1 of the main request and claim 1 of auxiliary request 1, respectively, except that they comprise the additional wording at the end of alternative a)

"[...] and wherein the reference IgM antibody is generated in transgenic mouse strain ((CMD)++; (JKD)++; (HCo7)11952+/++; (KCo5)9272+/++)."

and they no longer include alternative b).
Additionally, in the case of auxiliary request 3, the term "reference" is not present in this additional wording.

XI. The following documents are referred to in this decision:

D116: Declaration Sir Evans (13 December 2018)

D117: Declaration Prof. Oettinger (13 December 2018)

D131: US 5,770,429

D132: Declaration Prof. DeFranco (10 December 2018)

D154: Declaration Dr. King (6 February 2019)

XII. The appellant's arguments relevant to this decision may be summarised as follows:

*Main request and auxiliary request 1 - claim 1*

*Extension beyond the content of the earlier application as filed (Article 76(1) EPC)*

*Admittance of submissions by the appellant at the oral proceedings (Article 13(2) RPBA 2020)*

The submissions at the oral proceedings were not new to the respondents since they had been presented throughout the opposition proceedings, as reflected in the decision under appeal.

*The definition of the reference antibody*

The claim recited the features IgM, kappa light chain and SEQ ID numbers 6 and 8, or 26 and 24, for the variable light and heavy chains, and thus defined the reference antibody with the same level of characterising detail as provided in the earlier application.

Antibody 6-2 was characterised in the earlier application as filed by the sequence of its variable regions, i.e. SEQ ID NOs: 6 and 8. It was not

characterised by its whole sequence (see page 24, lines 6 to 9, 21 to 23 and 35 to 39). The same applied to antibody 1B7 (see page 28, line 29 onwards and page 29, line 8).

The kappa light chain was disclosed in figure 4 in combination with page 2, last two lines.

Article 76(1) EPC did not require any additional characterisation which was not present in the earlier application as filed to be provided in the claim.

As stated in the Guidelines for Examination at the EPO, G-II, 5.6.1.1., a claim defining an antibody structurally by the three CDRs of its light and heavy chains was clear.

The wording "particular antibody" and "examples", used in the same sentence as antibody 2-6, on page 24, lines 21 and 16, did not mean a "specific" antibody. Likewise the reference to a clone, in example 6, did not define a specific antibody either since the clone had not been characterised in the earlier application in any further detail.

Mention of derivatives, on page 25 and page 30, referred to alternative antibodies and was not to be confused with the reference antibody in the claim.

*Auxiliary requests 2 and 3 - claim 1*

*Clarity (Article 84 EPC)*

The expression "*transgenic mouse strain ((CMD)++; (JKD)++; (HCo7)11952+/++; (KCo5)9272+/++)*" used

standard terminology, as explained in document D154 (see pages 4 to 6). Thus, the claim was clear.

As regards the meaning and sequence of the transgenes HCo7 and KCo5, reference was made to the patent in paragraphs [0246] and [0247] and the reference therein to document D131 (document D131 corresponded to the patent document cited in the patent in paragraph [0246], penultimate line). Document D131 disclosed the terms HCo7 and and KCo5 and referred to a library of genomic DNA (see examples 21, 37 and 38). Reference was made in this context to document D154, which furthermore included a list of publications showing that the deletion of genes, represented by "CMD" and "JKD", was known in the state of the art.

In sum, the expression would have been understood by the skilled person.

XIII. The respondents' arguments relevant to this decision may be summarised as follows:

*Main request and auxiliary request 1 - claim 1*

*Extension beyond the content of the earlier application as filed (Article 76(1) EPC)*

*Admittance of submissions by the appellant at the oral proceedings (Article 13(2) RPBA 2020)*

In accordance with the RPBA, the parties should present their complete case as early as possible. However, up until the oral proceedings, the appellant had not presented its case on the relevant points and consequently any submissions that would result in a change of the board's preliminary opinion should not be

admitted into the appeal proceedings (Article 13(2) RPBA 2020). No exceptional circumstances had been advanced.

It was established case law of the boards of appeal that submissions made before the opposition division were not automatically part of the appeal proceedings, even when there was an explicit reference to those submissions in a letter (see Case Law of the Boards of Appeal of the EPO, 9th edition 2019 (hereinafter CLBA), pages 1173 to 1174).

*Definition of the reference antibody*

The "gold standard" required that subject-matter disclosed in a divisional application was directly and unambiguously derivable from the earlier application as filed and did not allow for any doubts that new technical matter was present.

The designations "6-2" and "1B7" in the earlier application related to specific antibodies (page 24, line 21 referring to "particular" antibodies and line 16, referring to "examples" of antibodies). However, the claims referred to only some of their characteristics when defining the reference antibody.

Also the examples in the earlier application disclosed that these designations related to specific antibodies since 6-2, for example, also designated a specific hybridoma clone (see example 6, page 46, lines 31 to 35, and example 4). The same applied to antibody and clone 1B7 (see example 9).

Furthermore, the earlier application did mention the heavy chains of the antibodies, stating "*The amino acid*

*sequence of the heavy chain of MAb 1B7 is identical to that of MAb 63*" (see page 29, lines 3 to 5) and disclosed that derivates could be prepared from the specific antibodies (see page 30, lines 3 to 5 and 8).

Thus, the description of the earlier application provided more detailed information on the reference antibodies than that present in the claim, which provided a generalised definition of the specific antibodies with the internal designations "6-2" and "1B7". The amendment contravened the requirements of Article 76(1) EPC.

Moreover, the disclosure of the kappa light chain, in figure 4, referred merely to the variable domain instead of referring to the light chain as a whole. Thus, also this feature in the claim was not disclosed in the earlier application as filed.

*Auxiliary requests 2 and 3 - claim 1*
*Clarity (Article 84 EPC)*

The claim was not clear because, by reference being made to the transgenic mouse strain, the antibody was defined in product-by-process terms.

Moreover, a claim should be clear on its own. In particular the meaning of an essential feature, as was the case here, needed to be clear from the wording of the claim alone (see opinion G 1/04 of the Enlarged Board of Appeal and CLBA, page 290). However, the skilled person was not able to determine the sequences of the transgenes, for three main reasons: (i) the terminology used to define the transgenic mouse strain was not standard in the field; (ii) even when using the description to interpret this feature, there were

discrepancies as to the transgene corresponding to the kappa light chain, as to the meaning of the symbol "++" and as to the meaning of the symbol "+/++"; and (iii) even when consulting the references cited in the description, the sequences for the transgenes KCo5 and HCo7 were not retrievable.

As regards (i), all the publications cited in the description originated from a single research group and consequently could not demonstrate that the meaning of the terminology in the claim was standard in the field. The authors of documents D116, D117 and D132 stated that the terminology was not standard in the field. As for document D154, it was apparent it could not have the same probatory value as documents D116, D117 and D132 since it was authored by an employee of the appellant.

As regards (iii), the reference in the patent to Chen *et al.*, in the context of JKD, could not be retrieved. The sequence of transgene HCo7 was not known even when taking into account the reference in the patent to document D131. The only information disclosed in this document about a sequence HCo7 was that it was derived from an anonymous phage library. It was therefore not possible to retrieve the sequence (see documents D116 and D117). Also, the sequence was not clear for the constant region designated by KCo5 (see document D116, paragraph 23).

XIV. The appellant's requests relevant to the decision were that the decision under appeal be set aside and that the case be remitted to the opposition division for consideration of outstanding grounds for opposition, namely novelty and inventive step, in relation to the sets of claims of the main request and of auxiliary

requests 1 to 3, all filed with the letter dated 6 March 2018.

Respondent I's request relevant to the decision was that the appeal be dismissed.

Respondent II's requests relevant to the decision were that the appeal be dismissed and that, should the board set aside the decision under appeal, the case be remitted to the opposition division for consideration of the outstanding grounds for opposition.

## Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 EPC and the further provisions referred to in Rule 101(1) EPC and is admissible.

*Main request and auxiliary request 1 - claim 1*
*Extension beyond the content of the earlier application as filed (Article 76(1) EPC)*

*Admittance of submissions by the appellant at the oral proceedings (Article 13(2) RPBA 2020)*

2. The respondents requested that new submissions by the appellant, made in the context of Article 76(1) EPC at the oral proceedings, not be admitted into the proceedings under Article 13(2) RPBA 2020, applicable to the present appeal case pursuant to Articles 24 and 25 RPBA 2020.

3. The board notes that the appellant's submissions did not go beyond the reasoning provided by the opposition division in its decision (see decision under appeal point 1.2.4, second paragraph). The decision under appeal is part of the appeal proceedings, as confirmed in Article 12(1)(a) RPBA 2020. Thus, the board concludes that no new submissions were presented.

*Definition of the reference antibody*

4. Article 76(1), second sentence, EPC provides that a European divisional application may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed. According to decision G 1/06 of the Enlarged Board of Appeal, it is a necessary and sufficient condition for a divisional application to comply with this provision that anything disclosed in that divisional application be directly and unambiguously derivable from what is disclosed in the earlier application as filed (see decision G 1/06, OJ EPO 2008, 307, Order).

5. Claim 1 is directed to antibodies defined *inter alia* by their ability to compete with a reference antibody for binding to a cell that expresses human IL-4 receptor. It was common ground that this ability was defined in the description of the earlier application as filed solely in respect of competition with antibodies designated "6-2" and "1B7" (see pages 24 and 28). The passage on page 24, reads "*Particular monoclonal antibodies of the invention are selected from the group consisting of MAb 6-2; a Mab that is cross-reactive with 6-2; a MAb that binds to the same epitope as 6-2; a MAb that competes with 6-2 for binding to a cell that expresses human IL-4R; a MAb that possesses a biological activity of 6-2; and an antigen-binding*

*fragment of any of the foregoing antibodies.*" (emphasis added by the board). The passage on page 28 reads similarly in respect of antibody 1B7.

6. Claim 1 recites the SEQ ID NOs 6 and 8, in part a), and SEQ ID NOs 26 and 24, in part b), which correspond to the sequences of the variable regions of the light and heavy chains of antibodies 6-2 and 1B7, respectively (see earlier application as filed on page 25, lines 35 to 38 and page 29 , lines 3 to 11, respectively).

7. The earlier application as filed does not disclose the specific sequences of the constant regions of the light and heavy chains of antibodies 6-2 and 1B7. The question in dispute between the parties was whether the absence of any constant region sequences from the claim led to a definition of the reference antibody which differed from antibodies 6-2 and 1B7 as disclosed in the above-mentioned pages 24 and 28 of the earlier application as filed.

8. Examples 4 and 6 of the earlier application describe the preparation of hybridomas and selection of a clone secreting the antibody 6-2. The same applies to example 9 with respect to antibody 1B7. Each hybridoma clone secretes only one specific (monoclonal) antibody and not a whole class of antibodies. The board concludes from this that the designations 6-2 and 1B7 denote specific monoclonal antibodies, entailing specific constant region sequences.

9. This view is supported by the passage of the earlier application describing the preparation of antibody 1B7 from antibody 63 and comparing their constant region sequences, as follows: "*MAb 1B7 was derived from MAb 63. The amino acid sequence of the heavy chain of*

*MAb 1B7 is identical to that of MAb 63.*" (see page 29, lines 3 to 5).

10. The fact that the sequences of the constant regions are not disclosed in the earlier application does not change the assessment that a specific full monoclonal antibody was meant by "6-2" and "1B7".

11. It follows from the above that the passages on pages 24 and 28 of the description define antibodies by reference to specific antibodies 6-2 and 1B7. However, the claim is directed to antibodies defined by reference to a generalisation of antibodies 6-2 and 1B7. The skilled person would not derive this definition directly and unambiguously from the earlier application as filed and accordingly the requirements of Article 76(1) EPC are not met.

12. Contrary to the appellant's argument, the board holds that the lack of full characterisation of antibodies 6-2 and 1B7 in the earlier application does not entitle the appellant to replace those specific monoclonal antibodies, for which there is disclosure in the context of competing antibodies, with a generalisation for which there is no basis in the earlier application as filed. In a case where the antibodies sought to be claimed cannot be defined by reference to competition with antibodies 6-2 and 1B7, which are internal designations in the case in hand, then an alternative definition must be pursued, relying on what was disclosed in the earlier application as filed.

13. Finally, the passage of the Guidelines for Examination at the EPO, G-II, 5.6.1.1, cited by the appellant, refers to the requirements of clarity (Guidelines for Examination, editions March 2021 and March 2022) and is

therefore not pertinent to the issue at hand, which is the requirement that the divisional application be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed.

14. Claim 1 of auxiliary request 1 also includes this definition of the antibodies. Therefore, the finding of lack of compliance with Article 76(1) EPC applies to both requests equally.

*Auxiliary requests 2 and 3 – claim 1*
*Clarity (Article 84 EPC)*

15. The feature "*wherein the reference IgM antibody is generated in transgenic mouse strain ((CMD)++; (JKD)++; (HCo7)11952+/++; (KCo5)9272+/++)*" was introduced into claim 1 of auxiliary request 2 during the proceedings before the opposition division. This feature is not included in any of the claims of the patent as granted. Rather it is based on a disclosure in the description (see paragraph [0246] of the patent). This amendment was therefore open to examination for compliance with the requirements of Article 84 EPC (see decision G 3/14, OJ EPO 2015, A102). This was not disputed by the appellant.

16. According to established case law of the boards of appeal of the EPO, the requirement for clarity of the claims in Article 84 EPC entails that the claims define and delimit the matter for which protection is sought in understandable and unambiguous terms. The claims must be clear in themselves when being read by the skilled person, including the knowledge about the prior art but not including any knowledge derived from the description of the patent application or the amended

patent (see decisions cited in the Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, II.A.3.1, first paragraph).

17. In their replies to the statement of grounds of appeal, the respondents submitted that the feature referring to a transgenic mouse was not clear. The appellant presented several lines of argument to argue the clarity of the claim.

18. In a first line of argument, the appellant submitted that the terminology used in the claim to define the transgenic mouse was standard in the technical field and its meaning clear to the skilled person.

19. The appellant relied in this respect on document D154, whereas respondent I referred to documents D116, D117 and D132. These declarations make contradictory statements on this issue. In document D154, it is asserted that the terminology was generally accepted in the field and the meaning of the expression at issue was clear. However, there is no documentary evidence on file which allows the board to establish that the terminology in question belonged to the common general knowledge of the skilled person at the relevant date. The only document filed in this respect is document D131 which corresponds to the patent document cited in paragraph [0246] of the patent. It is a patent document and therefore the fact that it uses a certain terminology does not on its own establish that such terminology belonged to the common general knowledge of the skilled person. Although document D154 refers to four scientific publications, these have not been filed and are not part of these proceedings. Moreover, they are referred to solely in respect of disclosing the terminology "HC" and "KC" but not in respect of

disclosing any of the other terms in the claim such as "HCo7" and "KCo5", addressed here below.

20. In a further line of argument, the appellant stated that the description provided an explanation of the terminology and contained references using that terminology. As regards specifically the meaning of HCo7 and KCo5, the appellant argued with reference to document D154 that the meaning would be known to the skilled person from paragraphs [0246] and [0247] of the patent and document D131 cited therein.

21. It was disputed by the respondents that the description of the patent could be taken into account for interpreting the claim. However, the board comes to the conclusion that, even when interpreting the claim in the light of the description, the sequence of transgenes HCo7 and KCo5 can nevertheless not be determined, even when further taking account of the contents of document D131. This is the case because neither the above-cited paragraphs of the description nor document D131 indicate the respective sequences of genes HCo7 and KCo5.

22. In document D154, examples 12, 21, 37 and 38 in document D131 are mentioned as disclosing how the transgenes were generated, namely that they were "*obtained from a phage library containing human genomic DNA*" (see page 6, first paragraph of document D154). This correct account of the disclosure of document D131 does not therefore indicate a passage in this, or any other document, which discloses the sequences of the genes. In fact, no such passage is present in document D131. This is consistent with the statements in declarations D116 (section F.) and D117 (section A)5.), filed by respondent I, pointing out

that the sequences of the heavy and light chain constant regions were not known since their source was not identified other than by reference to a phage P1 library of unspecified origin (see example 37, as regards transgene HCo7) and a library of human placental DNA of unspecified origin (see example 38 in combination with example 21, as regards transgene KCo5). Indeed document D131 describes in example 37 the generation of transgenic mice with inactivated endogenous light and heavy chain loci and containing transgene HCo7 (see example 37, column 133, lines 55 to 59). Preparation of transgene HCo7 is described with reference to five clones and refers to screening of a phage P1 library (see example 37, column 135, lines 36 to 39 and column 137, lines 12 to 14). As regards the source of DNA material for gene KCo5, example 21 refers to a human placental DNA library to generate a KCo4 transgene. The KCo5 transgene used in example 38 is described as corresponding to the DNA in KCo4 with additional DNA segments (see example 38, column 143, lines 5 to 7 and example 21, column 101, lines 25 to 27). The appellant has not directed the board to other passages of this or other documents which specifically disclose the sequences and rebut such statements.

23. Consequently, claim 1 lacks clarity, contrary to the requirements of Article 84 EPC.

24. Claim 1 of auxiliary request 3 includes the feature discussed with respect to claim 1 of auxiliary request 2, except that the term "reference" has been deleted (see the claim wording in point X.). Thus, the considerations in points 15. to 23. above apply equally to this claim.

25. In view of the foregoing, none of the claim requests forming part of the appeal proceedings meets the requirements of the EPC. Accordingly, the patent cannot be maintained on the basis of any of these requests.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay B. Claes

Decision electronically authenticated