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**Datasheet for the decision
of 19 September 2019**

Case Number: T 1656/13 - 3.3.04

Application Number: 03019221.5

Publication Number: 1396501

IPC: C07K16/28, C12N5/07

Language of the proceedings: EN

Title of invention:

Antibodies for identifying and/or isolating at least one cell population which is selected from the group comprising haematopoietic stem cells, neuronal stem cells, neuronal precursor cells, mesenchymal stem cells and mesenchymal precursor cells

Patent Proprietor:

F. Hoffmann-La Roche AG

Opponents:

UCB Pharma S.A.
Wilex AG

Headword:

Antibodies for identifying and/or isolating haematopoietic stem cells/HOFFMANN-LA ROCHE

Relevant legal provisions:

EPC Art. 123(2)

EPC R. 115(2)

RPBA Art. 15(3)

Keyword:

Main request, auxiliary request 1: amendments - undisclosed
disclaimer - allowable (no)

Decisions cited:

G 0001/03, G 0001/16

Catchword:



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Case Number: T 1656/13 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 19 September 2019

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 May 2013 concerning maintenance of the
European Patent No. 1396501 in amended form.**

Composition of the Board:

Chair G. Alt
Members: R. Morawetz
 L. Bühler

Summary of Facts and Submissions

- I. The appeals of opponent 1 ("appellant I") and opponent 2 ("appellant II") lie from the opposition division's interlocutory decision concerning the maintenance of European patent No. EP 1 396 501 in amended form. The patent is entitled "*Antibodies for identifying and/or isolating at least one cell population which is selected from the group comprising haematopoietic stem cells, neuronal stem cells, neuronal precursor cells, mesenchymal stem cells and mesenchymal precursor cells*".
- II. Two oppositions were filed against the patent. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) and Article 100(c) EPC.
- III. The opposition division decided that the subject-matter of claim 1 of the main request on file was anticipated by the disclosure of the monoclonal antibody 41-2 (mAb 41-2) in document D1 (US 6,245,898; 12 June 2001). The set of claims of auxiliary request 1 with claim 1 amended by the introduction of the disclaimer "*wherein said monoclonal anti-CDCP1 antibody is not mAb 41-2 (ATCC PTA-226)*" was considered to meet the requirements of the EPC. In relation to the disclaimer the opposition division held that its introduction did not contravene the requirements of Article 123(2) EPC because the disclosure of the antibody mAb 41-2 in document D1 was "accidental" within the meaning of decision G 1/03 (see decision under appeal, Reasons, points 15.1 to 15.6).

- IV. In their statement of grounds of appeal, the appellants contested *inter alia* that the disclaimer introduced into claim 1 of auxiliary request 1 considered in the decision under appeal was allowable under Article 123(2) EPC because, *inter alia*, its scope was too narrow.
- V. With their reply to the statements of grounds of appeal the patent proprietor ("respondent") responded *inter alia* to the appellants' argument that the scope of the disclaimer was too narrow. Moreover, they filed sets of claims of a main request and of an auxiliary request 1. The main request corresponded to auxiliary request 1 considered in the decision under appeal while auxiliary request 1 was a newly filed request.

Claim 1 of the main request reads as follows:

"1. A monoclonal anti-CDCP1 antibody, or a fragment thereof, capable of isolating and/or identifying a population of haematopoietic stem cells, characterized in that the antibody, or the fragment thereof, binds to an antigen which is the same as that bound by an antibody produced by the hybridoma cell line CUB1 (DSM ACC2569), CUB2 (DSM ACC2566), CUB3 (DSM ACC2565) and CUB4 (DSM ACC2551), wherein said monoclonal anti-CDCP1 antibody is not mAb 41-2 (ATCC PTA-226)."

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request.

- VI. The board scheduled oral proceedings as requested by the parties, and issued a communication pursuant to Article 15(1) RPBA setting out its preliminary opinion on some of the issues.

- VII. In response, the appellants and the respondent informed the board that they would not attend the oral proceedings. The appellants also withdrew their requests for oral proceedings.
- VIII. Oral proceedings were held on 19 September 2019. At their end, the chair announced the board's decision.
- IX. The appellants' arguments that are relevant to the present decision may be summarised as follows:

Main request, auxiliary request 1 - claim 1

Amendments (Article 123(2) EPC)

The disclaimer that was introduced into claim 1 was not allowable under Article 123(2) EPC. In order to restore novelty, a disclaimer needed to exclude from the claim all novelty-destroying disclosure of the relevant document. The disclaimer in claim 1 only excluded the specific monoclonal antibody 41-2 (mAb 41-2) of document D1. However, document D1 provided direct and unambiguous disclosure of more than just the antibody mAb 41-2. Column 6, lines 26 to 35, of document D1 described functional derivatives of the exemplified antibodies, including particular antibody fragments.

- X. The respondent's arguments that are relevant to the present decision may be summarised as follows:

Main request, auxiliary request 1 - claim 1

Amendments (Article 123(2) EPC)

The disclaimer excluded the specific subject-matter necessary to restore novelty over the disclosure of

document D1. The antibody derivatives listed in columns 6 to 7 of document D1 were merely a "laundry list" of the most standard functional antibody derivatives known in the art. However, document D1 failed to exemplify the activity of any of the antibody mAb 41-2 derivatives, and the appellants had not produced any evidence that the activity of any of the listed derivatives was the same as or similar to that of the antibody mAb 41-2. Humanisation and preparation of fragments could result in loss or alteration of activity compared with the parent antibody. The highly tentative potential conclusions regarding theoretical antibody activity did not give rise to the direct and unambiguous disclosure necessary to support a lack of novelty argument.

- XI. Both appellants requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent requested in writing that the patent be maintained on the basis of the set of claims of the main request or, alternatively, on the basis of the set of claims of auxiliary request 1, both filed with the reply to the statements of grounds of appeal.

Reasons for the Decision

1. The appeals comply with Articles 106 to 108 and Rule 99 EPC and are therefore admissible.
2. The duly summoned parties were neither present nor represented at the oral proceedings. The board decided to continue the proceedings without the parties in accordance with Rule 115(2) EPC and treated them as

relying on their written case in accordance with Article 15(3) RPBA.

Main request, auxiliary request 1 - claim 1

Amendments (Article 123(2) EPC)

3. In claim 1 of the main request the disclaimer "*wherein said monoclonal anti-CDCP1 antibody is not mAb 41-2 (ATCC PTA-226)*" was introduced to delimit the claimed subject-matter vis-à-vis the disclosure of document D1. It is not in dispute that this disclaimer does not have a basis in the application as filed; in other words, it is a undisclosed disclaimer within the meaning of decision G 1/03 (OJ EPO 2004, 413). Claim 1 of auxiliary request 1 is identical to claim 1 of the main request.
4. The opposition division considered that the introduction of the disclaimer was allowable under Article 123(2) EPC (see section III above). This is contested by the appellants.
5. The Enlarged Board confirmed in decision G 1/16 (OJ EPO 2018, 70, Reasons, points 44 and 45) that the introduction of an undisclosed disclaimer may be considered allowable under Article 123(2) EPC, if the criteria laid down in decision G 1/03 are met. In decision G 1/03 (*supra*, see Order, point 2.1, second indent, Reasons, point 2.2 and sub-points) the Enlarged Board held that a disclaimer which is not disclosed in the application as filed may be allowable in order to restore novelty by delimiting a claim against an accidental anticipation under Article 54(2) EPC; an anticipation being accidental if it is so unrelated to and remote from the claimed

invention that the person skilled in the art would never have taken it into consideration when making the invention.

6. It follows that one of the criteria the undisclosed disclaimer needs to fulfill in the present case is that it must delimit claim 1 with respect to the disclosure of document D1.
7. Document D1 relates to isolated monoclonal antibodies that inhibit tumor metastasis (see column 5, lines 51 to 52) and provides two antibodies, mAb 41-2 and mAb 50-6 that inhibit metastasis of tumours (see column 5, lines 61 to 62). It is undisputed that the antibody mAb 41-2 is characterised by the following feature in claim 1: "*binds an antigen which is the same as that bound by an antibody produced by the hybridoma cell line CUB1 (DSM ACC2569), CUB2 (DSM ACC2566), CUB3 (DSM ACC2565) and CUB4 (DSM ACC2551)*".
8. In addition to the specific antibody, mAb 41-2 (and mAb 50-6), document D1 also discloses that:

"Functional derivatives of the instant monoclonal antibodies are also contemplated by the present invention. "Functional derivatives" refer to antibody molecules or fragments thereof that are derived from the instant monoclonal antibodies and that have retained the antigen specificity of the instant monoclonal antibodies. Examples of functional derivatives include Fab, Fab', F(ab')₂ of the present mAbs, single chain antibodies, humanized antibodies and the like." (see column 6, lines 26 to 35)

9. Document D1 thus discloses Fab, Fab' and F(ab')₂ fragments of the antibody mAb 41-2 that *"have retained the antigen specificity of the parental antibody"*.
10. The skilled person familiar with the structure of the antibody fragments disclosed in document D1 would consider their common general knowledge reflected in this statement. Thus, the monovalent antigen-binding fragments Fab and Fab' lack the crystallisable fragment (Fc) region of the antibody but retain one antigen-binding region while the divalent antigen-binding fragment F(ab')₂ lacks the Fc region of the antibody but retains both antigen-binding regions. The skilled person would thus be aware that the Fab, Fab' and F(ab')₂ fragments of the antibody mAb 41-2 necessarily retain the antigen specificity of the antibody mAb 41-2.
11. Consequently, the board is not convinced by the respondent's arguments that document D1 fails to exemplify the activity of any of the mAb 41-2 derivatives, that preparation of fragments can result in loss or alteration of activity compared with the "parent" antibody and that therefore the derivative antibody need not necessarily have the same properties as the antibody mAb 4-12.
12. Document D1 therefore directly and unambiguously discloses more than just the antibody mAb 41-2, namely fragments thereof that bind the same antigen as antibody mAb 41-2 and fall within the scope of claim 1 of both claim requests. The disclaiming of the antibody mAb 41-2 is thus not sufficient to delimit claim 1 with respect to the disclosure of document D1; see point 6 above.

13. Since the disclaimer does not restore novelty over the disclosure of document D1, it does not fulfil at least one of the criteria set out in decision G 1/03 and is thus not allowable for non-compliance with the requirements of Article 123(2) EPC. Accordingly, the main request and auxiliary request 1 are not allowable.

Conclusion

14. In the absence of an allowable set of claims 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

G. Alt

Decision electronically authenticated