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**Datasheet for the decision
of 14 June 2016**

Case Number: T 0545/12 - 3.3.04

Application Number: 97933799.5

Publication Number: 0914157

IPC: A61K39/395, A61K31/505

Language of the proceedings: EN

Title of invention:

Anti-TNF antibodies / TNF receptor and methotrexate in the
treatment of autoimmune disease

Patent Proprietor:

The Kennedy Trust for Rheumatology Research

Opponents:

Wyeth LLC (opposition withdrawn)
UCB, S.A. (opposition withdrawn)
AbbVie Inc.
Schering Corporation
Amgen Inc.

Headword:

Anti-TNF antibodies and methotrexate/THE KENNEDY TRUST

Relevant legal provisions:

EPC Art. 111(1), 123(2)

Keyword:

Transfer of opponent status (yes)
Main request: amendments - allowable (yes)
Remittal to the opposition division (yes)

Decisions cited:

G 0004/88, G 0002/04, T 0298/97, T 1137/97, T 0273/02,
T 1178/04, T 0006/05, T 0194/15

Catchword:



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Case Number: T 0545/12 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 14 June 2016

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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 22 December
2011 revoking European patent No. 0914157
pursuant to Article 101(2) EPC.

Composition of the Board:

Chairwoman G. Alt
Members: R. Morawetz
M. Blasi

Summary of Facts and Submissions

- I. The appeal by the proprietor ("appellant") lies against the decision of the opposition division revoking European patent No. 0914157 pursuant to Article 101(2) EPC.
- II. The patent at issue has the title "Anti-TNF antibodies / TNF receptor and methotrexate in the treatment of autoimmune disease". It was granted in respect of European patent application No. 97933799.5, which originated from international patent application No. PCT/GB1997/002058, published as WO 1998/005357 ("application as filed").

Claims 3 and 16 as granted read:

"3. Use of an anti-human tumor necrosis factor- α monoclonal antibody or fragment thereof for the manufacture of a medicament for performing adjunctive therapy with methotrexate on an individual suffering from rheumatoid arthritis, wherein in the adjunctive therapy the anti-human tumor necrosis factor- α antibody- or antibody fragment-containing medicament is to be administered to the individual multiple times, each such administration (i) being separated by an interval of weeks from the prior administration, and (ii) delivering 0.01-100mg/kg/day of the anti-human tumor necrosis factor- α antibody or fragment thereof.

16. The use of any of claims 1-15, wherein the antibody is cA2."

- III. Five oppositions were filed, one of them in the name of Abbott Laboratories (opponent 03, referred to in this decision as "Abbott"). The patent was opposed under

Article 100(a) EPC 1973 on the grounds of exclusion from patentability (Article 52(4) EPC 1973), lack of novelty (Article 54 EPC 1973) and lack of inventive step (Article 56 EPC 1973), under Article 100(b) EPC 1973, and under Article 100(c) EPC 1973 on the ground that the subject-matter of the patent extended beyond the content of the application as filed (Article 123(2) EPC 1973).

- IV. During the opposition proceedings, opponent 02 withdrew its opposition.
- V. The opposition division revoked the patent because it found that the ground for opposition invoked pursuant to Article 100(c) EPC prejudiced its maintenance. It held *inter alia* that while the feature "an anti-human tumor necrosis factor- α monoclonal antibody" in claim 3 as granted did not have a basis in the application as filed, the feature "0.01-100 mg/kg/day" did have one.
- VI. With its statement of grounds of appeal the appellant filed a new main request consisting of claims 1 to 20 as granted and provided arguments as to why their subject-matter complied with Articles 123(2) and 123(3) EPC.
- VII. In response to the notice of appeal, opponent 04 ("respondent IV") requested dismissal of the appeal. In response to the statement of grounds of appeal, opponent 03 ("respondent III") and opponent 05 ("respondent V") filed counter-arguments, submitting *inter alia* that there was no basis in the application as filed for the feature "an anti-human tumor necrosis factor- α monoclonal antibody" in claim 3 of the main request.

VIII. With letter dated 3 January 2013 respondent III requested that its status as opponent be transferred to AbbVie Inc. (referred to in the present decision as "AbbVie"). In support of this request respondent III filed a declaration by John M. Leonard, M.D. (hereinafter "Declaration") and a copy of a "Contribution, Assignment and Assumption Agreement [...], dated as of August 1, 2012 (the "Effective Date") [...] by and between Abbott Laboratories [...] and AbbVie Inc. [...]" (hereinafter "Agreement").

IX. In a communication from the registrar of the board dated 25 January 2013 the parties were informed that "the transfer of the opposition (O3) from Abbott Laboratories to AbbVie Inc. as per attached request dated 3 January 2013 appears to be admissible and has been recorded on the Register of European Patents."

X. With letter dated 25 February 2013 the appellant filed claims of a new main request and an auxiliary request.

The set of claims of the main request consists of a sole claim which reads:

"1. Use of cA2 monoclonal antibody for the manufacture of a medicament for performing adjunctive therapy with methotrexate on an individual suffering from rheumatoid arthritis, wherein in the adjunctive therapy the cA2-containing medicament is to be administered to the individual multiple times, each such administration (i) being separated by an interval of weeks from the prior administration, and (ii) delivering 0.01-100mg/kg/day of cA2."

- XI. With letter dated 10 November 2015 opponent 01 ("respondent I") withdrew its opposition.
- XII. With letter dated 29 January 2016 the appellant questioned the allowability of the request of 3 January 2013 for transfer of opponent status and requested that it be refused.
- XIII. In a communication under Article 15(1) RPBA the board informed the parties of the issues to be discussed at the forthcoming oral proceedings.
- XIV. With letter dated 4 May 2016 respondent V informed the board that it would not be attending the oral proceedings.

On 10 June 2016 respondent IV informed the registrar of the board by telephone that it too would not be attending the oral proceedings.

- XV. At the end of the oral proceedings held on 14 June 2016 in the absence of respondents IV and V the chairwoman announced the board's decision.
- XVI. The arguments of the appellant presented orally and in writing can be summarised as follows:

Transfer of opponent status from Abbott to AbbVie

It was well established that a request for transfer of opponent status had to be supported by appropriate evidence, see T 298/97, reasons, point 7.2.

The documents filed on 3 January 2013 in support of the request for the transfer of the opponent status from Abbott to AbbVie were the Declaration and the Agreement

(see section VIII above). These documents did not establish that, as stated in the request, (i) all the assets of the business to which the opposition related had been transferred, and (ii) that they had all been transferred to AbbVie.

The Declaration itself did not prove which assets had been transferred, and referred to the Agreement as providing evidence of the transfer.

The Agreement provided evidence that a transfer of some form between Abbott and AbbVie had been contemplated and might be inferred to have actually taken place. However, it had been so heavily redacted that it provided very little information as to what had - or had not - been transferred. None the less, it was clear that the Agreement did not show either that all assets had been transferred or that they had all been transferred from Abbott to AbbVie, and to AbbVie only.

Since there was no adequate evidence for a valid transfer of opponent status to AbbVie, the proceedings should continue with the original respondent III, Abbott.

Moreover, the board (in a different composition) had already decided, as shown by the minutes of the oral proceedings held in case T 194/15, that the evidence on file was not sufficient to conclude that a valid transfer of opponent status had taken place.

Main request

Article 123(2) EPC

Claim 1 was a combination of claims 3 and 16 as granted.

In the opposition proceedings, no objections under Article 100(c) EPC had been raised against claim 16 as granted.

The sole feature of claim 3 as granted to which the respondents maintained objections in the appeal proceedings - "an anti-human tumor necrosis factor- α monoclonal antibody" - had now been replaced by the feature "cA2". Accordingly, there were no outstanding objections against the subject-matter of claim 1.

The subject-matter of claim 1 was based on the disclosure on page 4, lines 8 to 18 in combination with the disclosure on page 17, line 29 to page 18, line 3 and page 22, lines 6 to 8 and 11 to 13, in association with page 38, lines 5 to 7 and page 39, lines 6 to 7 of the application as filed.

Remittal

The case should be remitted to the opposition division for further prosecution on the basis of the set of claims of the main request.

XVII. The arguments of respondent III presented orally and in writing can be summarised as follows:

Transfer of opponent status from Abbott to AbbVie

With the request of transfer, two pieces of evidence had been provided: the Agreement and the Declaration. Together they provided the necessary evidence that all the assets of the business to which the opposition related had been transferred from Abbott to AbbVie.

The Agreement was not necessary to determine what assets had been transferred. It was referred to in the Declaration as evidence that such an agreement existed between Abbott and AbbVie, and that the transfer of assets from Abbott to AbbVie had actually occurred.

The Declaration had been made by the senior vice president, Pharmaceuticals, Research and Development at Abbott Laboratories who was therefore qualified to make it. It had been made in support of the transfer of opposition from Abbott to AbbVie and provided evidence in its point 4 of what had been transferred.

The appellant had provided no counter-evidence calling into question the statements made in the Declaration or suggesting that the transfer had not in fact occurred.

That the business assets of Abbott had been transferred solely to AbbVie was stated in the Declaration and was also evident from the Agreement, which indicated in Section 3.05 that there were no third party beneficiaries.

Main request

Article 123(2) EPC

No submissions were made.

Remittal

Respondent III agreed with the appellant that the case should be remitted to the opposition division for further prosecution on the basis of the set of claims of the main request.

- XVIII. Respondent IV did not submit any arguments.
- XIX. Respondent V did not submit any arguments on the matters at issue, i.e. the transfer of opponent status, the basis in the application as filed for the subject-matter of the claims of the main request, and remittal of the case to the opposition division.
- XX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the set of claims of the main request filed with letter of 25 February 2013.

Respondents III, IV and V requested that the appeal be dismissed.

Reasons for the Decision

1. The duly summoned respondents IV and V did not attend the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued in their absence and respondents IV and V were treated as relying on their written cases.

Transfer of opponent status from Abbott to AbbVie

2. It is well-established case law of the boards of appeal that opponent status is not freely transferable (see G 2/04, OJ EPO 2005, 549, Order, point I(a)). An opposition may, however, be transferred or assigned to a third party as part of the opponent's business assets, together with the assets in the interests of which the opposition was filed (see G 4/88, OJ EPO 1989, 480, Order and Case Law of the Boards of Appeal, 7th edition 2013, section IV.C.2.2.3). Moreover, such transfers must be made to one, and only one, third party (see T 298/97, OJ EPO 2002, 83, reasons, point 7.6).
3. As to the point in time when a transfer of opponent status becomes procedurally effective, the boards of appeal have, in such situations, applied *mutatis mutandis* the principle laid down in Rules 22(3) and 85 EPC, i.e. that transfers of European patents take effect for the European Patent Office's purposes only when and to the extent that the necessary documentary evidence has been produced. To apply the same requirements to patent proprietors and opponents would appear justified given the principle of equal treatment of parties to proceedings (see also e.g. T 6/05, reasons, point 1.6.1). Hence, the transferee acquires opponent status once the EPO has been asked to

make the transfer and adequate evidence has been provided (see e.g. T 1137/97, reasons, point 4).

4. The assessment of the validity of the transfer is to be made on the basis of the documents submitted as supporting evidence. That another document might have been a more direct piece of evidence than the one(s) submitted is irrelevant, and does not invalidate the proof actually offered (see also T 273/02, reasons, point 2.6; T 1178/04, reasons, point 40).
5. In the present case, a request was made in the course of the appeal proceedings to transfer the status of opponent (and hence respondent) from Abbott to AbbVie. In support of the request, a declaration from the Senior Vice President, Pharmaceuticals, Research and Development at Abbott and a redacted copy of an agreement between Abbott and AbbVie were filed (see section VIII above).
6. The board considers the evidence on file to constitute sufficient proof that (i) all the assets of the business to which the opposition related have been transferred and (ii) they have all been transferred to AbbVie.
7. As to (i), the board notes that the Declaration consists of an introduction setting out its purpose as follows: "In support of transfer of the above-mentioned opposition from Abbott Laboratories ("Abbott") to AbbVie Inc. ("AbbVie"), I, John M. Leonard, M.D., hereby declare and state as follows: (...)". Six numbered paragraphs then follow.
8. The first two paragraphs state Dr Leonard's position and responsibilities at Abbott, i.e. that he is the

senior vice president, Pharmaceuticals, Research and Development, and responsible *inter alia* for the management of global proprietary pharmaceutical discovery and development efforts. In the board's view this establishes that Dr Leonard was qualified to make the statements he was making.

9. Paragraphs 3 to 5 of the Declaration relate to the actual transfer and are set out below in full:

"3. Enclosed with this Declaration is a copy of a Contribution, Assignment and Assumption Agreement between Abbott and AbbVie which provides evidence of transfer of all proprietary pharmaceutical business assets from Abbott to AbbVie.

4. Specifically, the business assets included in the transfer encompass all of the business assets pertaining to human therapeutic use of anti-TNF antibodies. More specifically, the business assets encompass the commercial product HUMIRA, which is used in the treatment of autoimmune disease.

5. Thus, the opposition, along with all of the business assets and liabilities to which the opposition relates, have been transferred from Abbott to AbbVie."

10. Thus, the Declaration defines in paragraph 4 the assets that have been transferred from Abbott to AbbVie as "all of the business assets pertaining to human therapeutic use of anti-TNF antibodies". As the opposed patent relates to the use of anti-TNF antibodies in the treatment of autoimmune disease, the Declaration thus establishes that all the assets relating to the business in the interest of which the opposition had been filed were transferred.

11. The appellant submitted that it was not possible to establish from the Agreement which assets had been transferred.
12. It is true that the entire section setting out the assets of Abbott to be transferred to AbbVie (see Section 1.01 on pages 1 and 2 of the Agreement) is redacted in the Agreement, as are the sections on pages 3 and 4 setting out which assets are not being transferred and the sections on pages 6 and 7 setting out those whose transfer is being delayed.
13. However, in the board's judgement, this has no bearing on the issue to be decided. It is the Declaration which defines, in its paragraph 4, the assets transferred (see points 9 and 10 above). The Agreement merely serves to corroborate that a transfer of assets from Abbott to AbbVie has taken place. That a transfer has taken place is derivable not only from the Agreement but also from the Declaration and has not been contested by the appellant.
14. As to (ii) of point 6 above, i.e. the transfer to AbbVie, and to AbbVie only, this is, in the board's view, derivable from the Declaration stating that the Agreement provides "evidence of transfer of all proprietary pharmaceutical business assets from Abbott to AbbVie" (see point 9 above), from the first paragraph of the Agreement which states that it is "by and between" Abbott and AbbVie, and in particular from section 3.05 of the Agreement which makes it clear that there are no third party beneficiaries: "Section 3.05 No Third Party Beneficiaries. This Agreement is not intended to be for the benefit of and shall not be enforceable by any person that is not a party hereto" (emphasis in the original). The reference in

the Agreement (page 1, 4th paragraph) to yet another agreement, i.e. the "Separation and Distribution Agreement" by which further steps in the separation process are to be defined, namely "the allocation of Assets and Liabilities between Abbott and its Subsidiaries on the one hand and AbbVie and its Subsidiaries on the other hand", has no bearing on the fact that the Agreement itself provides for a transfer of the assets from Abbott to AbbVie.

15. The appellant has not provided any counter-evidence showing that the factual situation is not as given in the Declaration. The reference to case T 194/15, in which a transfer of opponent status from Abbott to AbbVie was also requested, does not support the appellant's case. In case T 194/15, the board decided that the evidence submitted failed to establish that the transfer of the business assets in the interest of which the opposition had been filed occurred only after the opposition had been filed. In the present case, in contrast, the transfer of the business assets took place after the opposition was filed, and in fact when appeal proceedings were already pending. This has not been contested by the appellant. The facts of the present case are therefore not comparable to case T 194/15.
16. In view of the above, the board was satisfied that the Agreement and the Declaration together proved that all the assets relating to the business in the interest of which the opposition had been filed had been transferred to AbbVie as sole transferee.

17. Accordingly, the board decided that the requested transfer of opponent status from Abbott to AbbVie could be allowed, and the appeal proceedings were continued with AbbVie as a party (opponent 03/respondent III).

Main request

Article 123(2) EPC

18. The main request consists of a sole claim which is a combination of independent claim 3 and dependent claim 16 as granted (see section X above for the complete wording of claim 1).
19. The board notes that no objections under Article 100(c) EPC were raised in the opposition proceedings against the subject-matter of claim 16 as granted. The sole feature of claim 3 as granted to which the respondents have maintained objections in the appeal proceedings - the anti-human tumor necrosis factor- α monoclonal antibody - has now been replaced by the feature "cA2" (see also sections V and VII above). Accordingly, there are no outstanding objections under Article 123(2) EPC against the subject-matter of claim 1.
20. The board is satisfied that the application as filed provides a basis for the subject-matter of claim 1 as follows: page 4, lines 8 to 18 in combination with the disclosure on page 17, line 29 to page 18, line 3 and page 22, lines 6 to 8 and 11 to 13, in association with page 38, lines 5 to 7 and page 39, lines 6 to 7.

21. The main request fulfils the requirements of Article 123(2) EPC. The appeal is thus allowable.

Remittal to the opposition division

22. The decision under appeal was based on only one of the grounds of opposition relied on by the opponents, namely that the subject-matter of the European patent extended beyond the content of the application as filed (Article 100(c) EPC). The opposition division did not decide on the other grounds of opposition put forward - exclusion from patentability, lack of novelty, lack of inventive step and insufficiency of disclosure (see section III above).
23. Under Article 111(1) EPC, when deciding on an appeal after examining its allowability, the board may either exercise any power within the competence of the department which took the decision appealed or remit the case for further prosecution.
24. In a case such as the present one, where the opposition division has dealt with only one of the grounds of opposition, the board considers it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the opposition division for further prosecution, thereby giving the parties the possibility of having their case heard by two instances. Moreover, the appellant has requested remittal and the respondent is in agreement with that.

Order

For these reasons it is decided that:

1. The request for transfer of the status as opponent from Abbott Laboratories to AbbVie Inc. is allowed.
2. The decision under appeal is set aside.
3. The case is remitted to the opposition division for further prosecution on the basis of the set of claims of the main request filed with the letter of 25 February 2013.

The Registrar:

The Chairwoman:



P. Cremona

G. Alt

Decision electronically authenticated