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**Datasheet for the decision
of 21 July 2014**

Case Number: T 0290/10 - 3.3.01

Application Number: 97946484.9

Publication Number: 0938315

IPC: A61K31/47, A61K31/435,
A61P37/08, A61P31/08,
A61P33/00, A61P37/00, A61P31/04

Language of the proceedings: EN

Title of invention:

IMMUNE RESPONSE MODIFIER COMPOUNDS FOR TREATMENT OF TH2
MEDIATED AND RELATED DISEASES

Patent Proprietor:

MINNESOTA MINING AND MANUFACTURING COMPANY

Opponent:

Telormedix SA

Headword:

imidazoquinoline amines/3M

Relevant legal provisions:

EPC 1973 Art. 100(a), 100(b), 87(1)
RPBA Art. 12(4), 15(3)

Keyword:

Request for decision in written proceedings - refused
Submissions and documents alleged to be late filed-
filed within the extended time period
Earliest priority claimed -
not valid for the claims of all requests
Main request, first and second auxiliary requests: inventive
step (no) -
obvious application of a known drug for its known purpose
Third auxiliary request: inventive step (yes)

Decisions cited:

T 0270/90, T 0352/07

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 0290/10 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 21 July 2014

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
15 December 2009 concerning maintenance of the
European Patent No. 0938315 in amended form.**

Composition of the Board:

Chairman A. Lindner
Members: C. M. Radke
T. Karamanli

Summary of Facts and Submissions

I. The patent in suit, published as EP-B9-0 938 315, relates to the use of immune response modifiers selected from imidazoquinoline amines for the preparation of a pharmaceutical composition for the treatment of certain diseases.

II. Both the patent proprietor and the only opponent appealed the interlocutory decision of the opposition division posted on 15 December 2009, maintaining the patent in suit in amended form with claims 1 to 5 and description pages 2 to 7 and 9 to 14 according to the third auxiliary request submitted during oral proceedings of 10 November 2009 before the opposition division.

Hereinafter, the appellant/patent proprietor will be denoted as patent proprietor, and the appellant/opponent as opponent.

III. The opposition was directed against the patent as a whole and was based on grounds under Article 100 (a) (alleged lack of novelty and of inventive step), (b) and (c) EPC.

IV. In particular, the opposition division rejected

- the main request as the deletion of the feature "in an amount effective to inhibit TH2 cell mediated immune response" in claim 3 contravened the requirements of Article 123(2) EPC;
- the first auxiliary request because the invention defined in claim 3 was not sufficiently disclosed; and

- the second auxiliary request as the subject-matter of claims 2 and 3 did not involve an inventive step in view of document (D3) as such.
- V. With a letter dated 21 April 2010 the opponent filed its statement setting out the grounds of appeal.
- VI. With a letter of 26 April 2010 the patent proprietor filed its statement setting out the grounds of appeal, together with claims according to a main and first to third auxiliary requests and an amended page 3 of the description.
- VII. With communications of the registrar of the board dated 6 May 2010 a copy of the statement setting out the grounds of appeal of each appellant was sent to the respective respondent and a time limit of four months for reply was set.
- VIII. With a letter dated 10 September 2010 the opponent filed its reply within the four-month time limit set by the registrar's communication.
- IX. With a letter dated 16 September 2010 the patent proprietor requested an extension of the four-month time limit by two months. The requested extension was granted by a communication of the registrar of the board dated 24 September 2010. With a letter dated 16 November 2010 the patent proprietor requested a further extension of the four-month time limit by one month. The requested further extension was also allowed by a communication of the registrar of the board dated 25 November 2010.
- X. With a letter dated 16 December 2010 the patent proprietor filed its reply to the opponent's statement

- of grounds of appeal together with documents (D27) to (D29).
- XI. With a response by fax of 22 December 2010 to a telephone call of the same date from the EPO the patent proprietor resubmitted its letter dated 16 December 2010.
- XII. With a communication of the registrar of the board dated 30 December 2010 the patent proprietors' letters dated 16 and 22 December 2010 were sent to the other party.
- XIII. With a communication of the registrar of the Board of Appeal 3302 dated 19 December 2013 the parties were informed that, according to the amended business distribution scheme for the year 2013, the present case had been transferred to the Board of Appeal 3301 as from 16 December 2013.
- XIV. During the appeal proceedings, the parties based their arguments on the following documents:
- (D1) H. Shiratsuchi et al., Abstracts of the Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco/US, 17-20 September 1995, abstract G110
- (D3) A. E. Varner et al., Abstract 516, "Effects of Imiquimod on post-viral asthma-like syndrome in BN rats", one page
- (D25) Internet information concerning the index of the Journal of Allergy and Clinical Immunology, vol. 99, issue 1, part 2 (January 1997); http://www.sciencedirect.com/science?_ob=PublicationURL&_tockey=%23TOC%23..., retrieved on 17 August 2010; two pages
- (D26) A. E. Varner et al., J. Allergy Clin. Immunol.,

vol.99, no.1 (January 1997), part 2, 127-128
(i. e. the pages of the journal containing
document (D3))

(D27) WO-A-2010/089 128

(D28) WO-A-2010/088 924

(D29) PubMed Abstract of J. Moisan et al.,
Am. J. Physiol. Lung Cell Mol Physiol., 2006 May,
290(5), L987-995.

XV. The present claims are

- claims 1-10 of the main request;
 - claim 1-10 of the first auxiliary request;
 - claim 1-9 of the second auxiliary request; and
 - claim 1-5 of the third auxiliary request;
- all submitted with the statement setting out the grounds
of appeal dated 26 April 2010.

According to the patent proprietor, these requests are
identical with those on which the decision under appeal
is based, apart from a correction of a typographical
error in claim 1 of the main request and the second
auxiliary request.

- a) The independent claims of the main request read as
follows:

"1. Use of an immune response modifier compound
selected from imidazoquinoline amines for the
preparation of a pharmaceutical composition for
the treatment of a disease selected from the group
consisting of asthma and allergy."

"3. Use of an immune response modifier compound
selected from imidazoquinoline amines for the
preparation of a pharmaceutical composition for
the treatment of a non-viral and non-tumor TH2 cell

mediated disease, whereby the induction of IL-4 and/or IL-5 cytokines is inhibited, with the proviso that said disease is other than eczema."

"4. Use of an immune response modifier compound selected from imidazoquinoline amines for the preparation of a pharmaceutical composition for the treatment of eosinophilia, with the proviso that said disease is other than eczema, wherein said composition is adapted to be administered via oral or nasal inhalation."

- b) The independent claims of the first auxiliary request read as follows:

Claims 1 and 4 read as claims 1 and 4 of the main request, respectively.

"3. Use of an immune response modifier compound selected from imidazoquinoline amines, for the preparation of a pharmaceutical composition for the treatment of a non-viral and non-tumor TH2 cell mediated disease, whereby the induction of IL-4 and/or IL-5 cytokines is inhibited **wherein the pharmaceutical composition comprises an amount effective to inhibit TH2 cell mediated immune response** with the proviso that said disease is other than eczema."

- c) The independent claims of the second auxiliary request read as follows:

Claims 1 and 3 read as claims 1 and 4 of the main request, respectively.

(Claim 3 of the main request has been deleted).

- d) The independent claim of the third auxiliary request reads as follows:

Claim 1 reads as claim 1 of the main request.

(Claims 3 and 4 of the main request have been deleted).

As far as the description of the third auxiliary request is concerned, the amended page 3 of the description filed with letter dated 26 April 2010 replaces page 3 of the description pages, forming the basis of the decision under appeal.

- XVI. The arguments of the opponent which are relevant for the present decision may be summarised as follows.

The submissions of the patent proprietor dated 22 December 2010 and documents (D27) to (D29) were filed after the extended time limit to respond to the opponent's grounds of appeal and thus late filed. Therefore, they should not be admitted into the appeal proceedings.

Article 100(b) EPC

The patent in suit only mentions that "Many imidazoquinoline amine ... compounds have demonstrated potent immunostimulating, activity (see paragraph [0002]). The claims as maintained cover the use of an overwhelming number of compounds; it is impossible that all of them are useful for the treatment of asthma and allergy. It needs a research program to find out which

of the imidazoquinoline amines have immune response modulating activity (see T 352/07).

Inventive step

Documents (D25) and (D26) show that (D3) was published in January 1997.

The first priority document discloses asthma and allergy only in the context of eosinophilia. Hence, the claims as maintained by the opposition division do not enjoy the first priority claimed. Therefore, (D3) belongs to the prior art. The subject-matter related to the treatment of asthma and allergy only differs from the disclosure of document (D3) in that the latter deals with the treatment of eosinophilic airway inflammation. This is limited neither to the lung nor to virus infections, in fact, the virus is only the cause to trigger the airway inflammation. The patent in suit states that eosinophilia is a hallmark of allergies. Hence it was obvious to use imiquimod disclosed in (D3) also in the treatment of allergies involving eosinophilia.

Claim 4 of the main request relates to inhalation. The patent proprietor alleges that not every compound is suitable for inhalation. The patent claims a multitude of compounds while only showing that one compound is suitable for inhalation. Therefore, the problem is not solved over the whole breadth of the claim.

XVII. The patent proprietor's arguments as far as they are relevant for the present decision may be summarised as follows:

Article 100(b) EPC

The patent discloses imidazoquinoline amines and the disorders to be treated therewith in detail (see page 3, lines 15-22). Therefore, it contains sufficient information to enable the person skilled in the art to carry out the subject-matter of claim 3 of the main request and of the first auxiliary request. It is not sufficient for the opponent to allege that several compounds will not work. That the compounds claimed are effective against asthma and allergy in general is shown in document (D29).

Inventive step

Claim 1 enjoys the first priority claimed (see page 3, lines 15 ff. of the first priority document).

The opposition division decided that the subject-matter of claim 1 of the second auxiliary request (which is identical with the one of the main request) is inventive.

There is no hint in (D3) to administer imiquimod by oral or nasal inhalation. Not every drug is suitable for inhalation. As imiquimod has no direct effect on the airway system the direct application to the site would not have been considered to be necessary.

XVIII. The board summoned the parties to oral proceedings for 21 July 2014. Both parties stated that they would not attend the oral proceedings (see patent proprietor's letter dated 25 June 2014 and opponent's letter dated 10 July 2014).

- XIX. The patent proprietor requested in writing that the decision under appeal be set aside and that the patent be maintained in amended form according to
- the main request, the first auxiliary request or the second auxiliary request, all requests filed with letter dated 26 April 2010, or
 - on the basis of the third auxiliary request with the following documents:

Description pages:

2, 4 to 7 and 9 to 14,
filed during oral proceedings on 10 November 2009 before the opposition division, and
3, filed with letter dated 26 April 2010;

Claims:

1 to 5 according to the third auxiliary request,
filed with letter dated 26 April 2010.

The opponent requested in writing that the decision under appeal be set aside and the patent be revoked. Finally it requested a decision in written proceedings.

- XX. The oral proceedings took place in the absence of the parties. At the end of these proceedings, the chairman announced the decision of the board.

Reasons for the Decision

1. The appeals are admissible.
2. Opponent's request for a decision in written proceedings

Both parties requested oral proceedings as an auxiliary measure (see point 1.2 on page 1 of patent proprietor's letter dated 26 April 2010; see point III c) on page 7

of opponent's letter dated 10 September 2010). Hence oral proceedings before the board were appointed. Both parties subsequently stated that they would not attend the oral proceedings (see point XVIII above).

Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA) reads as follows:

"The Board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case" (see the Supplementary publication to OJ EPO 1/2014, 44-53).

Therefore, it is within the board's discretion whether or not to delay any step in the proceedings due to the absence of the parties.

In the present case, the board considered that the parties had sufficient opportunity to comment on the grounds on which this decision is based. Moreover, in the parties' letters filed after the summons to oral proceedings there was nothing that indicated that the parties wished to file further submissions or evidence. Hence, the board did not decide in written proceedings but it maintained the date of oral proceedings and announced its decision at the end of those proceedings.

3. Opponent's request that the submissions of the patent proprietor dated 22 December 2010 and documents (D27) to (D29) enclosed therewith be not admitted into the proceedings
- 3.1 The patent proprietor's reply to the opponent's grounds of appeal was electronically filed on 16 December 2010

with a letter of the same date. Hence, this reply to the other party's grounds of appeal was filed within the time limit which was set and extended twice by the former board (see points VII, IX and XII above). The re-filing of this letter by fax of 22 December 2010 does not alter the board's conclusion on the observance of the time limit for reply.

According to Article 13(1) RPBA, it is within the discretion of the board to admit and consider any amendment to a party's case **after** it has filed its grounds of appeal or reply. Since, as set out above, the patent proprietor's reply to the opponent's grounds for appeal was filed in due time, the provisions of Article 13(1) RPBA do not apply in the present case. This is not altered by the fact that, due to the several extensions of the four-month time limit for reply, the patent proprietor could also respond in its letter dated 16 December 2010 to the opponent's reply to the patent proprietor's grounds of appeal.

- 3.2 However, even if the provisions of Article 13(1) RPBA did apply in the present case, the board would have admitted the submissions and documents filed with letter dated 16 December 2010 into the proceedings, for the reasons as follow.

The criteria to be employed by the board when exercising its discretion under Article 13(1) RPBA are *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

First of all, the letter dated 16 December 2010 is a response to the opponent's arguments presented in its grounds of appeal and its further letter dated

10 September 2010. The three documents introduced therewith are to provide evidence as to why the opponent's arguments were not deemed to be conclusive.

The opponent did not argue that these submissions were complex nor has the board reasons to consider the submitted letter of seven pages and the three documents to be complex. Since they were duly filed within the (extended) time limit set for reply to the opponent's grounds of appeal, they were filed early in the appeal proceedings. The opponent had also an opportunity to respond to the submissions and documents and the board could also take these submissions into account when summoning the parties to oral proceedings. Hence, the admission of these submissions and documents into the present appeal proceedings did not affect the procedural economy.

Since the patent proprietor's letter dated 16 December 2010 is a direct response to the opponent's arguments presented in its grounds of appeal and in its further letter dated 10 September 2010, the board had no discretion under Article 12(4) RPBA not to admit the submissions and documents filed with said letter into the appeal proceedings.

4. Article 100(b) EPC 1973

4.1 The following is a citation from decision T 270/90 (OJ EPO 1993, 725, point 2.1 of the Reasons):

"As far as each of the parties to the proceedings is concerned, they carry the separate burdens of proof of any fact they allege."

4.2 The opponent argued that it was impossible that all the imidazoquinoline amines were useful for the treatment of asthma and allergy. However, the opponent has not provided any evidence in support of these arguments; it referred to decision T 352/07 of 4 February 2010 in support of its argument. First of all, the objected feature in T 352/07, a "platinum compound having antitumor effects", was much more generally defined than the "imidazoquinoline amines" of present claim 1. Finally, further functional features, namely the tumor to be treated and the antibodies to be used, played also a role in the decision that the requirements of Article 83 EPC were not met (see point 4.2 of the Reasons of T 352/07). Hence, the case to be decided in T 352/07 is not comparable to the present one.

4.3 For these reasons and in the absence of any further objection of insufficient disclosure, the board concludes that the ground for opposition under Article 100(b) EPC 1973 does not prejudice the maintenance of the patent.

5. Priority

The patent in suit claims the priorities of

- U.S. patent application No. 60/029,301 filed on 25 October 1996, and
- U.S. patent application No. 60/045,331 filed on 1 May 1997.

As is evident from documents (D25) and (D26), the abstract (D3) was published in January 1997 (see, e. g., the date indicated in the header on page 128 of (D26)). Therefore, document (D3) is considered as prior art according to Article 54(2) EPC 1973 if and to the

extent that the present claims do not enjoy the priority of 25 October 1996.

Hence, it has to be assessed to which extent the present claims enjoy said priority. In the following, U.S. patent application No. 60/029,301 is denoted as the first priority document.

5.1 Claim 1 of the main request

Whereas the opponent argued that the first priority document disclosed asthma and allergy only in the context of eosinophilia, the patent proprietor considered that the treatment of these diseases was disclosed on page 3, lines 15 ff. of said document (see points XVI and XVII above).

The passage cited by the patent proprietor reads as follows:

"These observations are important since it is clear that certain diseases are actually TH2-mediated diseases. The hallmark of some of these diseases is over-production of IgE and eosinophilia.

These conditions include **asthma, allergy, ...**" (emphasis added by the board).

Due to the fact, that a new paragraph starts with the sentence "These conditions include asthma, allergy ...", it is indeed not absolutely clear whether these "conditions" refer to the "over-production of IgE and eosinophilia" or to other parts of the previous paragraph.

Therefore, this citation has to be interpreted in the light of the first priority document as a whole.

In the remaining parts of the first priority document, asthma is mentioned

- in the first paragraph of page 1 and in line 3 of page 2 ("... for example, asthma caused by pulmonary eosinophilia");
- on page 4, lines 1-3 ("Treatment of asthma and other diseases ... Chronic pulmonary inflammation involving eosinophil infiltration is a characteristic hallmark feature of bronchial asthma."); and
- in the third paragraph on page 5 ("... will be useful for the treatment of atopic diseases associated with eosinophilia such as asthma ...").

In all these parts of the first priority document, asthma is associated with eosinophilia. Therefore, it is apparent to the person skilled in the art that also the passage on page 3 cited above refers to asthma associated with eosinophilia.

Hence, claim 1 of the main request which refers to asthma in general does not enjoy the first priority under Article 87(1) EPC 1973.

5.2 Claim 3 and 4 of the main request

The feature "whereby the induction of IL-4 and/or IL-5 cytokines is inhibited" of claim 3 is not disclosed in the first priority document (see the last sentence of the chapter "Conclusion" on page 5 which mentions "through inhibition of IL-4 **and** IL-5 production and thus eosinophilia"; see also the last sentence on page 3; see

page 2, 2nd para., lines 9 ff which mentions as examples IL-3, IL-4, IL-5 and GM-CSF).

The first priority document also does not mention eczema (see present claims 3 and 4), let alone the feature "oral or nasal inhalation" in present claim 4 (note that the term "aerosol inhalation" disclosed in the first priority document on page 5, line 3 of the second paragraph is limited to aerosols).

5.3 Hence, independent claims 1, 3 and 4 of the main request do not enjoy the first priority.

6. Main request, first and second auxiliary requests - inventive step

6.1 As can be seen from point XV a) above, claim 4 of the main request concerns the oral or nasal inhalation of imidazoquinoline amines. It is identical with claim 4 of the first auxiliary request and claim 3 of the second auxiliary request.

6.2 As stated under point 5.2 above, this claim does not enjoy the first priority claimed. Consequently, document (D3) belongs to the state of the art under Article 54(2) EPC 1973 for this claim.

Document (D3) draws the conclusion from the experiments disclosed therein that imiquimod "may be an effective agent in the treatment of chronic eosinophilic airway inflammation" (see the last sentence of the document).

Imiquimod is one of the two most preferred active agents according to the patent in suit (see paragraph [0012] on page 3).

The subject-matter of claim 4 of the main request (and claim 4 of the first auxiliary request and claim 3 of the second auxiliary request) differs from the one disclosed in document (D3) in that the latter does not disclose oral or nasal inhalation. An unexpected effect of nasal or oral inhalation as compared to other modes of application has not been demonstrated by the patent proprietor.

- 6.3 The problem to be solved in view of document (D3) is therefore the provision of a different kind of administration of imiquimod.
- 6.4 Pharmaceutical compositions against chronic airway inflammations in the form of sprays for inhalation are most common (e. g. corticoid sprays against asthma, nasal sprays against allergic rhinitis). The fact that not every drug is suitable for oral or nasal inhalation would not have prevented the person skilled in the art from trying the obvious, i. e. from testing whether imiquimod is effective against chronic eosinophilic airway inflammations when inhaled nasally or orally.
- 6.5 Therefore, it was obvious for the person skilled in the art to administer imiquimod by oral or nasal inhalation in order to treat chronic eosinophilic airway inflammations and thus to make use of the teaching of claim 4 of the main request, claim 4 of the first auxiliary request and claim 3 of the second auxiliary request.
- 6.6 The board can only decide on a request as a whole. For this reason, the main request, the first and the second auxiliary request were not allowed.
7. Third auxiliary request

- 7.1 The only independent claim of this request is identical with claim 1 of the main request. This claim does not enjoy the first priority (namely that of 25 October 1996; see point 5.1 above). Consequently, document (D3), which was published in January 1997, forms part of the state of the art for this claim.
- 7.2 Document (D3) suggests that imiquimod "may be an effective agent in the treatment of chronic eosinophilic airway inflammation" (see the last sentence of the document).
- 7.3 Claim 1 of the third auxiliary request is a Swiss-type claim related to "the treatment of a disease selected from the group consisting of asthma and allergy".
- 7.4 The subject-matter of this claim differs from the one disclosed in document (D3) in that (D3) does not disclose the treatment of asthma and/or allergy.
- 7.5 The problem to be solved by the subject-matter of this claim in view of document (D3) may be considered as the provision of a new therapeutic application of imiquimod or other imidazoquinoline amines. In view of the data found in the patent in suit, the board is satisfied that the imidazoquinoline amines are indeed effective in the treatment of asthma and/or allergies.
- 7.6 The opponent argued that the use for the treatment of asthma and allergy was obvious as the patent in suit states that eosinophilia "is a hallmark of many TH2 mediated diseases, such as asthma, allergy, and atopic dermatitis" (see page 2, line 41).

7.7 However, neither is there any indication in the patent in suit that it was generally known to the person skilled in the art that eosinophilia is a hallmark of asthma and allergy, nor has the opponent provided any evidence in this respect. As to its burden of proof, reference is made to point 4.1 above.

Nor has the board found any evidence to this respect in the documents the parties relied upon during the appeal proceedings (see point XIV above).

7.8 For these reasons, the board proceeds from the fact that the person skilled in the art having read document (D3) would not have considered the use of imiquimod or other imidazoquinoline amines for the treatment of asthma or allergy.

7.9 Hence, the subject-matter of claim 1 of the third auxiliary request is based on an inventive step. The same applies to the remaining claims of this request as they are dependent from claim 1.

7.10 Further objections were not raised against the claims of this request.

7.11 Neither did the opponent object against the description adapted to the claims of this request, nor has the board found any reason to do so.

7.12 Hence, the patent as amended according to the third auxiliary request meets the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of the following documents:

Description pages:

2, 4 to 7 and 9 to 14, filed during oral proceedings on 10 November 2009 before the opposition division, and 3, filed with letter dated 26 April 2010;

Claims:

1 to 5 according to the third auxiliary request, filed with letter dated 26 April 2010.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated