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Datasheet for the decision of 15 September 2009

Case Number: W 0007/09 - 3.3.04

Application Number: PCT/EP2007/005620

Publication Number: WO2009000296

IPC: A61K 38/00

Language of the proceedings: EN

Title of invention:
TPP II Inhibitors for use in the treatment of autoimmune and inflammatory diseases and transplant rejection

Applicant:
OncoReg AB et al.

Headword:
TPP II Inhibitors/ONCOREG

Relevant legal provisions:
PCT Art. 17(3)(a)
PCT R. 13.1, 13.2, 40.1, 40.2(c)

Keyword:
"Lack of unity - no"

Decisions cited:
G 0001/89, W 0016/08

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: W 0007/09 - 3.3.04

International Application No. PCT/EP2007/005620

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 15 September 2009

Applicant: OncoReg AB et al.
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Decision under appeal: **Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 30 May 2008.**

Composition of the Board:

Chair: U. Kinkeldey
Members: G. Alt
T. Bokor

Summary of Facts and Submissions

I. International patent application No. PCT/EP 07/005620 was filed with fifty three claims relating to the treatment with tripeptidyl-peptidase II (TPP II) inhibitors of autoimmune or inflammatory disorders or transplant rejection and to the screening for tripeptidyl-peptidase II (TPP II) inhibitors.

II. The European Patent Office (EPO), acting in its capacity as an International Searching Authority (ISA) under Article 16 PCT and Article 154 EPC informed the applicant in an invitation pursuant to Article 17(3)(a) PCT and Rule 40.1 PCT that the application did not comply with the requirement of unity of invention (Rule 13.1 PCT) and invited the applicant to pay fees for the search of three additional inventions.

III. In the invitation to pay additional fees the ISA stated:

"The features "compound for use" and "TPP II inhibitor" of claim 1 are known from document WO03/105835:

The common concept linking together the independent claims 1, 35, 37, 38, 44-53 is the following: use of TPP II inhibitors in medicine as well as screening for TPP II inhibitors in order to use them in medicine.

This common concept is not novel, see document WO03/105835, page 3, line 15 to page 6, line 12 where TPP II inhibitors are used in the treatment of cancer and where the screening for an inhibitor of TPP II is disclosed.

The requirement for unity of invention is not fulfilled."

IV. The ISA found that the application was directed to four inventions, namely (in the order set out in the invitation to pay additional fees) to the "use of TPP II inhibitors for treating an autoimmune disease" (hereinafter referred to as "invention 1"), to the "use of TPP II inhibitors for treating an inflammatory disease"(hereinafter referred to as "invention 2"), to the "use of TPP II inhibitors for treating a transplant rejection"(hereinafter referred to as "invention 3") and to the "use of TPP II inhibitors for treating atherosclerosis"(hereinafter referred to as "invention 4").

V. With a letter dated 20 June 2008, the applicant paid the three additional search fees under protest (Rule 40.2(c) PCT). He requested that all the additionally paid fees be refunded.

It was inter alia stated in the letter that passages in the present application supported "the grouping of the four therapeutic applications into a single general inventive concept. In particular, page 2, lines 23 to 26 and page 8, lines 12 to 14, 21 to 25 and 27 to 32 refer to the link between the diseases, and page 6, lines 1 to 26 and page 7, lines 1 to 3 refer to the central role of the PI3K/Akt pathway."

VI. On 16 February 2009, the ISA invited the applicant to pay a protest fee and informed the applicant that a prior review of the justification for the invitation to

pay additional fees had confirmed that the invitation to pay such fee was justified.

In the annex the invitation to pay the protest fee the review panel noted that "the existence of TPP II inhibitors has been known at least since 1995" and that "it is immediately apparent that the "treatments of (1) autoimmune disease or (2) inflammatory disease or (3) transplant rejection or (4) atherosclerosis have nothing in common with each other." Therefore, the subject-matter of the claims lacked unity a priori. Moreover, since the use of TPP II inhibitors for the treatment of medical disorders was known from document WO 03/105835, the subject-matter of the claims also lacked unity a posteriori.

VII. The applicant paid the protest fee with a fee voucher included in a letter dated 12 March 2009.

Reasons for the decision

1. Given that the international application under consideration has an international filing date of 25 July 2007, the protest is subject to the provisions of the PCT as in force from 1 April 2007. The boards of appeal are responsible for deciding on protests relating to international applications pending at the time of entry of the EPC 2000. Details of the procedure are guided by the Decision of the President of the EPO dated 24 June 2007, Article 3 (OJ EPO 2007, Special Edition No. 3, 140), see also W 16/08 of 11 September 2008, point 1.1 to 1.5 of the reasons.

2. The invitation under Article 17(3)(a) PCT to pay additional fees is reasoned in accordance with Rule 40.1 PCT.

3. The protest against the invitation by the ISA to pay additional fees was filed in time, is reasoned and is hence admissible.

4. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Having regard to decision G 1/89 of the Enlarged Board of Appeal (OJ EPO 1991, 155), the ISA can raise an objection of lack of unity "*a posteriori*", i.e. after having taken the prior art into consideration.

5. According to Rule 13.2 PCT, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

6. If the ISA considers that the subject-matter of the claims lack unity of invention, it is empowered, under Article 17(3)(a) PCT, to invite the applicant to pay additional fees.

7. In view of Rule 40.2(c) PCT the objective of the examination of a protest against an invitation of the

ISA to pay additional search fees is to decide whether or not the ISA's invitation to pay additional fees was justified and whether or not, therefore, the additional fees paid by an applicant upon invitation by the ISA have to be reimbursed.

8. The question to be decided by the board in the present protest procedure is therefore whether or not the subject-matter of inventions 2 to 4 and that of invention 1 (see section IV above) are so linked as to form a single general inventive concept.

9. The PCT Guidelines state in Chapter 10.01 that the determination if the inventions in an international application are so linked as to form a single general inventive concept is "made on the contents of the claims as interpreted in the light of the description and drawings (if any)".

10. It can be taken from the description of the present application that the Pl3K/Akt pathway is thought to be involved in autoimmune and inflammatory diseases as well as in transplant rejection (page 6, lines 4 and 5 and lines 10-15). It is also derivable from the application that these disorders involve signal transduction from growth factor receptors and that the activation of Akt kinase is one component of this signalling pathway (page 6, lines 4 to 7).

Phosphorylation of the serine residue at position 473 of the Akt kinase is an event which induces its full activation (page 6, lines 6 and 7) and which requires signalling by the mammalian target of rapamycin (mTOR), a member of the Pl3K family of kinases (page 6, lines 9

to 10). On the other hand, mTOR controls TPP II expression (page 6, lines 10 to 11).

It is stated at the top of page 6:

"Without wishing to be bound by theory, the efficacy of the present invention is believed to be a consequence of the link between TPP II inhibition and the Pl3K/Akt pathway."

Furthermore it is stated at the top of page 7:

"Thus, we have recognized that the Pl3K/Akt pathway can be targeted for the purpose of down regulating the immune activation, thereby enabling therapy in auto-immune and inflammatory disease."

11. In view of the disclosure in the description as recited in paragraph 10 above, the board considers that all the four inventions defined by the ISA (section IV above) concern a priori a common concept, i.e. the treatment with TPP II inhibitors of medical disorders in which the Pl3K/Akt pathway is involved.

12. An a posteriori non-unity could arise if this concept had already been part of the prior art. In the invitation to pay additional fees, the ISA has argued that the application lacked unity of invention, because the common concept, which was seen in the "use of TPP II inhibitors in medicine as well as screening for TPP II inhibitors in order to use them in medicine" was considered not novel in view of document WO 03/105835 which disclosed the use of TPP II inhibitors in the treatment of cancer.

13. Document WO 03/105835 discloses that in Burkitt's lymphoma the proteasome machinery has been shown to be impaired and that this defect is compensated by an upregulation of alternative proteolytic pathways, for example tripeptidyl petpidase II (page 9, lines 17-19). It is therefore suggested that TPP II inhibitors might be able to selectively inhibit the growth of Burkitt's lymphoma and other cancer cells. It is shown in the document that growth and soft agar colony formation of cancer cells are inhibited by butabindide, a TPP II inhibitor (page 10, lines 6 to 9).

The document is silent about an involvement of the PI3K/Akt pathway in cancer development.

14. Accordingly, document WO 03/105835 does not disclose the common concept as defined by the board above, i.e. the treatment with TPP II inhibitors of medical disorders in which the Pl3K/Akt pathway is involved. Consequently, contrary to the finding of the ISA, there is a common concept to which all four defined inventions relate and which is novel.

15. Unity of invention can furthermore be at stake if the claimed subject-matter does not involve an inventive step because this equally may take away an a priori present common concept. According to decision G 1/89 (supra), restraint should however be exercised in the assessment of novelty and inventive step and in borderline cases it should be refrained from considering an application as not complying with the requirement of unity of invention on the ground of lack of novelty or inventive step.

16. Since in the present case the ISA considered that the concept underlying the application was not novel, it was not necessary for the ISA to further assess the common concept from the point of view of the inventive step.

In the board's view, prima facie, none of the documents cited in the partial international search report annexed to the invitation to pay additional fees, either alone or in combination, alludes to the treatment of diseases in which the PI3K/Akt pathway is involved. The board considers therefore that the present case cannot be considered as a straightforward one in which as assessment of inventive step should be made in the context of unity of invention.

17. In view of the above considerations therefore and having regard to Rule 13.2 PCT, the board considers that there is a technical relationship among the subject-matter of inventions 1 to 4 as defined by the ISA. Consequently, the requirement of unity is fulfilled.

Order

For these reasons it is decided that:

1. The three additional search fees are reimbursed.

2. The protest fee is reimbursed.

The Registrar: The Chair:

P. Cremona U. Kinkeldey