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Case Number: W 0005/09 - 3.3.04

Application Number: PCT/US 2007/015298

Publication Number: WO 2008/105797

IPC: C07K 14/43

Language of the proceedings: EN

Title of invention:
Polynucleotides encoding novel PCSK9 variants

Applicant:
Bristol-Myers-Squibb Company

Headword:
PCSK9 variants/BRISTOL-MYERS SQUIBB

Relevant legal provisions:
PCT Art. 17(3)(a)
PCT R. 13, 40
EPC Art. 154

Keyword:
"Invitation to pay additional fees - sufficiently reasoned - (no)"
"Refund of additional search fee, refund of protest fee - (yes)"

Decisions cited:
W 0004/85

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: W 0005/09 - 3.3.04

International Application No. PCT/US 2007/015298

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 7 July 2009

Applicant: Bristol-Myers Squibb Company
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Decision under appeal: **Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the Applicant against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 30 September 2008.**

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
T. Bokor

Summary of Facts and Submissions

I. International patent application no. PCT/US2007/015298 having the title "Polypeptides encoding novel PCSK9 variants" was filed on 29 June 2007 with twenty-two claims.

Claims 1, 21 and 22 read as follows:

"1. An isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence selected from the group consisting of:

(a) a polynucleotide encoding amino acids 1 to 315 of SEQ ID NO:2 or the PCSK9-b cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:1;

(b) a polynucleotide encoding amino acids 2 to 315 of SEQ ID NO:2 or the PCSK9-b cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:1;

(c) a polynucleotide encoding amino acids 2 to 284 of SEQ ID NO:2 or the PCSK9-b cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:1;

(d) a polynucleotide encoding amino acids 16 to 315 of SEQ ID NO:2 or the PCSK9-b cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:1;

(e) a polynucleotide encoding amino acids 1 to 523 of SEQ ID NO:4 or the PCSK9-c cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:3;

(f) a polynucleotide encoding amino acids 2 to 523 of SEQ ID NO:4 or the PCSK9-c cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:3;

(g) a polynucleotide encoding amino acids 2 to 306 of SEQ ID NO:4 or the PCSK9-c cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:3;

(h) a polynucleotide encoding amino acids 16 to 523 of SEQ ID NO:4 or the PCSK9-c cDNA sequence included in ATCC^{R} Deposit No: PTA-7622, which is hybridizable to SEQ ID NO:3; and

(i) the complete complementary sequence of (a), (b), (c), (d), (e), (f), (g), or (h).

21. An isolated polynucleotide comprising, or alternatively consisting of, an N-terminally truncated form of PCSK9 provided as SEQ ID NO:5, and wherein said truncated form has an elevated level of biological activity relative to the wild-type PCSK9.

22. The isolated polynucleotide according to Claim 21, wherein said truncation is between about 1 to about 218 amino acids of SEQ ID NO:5."

II. On 30 September 2008, the European Patent Office (EPO) acting in its capacity as International Searching Authority (ISA) under Article 16 PCT and Article 154 EPC, informed the Applicant that the application did not comply with the requirement of unity of invention (Rule 13.1) and invited the Applicant to pay within a time limit of one month eight additional search fees in accordance with Article 17(3)(a) PCT and Rule 40.1. PCT.

III. In the invitation to pay additional fees, the ISA defined the nine inventions to which the application related as follows:

"1. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 1 to 315 of SEQ ID NO:2;

2. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 2 to 315 of SEQ ID NO:2;

3. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 2 to 284 of SEQ ID NO:2;

4. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 16 to 315 of SEQ ID NO:2;

5. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 1 to 523 of SEQ ID NO:4;

6. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 2 to 523 of SEQ ID NO:4;

7. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 2 to 306 of SEQ ID NO:4;

8. claims 1-20 (all partially)
relates to an isolated polypeptide comprising amino acids 16 to 523 of SEQ ID NO:4;

9. claims 21-22
relates to an N-terminally truncated form of PCSK9 provided as SEQ ID NO:5"

The ISA stated that there was non-unity *a posteriori*, since prior art document WO 2004/097047 disclosed mutations in the human PCSK9 gene. Claim 15 thereof disclosed a mutant form which comprised "a fragment 100% identical to the residues 6-523 of SEQ ID NO:4 of the current application." The ISA defined the technical problem underlying the invention to be the provision of alternative mutants of PCSK9. The solutions to this problem provided by the application were the molecules PCSK9b and PCSK9c, their truncation mutants and truncation mutants of PCSK9 provided as SEQ ID NO:5. However, in the light of the disclosure in WO 2004/097047, the ISA concluded that the general concept of providing alternative mutants of PCSK9 was not novel and could not therefore serve as a special technical feature according to Rule 13(2) PCT. Since there was no further special technical feature, the

application was considered to contain nine different inventions.

IV. The communication of 30 September 2008 also contained the results of the partial international search.

V. With letter dated 30 October 2008, the Applicant authorized the ISA to charge his deposit account for the payment of two additional search fees for the subject-matter identified by the ISA as inventions 5 and 9. Only the search fee for invention 5 was paid under protest pursuant to Rule 40.2(c) PCT.

The Applicant argued that the requirement of unity of invention was fulfilled for inventions 1 and 5 as they referred to novel splice variant forms of the PCSK9 protein which shared a novel N-terminus which distinguished them from the known PCSK9 protein. The prior art document WO 2004/097047, which disclosed point mutations of PCSK9, did not represent a basis for establishing lack of unity amongst inventions 1 and 5. Inventions 1 and 5 did not represent point mutation mutants of PCSK9, nor did they represent point mutations relative to each other, but rather represented a unified concept as a result of their shared novel N-terminus which was not resident within the known PCSK9 protein.

VI. On 26 February 2009, the ISA invited the Applicant to pay a protest fee and informed the Applicant that a prior review according to Rule 40.2(e) PCT had reached the conclusion that the invitation to pay additional search fees was justified.

In point 6.3 of this prior review the ISA stated that prior art document WO 2004/097047, relied on in the invitation to pay additional fees (see section (III) above) was "not used to establish lack of unity amongst inventions 1 and 5, but rather for establishing lack of unity of inventions 1-9 of the application".

Nevertheless, the requirement of unity of invention was not fulfilled for inventions 1 and 5 as the ISA was aware of a further prior art document disclosing a splice variant form of PCSK9 having the same N-terminus as SEQ ID NOs:2 and 4, which therefore was no special technical feature as argued by the Applicant. This further prior art document, GENBANK^{R} Accession No: gi¦AK124635, was mentioned on page 20, lines 6-7 and in figures 3A-C of the application. "In the light of the disclosure in the application, there was no need for ISA to discuss whether the N-terminal part of SEQ ID NO:2 and SEQ ID NO:4 is a special technical feature. Using the splice variant disclosed in GENEBANK (*sic)* Accession No: gi¦AK124635 for argumentation has become necessary only in reply to the arguments brought forward by the applicant that inventions 1 and 5 represent novel splice variant forms of PCSK9 sharing a novel N-terminus."

Thus, the non-unity objection with regard to invention 5 was maintained.

VII. With letter of 4 March 2009, the Applicant authorized the ISA to charge its deposit account for the payment of the protest fee.

Reasons for the decision

1. The application was filed on 29 June 2007. Therefore, 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 PCT application pending at the time of entry into force of the EPC 2000 (13 December 2007). 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).

2. The protest fee has been paid in time and the protest contains a reasoned statement why the invention designated by the ISA as invention 5, for which an additional search fee has been paid, should fulfil the requirement of unity. Accordingly, the protest was properly made and it is admissible (Rule 40.2 (c) and (e) PCT).

3. As the additional search fee for invention 9 has not been paid under protest, the Board is only concerned with the question whether or not the invitation to pay an additional search fee in respect of invention 5 was justified.

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 inventive concept. If the ISA considers that the claims lack this unity, it is empowered, under Article 34(3) and Rule 68.2 PCT, to invite the Applicant to pay additional fees.

Rule 40.1 PCT stipulates that the invitation under Article 17(3)(a) PCT to pay additional fees must specify the reasons why the international application is not considered to comply with the requirement of unity of invention. The purpose of setting out reasons is to enable the Applicant (and the Board in case of a protest) to examine whether the invitation was justified.

5. In decision W 4/85 (OJ EPO 1987, 63) and many subsequent decisions, the Boards of Appeal expressed the view that the requirement to give reasons in an invitation pursuant to Article 17(3)(a) PCT was so fundamental that an unsubstantiated invitation could be regarded as legally ineffective.

6. In the invitation to pay additional fees, the only reason given by the ISA was, that prior art document WO 2004/097047 disclosed the general inventive concept involving the only common special technical feature of inventions 1 to 9, namely the provision of alternative mutants of PCSK9 (see section (III) above).

7. After having considered the arguments provided by the Applicant with the letter dated 30 October 2008, that the special technical feature forming a technical relationship among inventions 1 and 5 was the commonly shared N-terminus of the claimed PCSK9 mutant proteins, the ISA, in the result of the prior review according to Rule 40.2(e) PCT stated, that prior art document WO2004/097047 was not used to establish lack of unity amongst inventions 1 and 5 and referred for this purpose to another, freshly introduced prior art document (see section (VI) above).

8. As this was the only reason, given by the ISA in the invitation under Article 17(3)(a) PCT to pay additional fees, why inventions 1 to 9, and thus also inventions 1 and 5, were not so linked as to form a single general inventive concept, this has the consequence that the invitation under Article 17(3)(a) PCT, at least with regard to invention 5, is unsubstantiated and therefore legally not effective.

New reasons and evidence cannot be raised by the review panel against the Applicant, and thus cannot cure the deficiencies of the invitation under Article 17(3)(a) PCT (see Case Law of the Boards of Appeal of the EPO, 5th edition 20006, chapter IX.C.3.3.2(a)).

9. The invitation to pay does not meet the requirements of Rule 40.1 PCT, and therefore does not provide a basis for retaining the additional search fee paid under protest.

Order

For these reasons, it is decided that:

1. The refund of one additional search fee paid by the Applicant under protest is ordered.

2. The protest fee shall be refunded.

The Registrar: The Chair:

P. Cremona U. Kinkeldey