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D E C I S I O N
of 27 October 2004

Case Number: W 0026/03 - 3.3.4

Application Number: PCT/ EP 02/08942

Publication Number: WO 03014145

IPC: CO7K 4/00

Language of the proceedings: EN

Title of invention:
Peptides that bind to atherosclerotic lesions

Applicant:
Novartis AG

Opponent:
-

Headword:
Binding peptides/NOVARTIS

Relevant legal provisions:
PCT Art. 17(2), 17(3)(a)
PCT R. 40.1, 40.2
EPC Art. 154(3)

Keyword:
"Invitation to pay additional fee - not based on invention first mentioned in the claims - defective reasoning - refund - (yes)"

Decisions cited:
W 0007/90, W 0031/90, W 0003/93, W 0004/94

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: W 0026/03 - 3.3.4

International Application No. PCT/ EP 0208942

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 27 October 2004

Applicant: Novartis AG
Corporate Intellectual Property
CH-4002 Basel (CH)

Representative: HILLEBRAND, Dirk
CH-4002 Basel (CH)

Decision under appeal: **Protest according to Rule 68.3(c) of the Patent Cooperation Treaty made by the applicants against the invitation of the European Patent Office (International Searching Authority) to restrict the claims or pay additional fees dated 2 June 2003.**

Composition of the Board:

Chairwoman: U. Kinkeldey
Members: G. Alt
B. Günzel

Summary of Facts and Submissions

I. International patent application PCT/ EP 02/08942 was filed on 9 August 2002 with 49 claims.

Independent claims 1 and 7 read:

"1. An isolated peptide having any one of formulae I-IV:

Xaa_1-Xaa_2-Xaa_3-Xaa_4-Xaa_5-Xaa_6 (I)

Xaa_1-Xaa_2-Xaa_3-Xaa_4-Xaa^5-Xaa_6-Xaa_a (II)

Xaa_a-Xaa_1-Xaa_2-Xaa_3-Xaa_4-Xaa_5-Xaa_6 (III)

Xaa_a-Xaa_1-Xaa_2-Xaa_3-Xaa_4-Xaa_5-Xaa_6-Xaa_a (IV)

wherein Xaa_1 is an aliphatic amino acid;
wherein Xaa_2, Xaa_3 and Xaa_4 are separately each an apolar amino acid;
wherein Xaa_5 and Xaa_7 are separately each a polar amino acid;
wherein Xaa_6 is a basic amino acid;
wherein Xaa_a is a cysteine-like amino acid;
and wherein the peptides can bind with specificity to a biomolecule or tissue in vivo."

"7. An isolated peptide comprising SEQ ID NO : 2, SEQ ID NO : 4, SEQ ID NO : 6, SEQ ID NO : 8, SEQ ID NO : 10, SEQ ID NO : 12, SEQ ID NO : 14, SEQ ID NO : 16, SEQ ID NO : 18, SEQ ID NO : 20, SEQ ID NO : 22, SEQ ID NO : 24, SEQ ID NO : 26, SEQ ID NO : 28, SEQ ID NO : 30, SEQ ID NO : 32, SEQ ID NO : 34, SEQ ID NO : 36, SEQ ID N0 : 38, SEQ ID NO : 40, SEQ ID NO : 42, SEQ ID NO : 44, SEQ ID NO : 46, SEQ ID NO : 48, SEQ ID NO : 50, SEQ ID NO : 52, SEQ ID NO : 54, SEQ ID NO : 56, SEQ ID NO : 58, SEQ ID NO : 60, SEQ ID NO : 62, SEQ ID NO : 64, SEQ ID NO :

66, SEQ D NO : 68, SEQ ID NO : 70, SEQ ID NO : 72, SEQ ID NO : 74, SEQ ID NO : 76, SEQ ID NO : 78, SEQ ID NO : 80, SEQ ID NO : 82, SEQ ID NO : 84, SEQ ID NO : 86, SEQ ID NO : 88, SEQ ID NO : 90, SEQ ID NO : 92, SEQ ID NO : 94, SEQ ID NO : 96, SEQ ID NO : 98, SEQ ID NO : 100, SEQ ID NO : 102, SEQ ID NO : 104, SEQ ID NO : 106, SEQ ID NO : 108, SEQ ID NO : 110, SEQ ID NO : 112, SEQ ID NO : 114, SEQ ID NO : 116, SEQ ID NO : 118, SEQ ID NO : 120, SEQ ID NO : 122, SEQ ID NO : 124, SEQ ID NO : 126, SEQ ID NO : 128, SEQ ID NO : 130, SEQ ID NO : 132, SEQ ID NO : 134, SEQ ID NO : 136, SEQ ID NO : 138, SEQ ID NO : 140, SEQ ID NO : 142, SEQ ID NO : 144, SEQ ID NO : 146, SEQ ID NO : 148, SEQ ID NO : 150, SEQ ID NO : 152, SEQ ID NO : 154, SEQ ID NO : 156, SEQ ID NO : 158, SEQ ID NO : 160, SEQ ID NO : 162, SEQ ID NO : 164, SEQ ID NO : 166, SEQ ID NO : 168, SEQ ID NO : 170, SEQ ID NO : 172, SEQ ID NO : 174, SEQ ID NO : 176, SEQ ID NO : 178, SEQ ID NO : 180, SEQ ID NO : 182, SEQ ID NO : 184, SEQ ID NO : 186, SEQ ID NO : 188, SEQ ID NO:190, SEQ ID NO : 192, SEQ ID NO : 194, SEQ ID NO : 196, SEQ ID NO : 198, SEQ ID NO : 200, SEQ ID NO : 202, SEQ ID NO : 204, SEQ ID NO : 206, SEQ ID NO : 208, SEQ ID NO : 210, SEQ ID NO : 212, SEQ ID NO : 214, SEQ ID NO : 216, SEQ ID NO : 218, SEQ ID NO : 220, SEQ ID NO : 222, SEQ ID NO : 224, SEQ ID NO : 226, SEQ ID NO : 228, SEQ ID NO : 230, SEQ ID NO : 232, SEQ ID NO : 234, SEQ ID NO : 236, SEQ ID NO : 238, SEQ ID NO : 240, SEQ ID NO : 242, SEQ ID NO : 244, SEQ ID NO : 246, SEQ ID NO : 248, SEQ ID NO : 250, SEQ ID NO : 252, SEQ ID NO : 254, SEQ ID NO : 256, SEQ ID NO : 258, SEQ ID NO : 260, SEQ ID NO : 262, SEQ ID NO : 264, SEQ ID NO : 266, SEQ ID NO : 268, SEQ ID NO : 270, SEQ ID NO : 272, SEQ ID NO : 274, SEQ ID NO : 276, SEQ ID NO : 278, SEQ ID NO : 280, SEQ ID NO : 282, SEQ ID NO : 284, SEQ ID NO : 286, SEQ ID NO : 288, SEQ

ID NO : 290, SEQ ID NO : 292, SEQ ID NO : 294, SEQ ID NO : 296, SEQ ID NO : 298, SEQ ID NO : 300, SEQ ID NO : 302, SEQ ID NO : 304, SEQ ID NO : 306, SEQ ID NO : 308, SEQ ID NO : 310, SEQ ID NO : 312, SEQ ID NO : 314, SEQ ID NO : 316, SEQ ID NO : 318, SEQ ID NO : 320, SEQ ID NO : 322, SEQ ID NO : 324, SEQ ID NO : 326, SEQ ID NO : 328, SEQ ID NO : 330, SEQ ID NO : 332, SEQ ID NO : 334, SEQ ID NO : 336, SEQ ID NO : 338, SEQ ID NO : 340, SEQ ID NO : 342, SEQ ID NO : 344, SEQ ID NO : 346, SEQ ID NO : 348, SEQ ID NO : 350, SEQ ID NO : 352, SEQ ID NO : 354, SEQ ID NO : 356, SEQ ID NO : 358, SEQ ID NO : 360, SEQ ID N0 : 362, SEQ ID NO : 364, SEQ ID NO : 366, SEQ ID NO : 368, SEQ ID N0 : 370, SEQ ID NO : 372, SEQ ID NO : 374, SEQ ID NO : 376, SEQ ID NO : 378, SEQ ID NO : 380, SEQ ID NO : 382, SEQ ID NO : 384, SEQ ID NO : 386, SEQ ID NO : 388, SEQ ID NO : 390, SEQ ID NO : 392, SEQ ID NO : 394, SEQ ID NO : 396, SEQ ID NO : 398, SEQ ID NO : 400, SEQ ID NO : 402, SEQ ID NO : 404, SEQ ID NO : 406, SEQ ID NO : 408, SEQ ID NO : 410, SEQ ID NO : 412, SEQ ID NO : 414, SEQ ID NO : 416, SEQ ID NO : 418, SEQ ID NO : 420, SEQ ID NO : 422, SEQ ID NO : 424, SEQ ID NO : 426, SEQ ID NO : 428, SEQ ID NO : 430, SEQ ID NO : 432, SEQ ID NO : 434, SEQ ID NO : 436, SEQ ID NO : 438, SEQ ID NO : 440, SEQ ID NO : 442, SEQ D NO : 444, SEQ ID NO : 446, SEQ ID NO : 448, SEQ ID NO : 450, SEQ ID NO : 452, SEQ ID NO : 454, SEQ ID NO : 456, SEQ ID NO : 458, SEQ ID NO : 460, SEQ ID NO : 462, SEQ ID NO : 464, SEQ ID NO : 468, SEQ ID NO : 470, SEQ ID NO : 472, or SEQ ID NO : 474, which is capable of binding to an atherosclerotic lesion in a mammal."

The application contained further independent claims.

II. On 2 June 2003 the European Patent Office, acting as an International Searching Authority (ISA), invited the applicant to pay 127 additional search fees pursuant to Article 17(3)(a) PCT and Rule 40.1 PCT.

III. The invitation identified 128 inventions, classified into seven groups of inventions.

Invention 1 was identified in claims 7 to 17(in part) and 22 to 49(in part) and was defined as "an isolated peptide comprising SEQ ID NO: 2 and which is capable of binding to an atherosclerotic lesion in a mammal; ..."

Groups of inventions 2 and 3 identified in the same claims were said to comprise inventions 2 to 124.

As the fourth group invention 125 was identified in claims 1 to 6(full), 7 to 17 (in part), 22 to 49 (in part) and was defined as follows: "An isolated peptide having any one of formulae I-IV as defined in claim 1 and which is capable of binding with specificity to a biomolecule or tissue in vivo (Obs: SEQ ID NO: 462 is of formula I as defined in claim 1); ...".

IV. The ISA reasoned that there existed an *a priori* non-unity between a peptide according to claim 1 and a peptide according to claim 7 because "a peptide having one of formulae I-IV as defined in claim 1 is different to a peptide comprising the 7-mer APGPSKS (SEQ ID NO: 2)".

V. Moreover, it was stated that there was no common concept *a posteriori* between an isolated peptide comprising SEQ ID NO: 2 and an isolated peptide

comprising e.g. SEQ ID NO: 452 as defined in claim 7 of the application. Document (1) US-A-5827516 disclosed 2 peptides, SEQ ID NOs: 245 and 246, comprising a sequence identified by SEQ ID NO: 452 of the application and thus, rendered the subject-matter of claim 7 not novel.

Another document (2), Journal of Vascular Research, vol. 32, No. 2, 1995, pages 93 to 99, Luu et al. disclosed a peptide (C.G.R.P.) that binds, *in vivo*, to atheromatous human coronary arteries.

VI. The invitation further stated in Box 3 that claims 1 to 6 had been found unsearchable under Article 17(2)(b) PCT because of defects under Article 17(2)(a) PCT and therefore had not been included within any invention.

The following information was added thereto:

"Claims 1-6 relate to an extremely large number of possible compounds/products. In fact, the claims contain so many variables that a lack of clarity (and/or conciseness) within the meaning of Article 6 PCT arises to such an extent as to render a meaningful search of the claims impossible.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the product/compound/method/apparatus by reference to a result to be achieved ("can bind with specificity to a biomolecule or tissue in vivo"). Again, a meaningful search over the whole of the claimed scope is impossible.

Consequently, the search could only be carried out for those parts of the application which do appear to be clear (and/or concise), namely an isolated peptide of formula APGPSK (SEQ ID NO: 462), which is the only peptide according to claim 1 for which a sequence listing is provided."

VII. On 2 July 2003 the applicant filed a letter setting out reasons why he disagreed with the finding of the ISA that there were 128 inventions comprised in the application.

He paid 5 additional search fees under protest for additional searches based on SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 336, SEQ ID NO: 344 and SEQ ID NO: 464.

VIII. With a notification dated 2 October 2003, a review panel within the meaning of Rules 105(3) EPC and 68.3(c) PCT commented on the points raised by the applicant and confirmed the ISA's opinion regarding lack of unity.

IX. The protest fee was paid on 30 October 2003.

Reasons for the Decision

1. The protest is admissible.

2. Pursuant to Article 154(3) EPC the Boards of Appeal of the EPO are responsible for deciding on a protest made by an applicant against the payment of an additional fee charged by the EPO under the provisions of Article 17(3)(a) PCT.

3. Pursuant to Rule 40.2(c) PCT the Boards of Appeal are empowered to examine protests against the payment of additional search fees and shall, to the extent that they find the protest justified, order the total or partial reimbursement of the additional fee.

4. According to Article 17(3)(a), first sentence, PCT if the ISA considers that the international application does not comply with the requirement of unity of invention as set out in the Regulations it shall invite the applicant to pay additional fees. Article 17(3)(a), second sentence, PCT further stipulates that the ISA shall establish the international search report on those parts of the international application which relate to the invention first mentioned in the claims ("main invention") and, provided the required fees have been paid within the prescribed time limit, on those parts of the international application which relate to inventions in respect of which additional fees were paid.

It follows therefrom that, when deciding for which of multiple inventions contained in an application the search fee already paid is to be used and for which invention(s) additional search fees are to be requested, the ISA is not free to choose at its discretion. It has the legal obligation to search for the one search fee paid for the first invention, i.e. the invention first mentioned in the claims, and it can ask for the payment of additional fees only for searching further inventions contained in the application (see e.g. decisions W 7/90 dated 19 October 1990, point 4 et seq. of the reasons and W 31/90 dated

30 November 1990, point 7 of the reasons). It also follows therefrom that the justification for asking for the payment of additional fees has to be based on the finding that there are further inventions which are non-unitary *a priori* or *a posteriori* in comparison with the invention first mentioned in the claims ("main invention").

This requirement is not a formality but an important procedural requirement which is intended to prevent the ISA from choosing arbitrarily which invention to search. It is up to the applicant to determine by the way and the order in which he drafts the claims which invention is in the context of the search to be regarded as the core of his application and shall therefore form the starting point for any search to be made.

5. In the present case the ISA has not grouped an invention first mentioned in the claims as first invention and has not prepared an international search report on it. Instead, an invention contained in claims 7 to 17(in part) and 22 to 49(in part) - an isolated peptide comprising SEQ ID NO: 2 and which is capable of binding to an atherosclerotic lesion in a mammal - was defined as the first invention, was searched, was compared with the invention classified as invention No. 125 contained in claim 1 and led to the ISA's finding that the application contained 127 inventions.

The reasons given by the ISA for this way of acting are legally defective and do not justify that an invention other than that contained in claim 1 be defined as the

first invention ("main invention") and be made the basis for the ISA's finding of non-unity in the present case.

The ISA has indicated that claims 1 to 6 had been found unsearchable under Article 17(2)(b) PCT because of defects under Article 17(2)(a) PCT and therefore had not been included with any invention. It was further stated that claims 1 to 6 related to an extremely large number of possible compounds/products and moreover, attempted to define the product/compound by reference to a result to be achieved. The resulting lack of clarity/conciseness within the meaning of Article 6 PCT arose to such an extent as to render a meaningful search over the whole of the claimed scope impossible.

However, the ISA's conclusion that claims 1 to 6 were unsearchable is contradicted by its own statement that a sequence with SEQ ID NO: 462, enumerated in claim 7, fell within the definition of the formulae contained in claim 1. Thus, as the ISA explicitly recognises, some kind of subject-matter of claim 1 could be clearly defined and it appears from the ISA's own reasoning that with a reasonable amount of effort, a meaningful search of parts of subject-matter contained in claim 1 could have been made. It is not a requirement of Article 17(2)(a)(ii) PCT that the search must be possible with respect to the whole scope of the claim, as the ISA has put it. On the contrary, as is also explained in the PCT International Search Guidelines (as in force from 18 September 1998, VIII, 2.1) which are binding on the EPO, it derives from Article 17(2)(b) PCT that even where the international application contains obscurities, making it impossible

to arrive at a reasonable conclusion as to the scope of the claimed invention, the ISA should make a meaningful search to the extent that this is possible.

The reasons given by the ISA do not therefore provide a legal basis for ignoring the "main invention", i.e. an invention first mentioned in the claims and for defining an invention contained in independent claim 7 as the "main invention" based on which non-unity was established in relation to the other subject-matter contained in the application.

6. According to Rule 40.1 PCT the ISA's invitation to pay additional fees provided for in Article 17(3)(a) PCT shall specify the reasons for which the international application is not considered as complying with the requirement of unity invention.

The purpose of the protest procedure under Rule 40.2 PCT is to enable the justification for the invitation to pay additional fees to be submitted to substantive review. The only issue to be examined by the Board therefore is whether, considering the reasons given by the ISA and the submissions made by the applicant in support of the protest, retaining additional search fees was justified. The Board cannot investigate *ex-officio* whether an objection of lack of unity would have been justified for reasons other than those given (W 3/93, OJ EPO 1994, 931, Headnote III and point 4 of the reasons; W 4/94, OJ EPO 1996, 73, point 5.5 of the reasons). To the extent that the reasons given by the ISA for charging additional fees are insufficient or wrong, the protest is justified and the fees have to be reimbursed, irrespective of whether or not, as a

result, the finding of non-unity could be regarded as justified as to substance.

7. It follows therefrom that in the present case the additional fees paid under protest are to be reimbursed without considering the question of unity in substance. Moreover, the protest fee must also be refunded.

Order

For these reasons it is decided that:

1. Five additional search fees are reimbursed.

2. The protest fee is reimbursed.

The Registrar: The Chairwoman:

P. Cremona U. Kinkeldey