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**Datasheet for the decision
of 6 October 2014**

Case Number: T 1039/10 - 3.3.04

Application Number: 02800437.2

Publication Number: 1438061

IPC: A61K38/00, A61K39/00, C07K14/00

Language of the proceedings: EN

Title of invention:
Copolymers for suppression of autoimmune diseases, and methods
of use

Applicant:
President and Fellows of Harvard College

Headword:
Copolymers/HARVARD COLLEGE

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"claim 7 - added matter (no)"

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 1039/10 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 6 October 2014

Appellant:
(Applicant)

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 21 December
2009 refusing European patent application No.
02800437.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman

G. Alt

Members:

B. Claes

K. Garnett

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division to refuse European patent application No. 02800437.2 with the title "*Copolymers for suppression of autoimmune diseases, and methods of use*" which was published as WO 03/029276 (hereinafter referred to as "application as filed").
- II. Independent claims 1 and 7 of the sole request before the examining division, which was filed as the main request with a letter dated 10 February 2009, read:
- "1. Linear random amino acid copolymers characterised by substantially comprising amino acids tyrosine (Y), phenylalanine (F), alanine (A) and lysine (K) in a molar ratio of (Y+F):A:K of about 1:5:3.
7. Linear random amino acid copolymers characterised by substantially comprising amino acids tyrosine (Y), phenylalanine (F), alanine (A) and lysine (K)."
- III. The sole reason in the decision for refusing the application in suit was that the subject-matter of claim 7 of the main request did not comply with the requirements of Article 123(2) EPC. The application as filed was held to have only disclosed the linear random amino acid copolymer YFAK with the limitation of the monomer ratios put forward on page 2, lines 12 to 15 of the application as filed (and contained in claim 1). The disclosure of "copolymer YFAK", devoid of any ratio-limitation, in other parts of the description was considered by the examining division to refer to the ratio-limited copolymer of page 2, lines 12 to 15.

IV. With the statement of the grounds of appeal the appellant argued in favour of the compliance of claim 7 with the requirements of Article 123(2) EPC and filed a further document. The appellant argued essentially as follows:

- The skilled person had no difficulty in identifying the disclosure of YFAK copolymers without any monomer-ratio limitation in the application as filed.
- The random nature of the copolymer compositions themselves was indicative of the variability of YFAK monomer ratios.
- The term "substantially" in claim 7 provided a basis for variation in molar ratios. Furthermore, the application as filed disclosed a variance of "about 10% from input molar ratios" (see page 18, line 27 to 29 and example 7, in particular on 27, lines 23 to 29 of the application as filed).
- An explicit basis for the broad genus of YFAK copolymers of claim 7 was located on page 3, lines 28 to 30 and page 4, lines 15 to 18 of the description of the application as filed.

V. The appellant requested in a letter dated 29 September 2014 that the decision under appeal be set aside and the case is remitted to the department of first instance for further prosecution.

Reasons for the Decision

1. The appeal is admissible

Article 123(2) EPC - claim 7

2. The examining division considered that the subject-matter of claim 7 could not be directly and unambiguously derived from the application as filed (see Section III, above).
3. The board takes note that the initial reference to the random amino acid copolymer YFAK in the description as filed appears indeed on page 2, lines 12 to 15. The passage reads:

"A feature of the invention is a linear random amino acid copolymer YFAK comprising tyrosine (Y), phenylalanine (F), alanine (A) and lysine (K) in a molar ratio of (Y+F):A:K of about 1:5:3. The expression "(Y+F) means the sum of the molar ratios of Y and F, compared to the molar ratios of A and K." (emphasis added by the board)

The numbers indicate the molar ratio of amino acids at the onset of each polymerisation cycle (see page 18, lines 3 to 7 and 25 to 29 of the description of the application as filed).

Further embodiments within this ratio are disclosed in the following paragraphs on page 2, lines 16 to 31.

4. The board also takes note that all the YFAK copolymers disclosed in the examples of the application as filed have this indicated molar ratio. In fact, the terminology used is precise and consistent, and any reference to an YFAK copolymer in the examples and drawings includes an indication of the molar proportion of tyrosine (Y) and phenylalanine (F) (see the YFAK copolymers referred to on pages 5 to 7, 18 and 28 to

32, in Table 2 on page 34 and in Figures 4 to 8 which refer to YFAK (0.2:0.8), YFAK (0.5:0.5) and YFAK (0.8:0.2)).

5. The board notes however that, in addition to the specific terminology relating to YFAK copolymers including molar ratios (see above), the description as filed also comprises two general references to YFAK copolymers, namely on page 3, line 28 to page 4, line 3 and on page 4, lines 15 to 17.

The passage bridging pages 3 and 4 reads:

*"The featured copolymers herein are comprised of amino acids as described, and are further considered to be equivalent to copolymers sharing the amino acid compositions as described and also containing one or more additional substituents, for example, have one or more additional amino acids, such that the resulting copolymer has about the same function. For example, a **copolymer** FEAK, FAK, VWAK, VYAK, **YFAK**, or any of the copolymer compositions as provided herein, which is comprised substantially of this composition, i.e., is at least about 60% ... the composition provided herein, and has about the same functional properties as a copolymer provided herein, **is considered equivalent to the compositions as provided herein.**"* (emphasis added by the board)

The passage on page 4 (lines 15 to 17) reads:

*"**A feature of the invention is** a method of manufacture of a composition for use in treating a subject having an autoimmune disease, wherein **the composition comprises** any of random linear amino acid copolymers*

FAK, **YFAK**, VYAK, VWAK, VEAK and FEAK." (emphasis added by the board)

A further general reference to the copolymer can be found in claims 34 and 49 as filed.

Claim 34 as filed reads:

"34. A method of manufacture of a composition for use in treating a subject having an autoimmune disease, wherein the **composition comprises** any of random linear amino acid copolymers FAK, **YFAK**, VYAK, VWAK, VEAK and FAEAK." (emphasis added by the board)

Claim 49 as filed read:

"49. A method according to claim 34, whereby the copolymer is selected from at least one of **YFAK**, VYAK, and VWAK." (emphasis added by the board)

Accordingly, in both passages and in these claims the mention of YFAK is part of a list including other random linear amino acid copolymers such as FAK, VYAK, VWAK and FEAK. The passages and these claims are devoid of any indication of a molar ratio for the copolymers to which they refer.

6. The examining division considered and decided that the general reference to "copolymer YFAK" in the indicated passages in the description, which are devoid of any ratio-limitation, in fact referred to the ratio-limited copolymer, i.e. with the molar ratio of (Y+1F):A:K of 1:5:3 at the start of each polymerisation cycle (see point 3, above).

7. The board notes that both the passage on page 2, referring to YFAK copolymers in combination with a particular molar ratio (see point 3, above), and the passage on page 4, referring to YFAK without an indication of a particular molar ratio (see point 5, above), start with the expression "*A feature of the invention is ...*". The board considers that since both the molar-ratio limited and the molar-ratio unlimited disclosures of the YFAK copolymer are stated to constitute features of the invention, the general reference to the YFAK copolymer disclosed on page 4 cannot be interpreted as meaning molar-ratio limited YFAK copolymer in the context of the disclosure on page 2. Rather, the board considers that the general reference to copolymer YFAK on page 4 is a further "*feature of the invention*", independent of the embodiments disclosed on page 2. This conclusion is corroborated by the formulation of independent claims 34 and 49 (see point 5, above) in the application as filed.
8. The board accepts that the skilled person reading the application as filed would understand that YFAK copolymers not having the molar ratio (Y+F):A:K of 1:5:3 at the start of each polymerisation cycle had been neither prepared nor tested (see point 4, above). This is however not equivalent to not having been disclosed. In fact, for the requirements of Article 123(2) EPC to be met, it is sufficient that a general disclosure of the copolymers of claim 7 is directly and unambiguously derivable from the application as filed.
9. In the present case, the board is satisfied that the passages on pages 3 and 4, and claims 34 and 49 of the application as filed disclose YFAK copolymers as

subject-matter of claim 7, i.e. being devoid of any molar-ratio restriction. Accordingly, claim 7 satisfies the requirements of Article 123(2) EPC.

10. The appellant has argued in the appeal proceedings that the examples of the present application support the therapeutic efficacy of YFAK copolymers in general. The board notes however that the question of whether or not random linear YFAK copolymers, i.e. not having the specific molar ratio set forth on page 2, lines 12 to 15, have any pharmacological value is not relevant within the framework of the assessment of added matter (Article 123(2) EPC), but rather within the framework of the assessment of inventive step (Article 56 EPC) or sufficiency of disclosure (Article 83 EPC) if the claimed subject-matter concerns a medical use.

11. The board notes that the examining division has not taken a position during the examination proceedings or in the decision under appeal on the compliance of the subject-matter of claim 7 with the requirements of any of Articles 83, 84, 54 and 56 EPC. Accordingly and in accordance with the request of the appellant, the board decides to remit the case to the department of first instance for further prosecution (Article 111(1) 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 for further prosecution.

The Registrar:

The Chairwoman:



P. Cremona

G. Alt

Decision electronically authenticated