

Publication in the Official Journal ~~Yes~~ / No

File Number: W 17/91 - 3.3.2

Application No.: PCT/EP 90/01302

Publication No.: WO 9102064

Title of invention: Modified Proteases and their use in foodstuffs

Classification:

D E C I S I O N
of 8 August 1991

Applicant: Nederlands Instituut Voor Zuivelonderzoek

Headword: DNA fragment/N.I. ZUIVELONDERZOEK

PCT Art. 17(3)(a), Rules 13 and 40

Keyword: "Lack of unity "a posteriori" - Insufficient reasons in the invitation"

Headnote



Case Number : W 17/91 - 3.3.2
International Application No. PCT/EP 90/01302

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 8 August 1991

Applicant : Nederlands Instituut Voor Zuivelonderzoek
Kernhemseweg 2
NL - 6718 ZB Ede

Representative : L.C. De Bruijn et al.
Nederlandsch Octrooibureau
Scheveningseweg 82
NL - 2502 LS The Hague

Subject of the Decision : Protest according to Rule 40.2(c) of the Patent
Cooperation Treaty made by the applicants against
the invitation (payment of additional fee) of the
European Patent Office (branch at The Hague)
dated 21 February 1991.

Composition of the Board :

Chairman : P. Lançon
Members : U. Kinkeldey
C. Holtz

Summary of Facts and Submissions

- I. The applicant filed an international patent application PCT/EP 90/01302 with 25 claims.

Claim 1 reads as follows:

"1. DNA fragment containing at least one "mutant protease gene", which "mutant protease gene" is understood to mean:

- a gene made up of sections of protease genes of several lactococcal strains, as well as
- a protease gene of a lactococcal strain, the DNA sequence of which has been altered in a manner such that in the protease for which the gene codes:
 - (a) an amino acid other than that of the "wild-type" protease is present at at least one site, and/or
 - (b) at at least one site within the first 1350 residues of the amino acid sequence, calculated from the N-terminus, at least one amino acid of the "wild-type" protease is missing and/or one or more amino acids have been inserted, or
 - (c) at at least two sites separated from each other, one or more amino acids are missing and/or one or more amino acids have been inserted."

Claims 2 to 25 are directly or indirectly dependent on Claim 1 and thus relate to certain embodiments of that claim.

- II. The EPO acting as an International Search Authority (ISA) sent to the applicants an invitation to pay one additional search fee pursuant to Article 17(3)(a) and Rule 40.1 PCT.

With regard to non-unity the ISA found that "proteases from lactococcal strains are known from the prior art (see Biochimie vol 70, 1988, p. 475-488, cited in the search report). The underlying application describes 2 fundamentally different methods to obtain PROTEASES having improved properties.

1. In the first method, a modified protease is created by combining advantageous properties of proteases of DIFFERENT lactococcal strains. The modified protease is a FUSION protein.
2. In the second method, a modified protease is obtained by the modification of a SINGLE lactococcal protease. The modified protease is NO FUSION protein.

Given the fundamental difference in the two methods of obtaining a protease with improved properties, the ISA finds NON-UNITY according to Rule 13 PCT and proposes a subdivision in the following 2 inventions:"

There followed a definition of the two groups of inventions, specified by a separation of claims according to the above-mentioned differences in the methods to produce the modified protease.

III. The applicants paid the fee under protest. In support of the protest, they submitted that it was possible to construct a specific gene coding for a particular "mutant" protease on both ways defined in the present main claim. More in particular it was possible to construct such a specific gene by

- modifying a protease gene by deleting a specific group of codons and inserting - at the same position - another group of codons, derived from another protease gene or

- modifying the protease gene by deleting the same specific group of codons and inserting - at the same position - another group of codons, prepared synthetically but corresponding to the group of codons derived from other protease genes, i.e. the result of both construction methods will lead to the same DNA fragments for the same "mutant" protease. This situation was exemplified in the specification in detail.

Reasons for the Decision

1. The protest is admissible.
2. The objection of lack of unity made by the ISA only arose after a preliminary search had been carried out and was accordingly made "a posteriori", i.e. after taking prior art into consideration. The question of whether the EPO when acting as an ISA is entitled to raise an "a posteriori" lack of unity objection or whether such an objection pre-empts the separate preliminary examination under Chapter II PCT was referred to the Enlarged Board of Appeal of the EPO. In its recent decision G 1/89 (OJ EPO 1991, 155) the Enlarged Board concluded that "a posteriori" objection of lack of unity was allowable since the ISA only formed a provisional opinion on novelty and inventive step for the purpose of carrying out an effective search which did not constitute a substantive examination in the normal sense of that term. The Enlarged Board stated that consideration of the requirement of unity of invention should always be made with a view to giving the applicant fair treatment and that the charging of additional fees under Article 17(3)(a) PCT should be made only in clear cases; restraint should be exercised in

the assessment of novelty and inventive step and borderline cases preferably resolved in favour of the applicant.

In the present case it is not even clear whether there was a novelty or inventive step objection by the ISA which resulted in the statement of non-unity. The subject-matter of the mentioned prior art clearly differs from that of Claim 1.

3. The subject-matter of Claim 1 is directed to DNA fragments containing at least one "mutant protease gene", whereby this mutant protease gene is prepared by either combining parts of protease genes derived from different lactococcal strains or of only one lactococcal strain. It is thus apparent that the invention relates to a DNA fragment carrying a modified gene coding for protease, and thus is represented by substance claims.
4. Having considered the prior art which led the ISA to an a posteriori objection to lack of unity, the Board takes the position, that in the light of this prior art document novelty is not an issue.
5. Regarding inventive step, the Board is of the opinion that the reasons given in the invitation to pay an additional fee are not sufficient inasfar as there is no indication about the problem to be solved in the light of the prior art document so that one cannot conclude whether the solution given by the DNA fragment as claimed in Claim 1 represents one or more inventive concepts. In fact, the reason given for the invitation to pay the additional fee is confusing because it is based on the observation that proteases from lactococcal strains were known, from prior art, whereas the objected claim relates to DNA fragments, coding for the proteases and thus are also substance claims. The reasons given by the ISA, however, stated that

the underlying application described two fundamentally different methods. It is thus anything but clear from the reasons given by the ISA and from a consideration of the complex technical subject-matter of the present case whether Claim 1 may still involve an inventive step in the light of the prior art cited by the ISA.

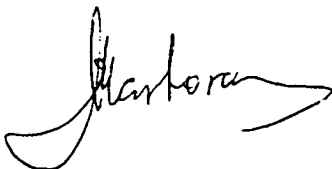
6. The ISA, therefore, did not provide sufficient reasons why, according to its opinion the subject-matter of Claims 2 to 4, 6, 7, 11, 12 and 1, 16 to 25 partially on the one hand and Claims 5, 8, 9, 10, 13 to 15 and 1, 16 to 25 partially on the other hand results in two different inventive concepts.
7. The invitation to pay an additional fee therefore violates the obligation to provide reasons within the meaning of Rule 40.1 PCT and thus cannot be considered as legally effective.
8. Since the applicant has paid the additional fee without legal basis, the conditions of Rules 13.1 and 13.2 PCT are fulfilled. The additional fee, therefore, has to be refunded.

Order

For these reasons, it is decided that:

Refund of the additional search fee is ordered.

The Registrar:



P. Martorana

The Chairman:



P. Lançon

03363

9.8 al
liberty