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D E C I S I O N
of 22 November 1993

Case Number: T 0391/91 - 3.3.2

Application Number: 83901775.3

Publication Number: 0112342

IPC: C07H 21/04

Language of the proceedings: EN

Title of invention:
Novel ice nucleating microorganisms

Applicant:
The Regents of the University of California

Opponent:
-

Headword:
Ice nucleating/UNIVERSITY OF CALIFORNIA

Relevant legal norms:
EPC Art. 84, 83

Keyword:
"Claims - functional features - clarity (yes)"
"Claims - extent of generalisation"

Decisions cited:
T 0032/84, T 0068/85, T 0292/85, T 0218/86

Catchword:
-

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Case Number: T 0391/91 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 22 November 1993

Appellant: The Regents of the University of California
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Decision under appeal: **Decision of the Examining Division of the European Patent Office dated 28 December 1990 refusing European patent application No. 83901775.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P.A.M. Lançon
Members: L. Galligani
S.C. Perryman

Summary of Facts and Submissions

I. European patent application No. 83 901 775.3 published as an International patent application under No. WO 83/03831 was refused by the Examining Division.

The decision was taken on the basis of a main request which comprised Claims 1 to 10 filed at oral proceedings on 6 December 1990. The first and second auxiliary requests filed on the same date which comprised a modified version of Claim 1 were also rejected.

Claim 1 of the main request read as follows:

" A method for producing unicellular microorganism host cells having enhanced ice nucleation activity (INA), which comprises:

isolating from a donor microorganism heterologous to said host cell and expressing an INA$^+$ phenotype a DNA segment including a single gene site encoding an expression product responsible for said INA$^+$ phenotype;

introducing said DNA segment into said host cells so as to increase the copy number of INA encoding DNA in the resulting cells;

producing therefrom a culture of said transformants which have additional INA encoding DNA and thereby have acquired enhanced INA as compared to untransformed host cells. "

II. The Examining Division refused the application under Article 97(1) EPC on the grounds that Claims 1-6 and 8-10 of all requests did not comply with the requirements of Article 84 EPC.

The decision is based on the following main reasons:

(a) the DNA sequence coding for the INA activity is not properly identified in Claim 1 of the main request. The DNA fragment is, in fact, defined merely on the basis of its function. In order to reduce the teaching of the claim to practice the skilled person has to carry out at least tedious work which might require the application of inventive skill;

(b) the technical features found in dependent Claims 2-6 and 8-10 do not contribute to the clarity of the definition as they either relate to the source of the DNA or to its length or to the type of host transformed therewith;

(c) on the other hand, Claim 7 of the main request is clearly formulated, but in respect thereof the question of the availability of the quoted strain has to be clarified.

III. The appellant lodged an appeal against this decision and paid the appeal fee. A modified version of Claim 1 of the main request was filed with the Statement of Grounds of Appeal by letter dated 3 May 1991. The appellant reminded the Board that he intended to maintain also the remaining Claims 10 to 22 (with the exception of Claim 14) of the set filed by letter dated 2 August 1989.

Modified Claim 1 reads as follows:

"A method for producing unicellular microorganism host cells having ice nucleation activity (INA), or enhanced INA activity, which comprises:

isolating from a donor microorganism expressing an INA$^+$ phenotype a DNA segment including a single gene encoding an expression product responsible for said INA$^+$ phenotype;

introducing said DNA segment into said host cells so that the gene will be expressed therein;

producing therefrom a culture of said cells which have additional DNA encoding INA and thereby have acquired INA, or enhanced INA, as compared to the host cells before introducing said DNA."

The appellant's arguments are essentially as follows:

(a) the most important aspect of the present invention lies in the discovery that ice nucleation activity (INA) in those microorganisms with that phenotype, is provided by a single gene and is transferrable to other organisms;

(b) having been presented with a description of this finding and of the way in which the transfer of the INA phenotype can be put into practice, the skilled person can carry out the invention with the guidance of the present application using only routine procedures and with every expectation of success. The knowledge of the actual sequence of the INA gene is not necessary therefor, because as exemplified in the application the isolation, the transfer and expression of the INA gene do not require said knowledge;

(c) the introduction of the specific features of the INA-encoding DNA of the examples as apparently required by the Examining Division for a clear

definition would result in an unacceptable restriction of the protection.

IV. The appellant requests the grant of a patent on the basis of the modified Claim 1 followed by Claims 2 to 10 filed at oral proceedings on 6 December 1990 as well as by Claims 10 to 22 (with the exception of Claim 14 which is a duplication) filed on 2 August 1989.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments (Article 123(2) EPC)*

New Claim 1 differs from the "rejected" Claim 1 in that:

a) in the first paragraph it refers not merely to "host cells having enhanced INA", but to "host cells having INA or enhanced INA" (a corresponding amendment is also introduced in the fourth paragraph of the claim);

(b) in the second paragraph it does not specify that the donor microorganism is heterologous to the host cell;

(c) in the third paragraph the expression "so that the gene will be expressed therein" replaces the expression "so as to increase the copy number of INA encoding DNA in the resulting cells";

(d) in the fourth paragraph "said cells" replaces "said transformants".

All the above amendments find support in the application as originally filed. In fact:

- as for (a), both possibilities are envisaged by the application (see description, page 9, lines 5-10);

- as for (b), the original application is not strictly limited to the transfer of genes heterologous to the host because it mentions the possibility of increasing the INA in an organism that already has that phenotype (see description, page 9, lines 5-10);

- as for (c), the new wording finds support e.g. in the examples where it is shown that the gene is expressed in the transformed host cells;

- as for (d), the two expressions are equivalent in the context of the claim.

Thus, no objection under Article 123(2) EPC arises.

3. *Clarity (Article 84 EPC)*

3.1 The "rejected" Claims 1 to 10

3.1.1 Claim 1 (a method claim) sets out in general terms the sequence of steps which have to be followed in order to put the invention into practice, i.e. in order to produce unicellular microorganism host cells having INA or enhanced INA.

The skilled person is instructed by the claim that in order to obtain the desired effect he/she should:

(i) isolate from an INA$^+$ donor microorganism a DNA fragment including a single gene responsible for the INA phenotype;

(ii) introduce said DNA fragment into host cells so that the gene will be expressed therein;

(iii) produce a culture of the cells which have acquired the INA phenotype, or an enhanced INA phenotype, as compared to the host cells before introducing said DNA.

The experimental part of the present application demonstrates that the above sequence of steps leads indeed to the desired result. It is shown, for example, that a DNA fragment of about 10kb can be isolated from a strain of **Pseudomonas syringae** and that, when this fragment is properly inserted into a vector and transferred to **E.coli** host cells, the latter acquire the INA phenotype.

Present Claim 1 is, in fact, a generalisation from the particular examples.

In the appealed decision essentially the extent of this generalisation was considered too broad. The Examining Division considered, for example, inadmissible under Article 84 EPC the definition in general functional terms of the DNA fragment encoding an expression product responsible for the INA+ phenotype. In its opinion the clarity requirements were satisfied only by Claim 7 which is restricted to a "DNA fragment obtainable as EcoRI fragment" from a specific **P.syringae** strain (see Section 8.5, last paragraph of the appealed decision).

3.1.2 Article 84 requires that the matter for which protection is sought be defined in a clear and concise manner. This means not only that the claim must be comprehensible, but also that all essential features must be indicated, these being the features which are necessary to obtain the desired effect (see T 32/82 OJ EPO, 1984, 354).

These requirements are met by the wording of present Claim 1 because the claim is comprehensible and contains all the essential features.

According to established jurisprudence of the EPO the essential technical features may be expressed in general functional terms, if, from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the invention and if in relation to these features the description provides instructions which are sufficiently clear for the expert to put the invention into practice with no more than a reasonable amount of experimentation (see, for example, T 68/85 OJ EPO, 1987, 228).

This appears to be the case here, especially in view of the fact that the merit of the invention lies in the discovery that relatively small DNA fragments can be isolated from INA$^+$ organisms which carry on a single gene the genetic information responsible for the INA phenotype and that said fragments can be used to transfer the said phenotype to other organisms, thereby either conferring or enhancing the INA. This was apparently unrecognized in the art and constitutes the basis for the claimed subject-matter.

Having been presented with these findings and with practical examples of their application, the skilled person is in the position to put the invention into practice by using routine procedures. The skilled person is not obliged to use the described donor strains or to isolate DNA fragments of specific lengths or of specific sequences or to use the same host cells. As there is no reason to doubt that it is possible to generalize the specific teaching of the present examples, it would be unfair to the appellant to require a restriction of

Claim 1 by incorporation therein of the specific features of the examples.

This is normally done in the dependent claims which can set out particular embodiments of the invention (see, for example, dependent Claim 7).

The function of the examples is primarily that of providing a guidance for the successful execution of the invention in its broader outline. The skilled person is likely to refer to the examples in order to design a strategy to cut the genomic DNA of the donor organism, in order to test the INA, in order to construct a suitable expression vector and to choose a suitable host system. However, the skilled person can use any suitable variant capable of providing the same effect of the invention (see T 292/85 OJ EPO, 1989, 275). This might be tedious, but it is nothing out of the ordinary in this field and involves only routine trials.

Thus, the reasoning which led to the rejection of Claim 1 cannot be followed, and Claim 1 must be considered allowable under Article 84 EPC.

Similarly Claims 2 to 10 filed at oral proceedings on 6 December 1990 which are concerned, respectively, with specific embodiments of the method of Claim 1 and with the resulting products, are allowable under Article 84 EPC.

3.2 Claims 10 to 22 as filed by letter dated 2 August 1989

The decision under appeal refers only to Claims 1 to 10 as filed at oral proceedings on 6 December 1990 (see item 3 therein), and the minutes of the said oral proceedings do not make any reference to Claims 10 to 22 filed by letter dated 2 August 1989. Apparently, the

Examining Division had interpreted the main request (Claims 1 to 10) as replacing all the claims on file (Claims 1 to 22 filed by letter dated 2 August 1989).

It appears, however, that the said claims had not all been withdrawn by the appellant during the examination proceedings. The appellant wishes to maintain Claims 10 to 13 and 15 to 22 of these (see page 29 of the Statement of Grounds of Appeal).

The Board has, therefore, decided to examine the said claims of its own motion under Article 114(1) EPC since the exact position of the Examining Division on their clarity is not fully known.

Apart from the fact that the said claims need extensive revision of their numbering and dependency, in the Board's opinion they satisfy the clarity criteria of Article 84 EPC. In particular, with respect to Claim 10 of the letter of 2 August 1989 the Board is of the opinion that the technical features used for its definition, namely its size (10kb), its activity (encodes INA) and the source (derived from a unicellular source having INA), are, in the context of the present application, sufficient to clearly identify the product (an isolated DNA sequence) for which protection is sought. In fact, the skilled person can readily recognize and test whether a specific DNA sequence falls within the terms of the claim.

3.3 For the above reasons, the Board finds that the invention as claimed is clearly enough stated to meet the requirements of Article 84 EPC.

4. *Sufficiency of disclosure (Article 83 EPC)*

Claim 7 is concerned with a specific embodiment of the method according to Claim 1. This embodiment can be put into practice by the skilled person **only if** the quoted strain **P.syringae cit-7** is publicly available.

It is noted that, according to item 15 of the minutes of oral proceedings held on 6 December 1990 before the Examining Division, "the Agent was not sure whether the strains were actually available to the public".

This question will have to be investigated during the further prosecution of the case by the Examining Division (see Section 6 below). If the said strain was indeed not available to the public, then the application would not meet the requirements of Article 83 as far as Claim 7 is concerned, because the skilled person would not have been in a position to put into practice this claimed embodiment. This, however, would not prejudice the reproducibility of the teaching of the application as a whole in view of the generality of its teaching and of the availability of other suitable INA$^+$ microbial strains (see also decisions T 292/85 OJ EPO, 1989, 275 and T 218/86 OJ EPO, 1989, 202).

5. *Novelty (Article 54 EPC)*

Novelty has never been at issue in this case during its prosecution.

In the Board's opinion none of the documents in the proceedings discloses a process having all the features of Claim 1, which can, therefore, be considered as novel.

6. *Inventive step (Article 56 EPC)*

During the prosecution of the present case by the first instance a general objection of lack of inventive step *vis-à-vis* the prior art document Phytopathology, Vol.71, 1981, page 237 was raised in two official communications (see official communications dated 7 October 1988 - in particular item 4 - and 12 April 1989 - in particular item 2) and subsequently withdrawn in a further official communication (see communication dated 5 February 1990 - in particular item 2).

With respect to this issue the Board observes that, while present Claims 1 to 9 are concerned with a method for producing unicellular microorganisms host cells having ice nucleation activity (INA), or enhanced INA activity, Claim 10 is concerned with a product, namely "a genetically modified microorganism having enhanced INA as compared with an unmodified said microorganism, **as obtainable by a method according to any one of Claims 1 to 9**" ("product-by-process" type of claim).

It is well established jurisprudence of the EPO that claims for products defined in terms of a process of preparation are allowable only if the products as such fulfil the requirements for patentability, i.e. *inter alia* that they are new and inventive (see, for example, T 150/82, OJ EPO 1984, 309).

It appears that the issue of the inventiveness of the product obtainable by the method of Claims 1 to 9 (Claim 10 of the set submitted on 6 December 1990) and of its use (see Claims 20-22 filed by letter dated 2 August 1989; N.B. the latter claims in their present form refer to "cells according to any one of Claims 1 to

9", which for consistency should apparently be changed to "cells according to Claim 10") has not yet been examined.

In order to guarantee such examination without loss of instance, the Board considers it appropriate to make use of the power granted to it under Article 111(1) EPC and to remit the case to the Examining Division for further prosecution.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Examining Division for further prosecution on the basis of the following documents:

Description: Pages 1 to 9, as originally filed;
Claims: No. 1 received on 10 May 1991 with letter dated 3 May 1991;
No. 2 to 10 received on 6 December 1990;
No. 10 to 13 and 15 to 22 (to be renumbered appropriately) received on 5 August 1989 with letter of 2 August 1989.

The Registrar: The Chairman:

P.Martorana P.A.M.Lançon