BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen

D E C I S I O N
of 6 December 2000

Case Number: T 1054/96 - 3.3.4

Application Number: 91810144.5

Publication Number: 0448511

IPC: A01N 63/00

Language of the proceedings: EN

Title of invention:
Anti-pathogenically effective compositions comprising lytic peptides and hydrolytic enzymes

Applicant:
Novartis AG

Opponent:
-

Headword:
Anti-pathogenic compositions/NOVARTIS III

Relevant legal provisions:
EPC Art. 53, 83

Keyword:
"exceptions to patentability - no"

Decisions cited:
G 0001/98; T 1054/96(I)

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1054/96 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 6 December 2000

Respondent: (Proprietor of the patent)
Novartis AG
Schwarzwaldallee 215
CH-4058 Basel (CH)

Representative:
VOSSIUS & PARTNER
Dr Jaenichen, H. R.
Postfach 86 07 67
D-81634 München (DE)

Decision under appeal: Decision of the Examining Division of the European Patent Office posted 26 June 1996 refusing European patent No. 91 810 144.5 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: F. L. Davison-Brunel
S. C. Perryman

Summary of Facts and Submissions

I. European application No. 91 810 144.5 published under No. 0 448 511, with the title "Anti-pathogenically effective compositions comprising lytic peptides and hydrolytic enzymes" was refused by the Examining Division on the basis of a request filed by letter of 12 May 1995, comprising 24 claims for Contracting States other than ES and 21 claims for ES.

Claims 19, 23 and 24 for the Contracting States other than ES read as follows:

"19. A transgenic plant and the seed thereof comprising recombinant DNA sequences encoding

a) one or more lytic peptides, which is not lysozyme, in combination with;

b) one or more chitinases; and/or

c) one or more β-1,3-glucanases in a synergistically effective amount."

"23. A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides together with one or more chitinases; and/or one or more β-1,3-glucanases in a synergistically effective amount; said method comprising the steps of preparing a transgenic plant comprising recombinant DNA sequences encoding one or more lytic peptides, which is not lysozyme together with one or more chitinases; and/or one or more β-1,3-glucanases."

"24. A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides, which is not lysozyme together with one or more chitinases; and/or one or more β-1,3-glucanases in a synergistically effective amount; said method

comprising the steps of preparing two or more transgenic plants comprising recombinant DNA sequences encoding one or more lytic peptides together with one or more chitinases; and/or one or more β-1,3-glucanases, and crossing said plants using conventional breeding techniques."

Claims 1 to 14 were directed to anti-pathogenic compositions for controlling plant pathogens comprising the enzymes listed in points (a) to (c) of claim 19. Claims 15 to 18 related to methods of controlling plant pathogens. Claims 20 to 22 related to further embodiments of the plant of claim 19.

The claim request for ES corresponded to the claims defined above but did not contain any claims directed to plants or plant material per se.

II. The reason which led the Examining Division to refuse the patent application was that the subject-matter of claims 19 to 22 for Contracting States other than ES fell under the exclusion of patentability of Article 53(b) EPC.

All claims including claims 19 to 22 were examined and found to meet the requirements of the EPC (communication of the Examining Division dated 27 February 1996).

III. The Appellant lodged an appeal against the decision of the Examining Division, paid the appeal fee and submitted a statement of grounds of appeal.

IV. Oral proceedings were scheduled for the 13 October 1997. On 5 September 1997, the Board sent a communication to convey to the party the provisional opinion that:

- product claims 19 to 22 could be found unallowable under Article 53(b) EPC, and

- as regards claims 23 and 24, the use in these of the terms "transgenic" plant and "recombinant" DNA sequence was objectionable under Article 84 EPC because these process claims did not recite any process steps directly involving insertion of a DNA sequence into a plant. In addition, claim 23 seemed objectionable under Article 84 EPC in that it did not recite any method feature. As claims 23 and 24 read onto ordinary biological processes, they also appeared to be objectionable under the prohibition of Article 53(b) EPC that patents shall not be granted for essentially biological processes.

V. At the end of oral proceedings, the Board decided to refer a number of questions to the Enlarged Board of Appeal (EBA; cf the referral-decision T 1054/96, OJ EPO 1998, 511). The EBA answered these questions with decision G 1/98 (OJ EPO 2000, 111).

VI. On 8 March 2000, the Board issued a communication informing the party of its view that, based on the EBA decision, claims 19 to 22 were to be considered as not falling under the exclusion of patentability of Article 53(b) EPC. The objections raised in the communication dated 5 September 1997 in relation to the method claims 23 and 24 were maintained.

VII. On 10 March 2000, the Appellant filed a new set of 24 claims for all Contracting States except ES and a new set of 20 claims for ES. The new set of claims 1 to 24 differed from the set of claims refused by the Examining Division in that:

- claim 2 was deleted and claims 3 to 18 were renumbered claims 2 to 17,

- the expression "and the seeds thereof" was deleted in claim 18 (former claim 19).

- new claims 19 to 21 corresponded to previous claims 20 to 22 with the dependencies adjusted,

Claims 22 to 24 read as follows:

"22. A seed of a plant according to anyone of claims 18 to 21 comprising recombinant DNA sequences as defined in anyone of claims 18 to 20."

"23. A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides together with one or more chitinases; and/or one or more β-1,3-glucanases in a synergistically effective amount; said method comprising the steps of preparing by **transformation and regeneration** a transgenic plant comprising recombinant DNA sequences encoding one or more lytic peptides, which is not lysozyme together with one or more chitinases; and/or one or more β-1,3-glucanases." (emphasis by the Board)

"24. A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides which is not lysozyme together with one or more chitinases; and/or one or more β-1,3-glucanases in a synergistically effective amount; said method comprising the steps of preparing by **transformation and regeneration** two or more transgenic plants comprising recombinant DNA sequences encoding one or more lytic peptides

together with one or more chitinases; and/or one or more β-1,3-glucanases, and crossing said plants using conventional breeding techniques."(emphasis by the Board)

VIII. The Appellant requested that the decision of the Examining Division be set aside and a patent be granted on the basis of the claim requests filed on 10 March 2000.

Reasons for the Decision

Article 53(b) EPC: exceptions to patentability
Claims 18 to 24

1. Claims 18 to 21 are directed to transgenic plants and embrace plant varieties. Yet, no plant variety defined by taxonomic name and further variety specific characteristics is individually claimed. In their decision G 1/98 (see supra), the EBA decided that "a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties". Pursuant to Article 112(2) EPC, this decision is binding in deciding this case and claims 18 to 21 must be considered as falling outside of the exceptions to patentability laid down in Article 53(b) EPC.

2. Claim 22 is directed to a seed of a transgenic plant but seeds of one or more plant variety(ies) defined by taxonomic name and further variety specific characteristics are not individually claimed. In the Board's judgment, this implies that the claim does not cover specific individual plant varieties in the form

of seeds. The same conclusion is, thus, reached as in point 1 above that following decision G 1/98 (see supra), claim 22 does not fall under the exceptions to patentability of Article 53(b) EPC.

3. Claims 23 and 24 require that the transgenic plant be prepared by transformation and regeneration. The step of transforming the host plant requires that DNA be introduced into it, i.e. that a number of mere technical manipulations such as isolating the transforming DNA (pages 21 to 32 of the application), making the host permeable to said DNA (page 32), screening the transformants (pages 38 and 42) have to be performed. It is, thus, of the essence of the method of claims 23 and 24 now put forward that genetic engineering steps are performed, so that the claim cannot be considered to be directed to an essentially biological process for the production of plants, which would be excluded from patentability under the provisions of Article 53(b) EPC. The same conclusion would be reached by applying Rule 23b(5) EPC, in force since 1 September 1999 which states that "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection", so that no case of a conflict between the provisions of the European Convention and those of the Implementing regulations for consideration under Article 164(2) EPC arises for consideration.

4. None of the claimed subject-matter falls under the prohibition from patentability under the provisions of Article 53(b) EPC.

Article 123(2) EPC, Article 84 EPC

5. Claims 1 to 17, 19 to 21 do not differ from claims 1, 3 to 18, 20 to 22 which were found allowable by the

Examining Division under Article 123(2) EPC (see section II supra). Claim 18 only differs from claim 19 then on file by the deletion of the expression "and seeds thereof" which does not alter the findings of the Examining Division in relation to this Article.

6. Support for claim 22 depending on claims 18 to 21 may be found in Example 9 of the application as filed disclosing seeds of transgenic plants, taken together with the disclosure on page 3, fourth paragraph and on page 4, of the lytic and hydrolytic enzymes to be cloned as well as of the plants to be transformed.

7. The basis for a step of preparing a transgenic plant by transformation and regeneration in the methods of claims 23 and 24 is found in the application as filed on page 32, last paragraph to page 43, third paragraph.

8. Claims 1 to 22 are now clear. An objection for lack of clarity was raised by the Board against claims 23 and 24 of the claim request refused by the Examining Division (see section IV, above), for the reason that the terms transgenic plant" and "recombinant DNA sequence" had no meaning in terms of the process which was then claimed, which did not necessarily require a step involving transformation and regeneration of the host cell. This objection does not hold against present claims 23 and 24 which comprise these steps (see section VII, above)

9. The requirements of Articles 123(2) and 84 EPC are fulfilled.

Other requirements for patentability

10. The Examining Division established that the requirements for patentability were fulfilled. In view of these findings and of the conclusions in points 4

and 9 above, a patent may be granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the following documents:

   - the set of claims 1 to 24 for all Contracting States except for ES filed with letter of 10 March 2000 and

   - the set of claims 1 to 20 for ES filed with letter of 10 March 2000 and

   - pages 1, 8, 10 to 51 of the description as originally filed and

   - pages 2 to 7 and 9 as filed with letter of 12 May 1995.

The Registrar: The Chairman:

U. Bultmann U. Kinkeldey