

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 15 January 2003

Case Number: T 0222/00 - 3.3.8

Application Number: 91914361.0

Publication Number: 0545958

IPC: C12N 9/42

Language of the proceedings: EN

Title of invention:

A process for hydrolyzing hemicellulose by enzymes produced by *Trichoderma reesei*

Patentee:

VALTION TEKNILLINEN TUTKIMUSKESKUS

Opponent:

DSM Gist B.V.

Headword:

Hemicellulose degradation/VALTION

Relevant legal provisions:

EPC Art. 83

Keyword:

"Sufficiency of disclosure - no"

Decisions cited:

G 0009/92, T 0226/85, T 0639/95

Catchword:

-



Case Number: T 0222/00 - 3.3.8

D E C I S I O N
of the Technical Board of Appeal 3.3.8
of 15 January 2003

Appellant:
(Proprietor of the patent) VALTION TEKNIILLINEN TUTKIMUSKESKUS
c/o VTT Technology Oy, PL 402
FI-02151 Espoo (FI)

Representative: Knuth-Lehtola, Sisko Hillevi
Seppo Laine Oy
P.O.B. 339
FI-00181 Helsinki (FI)

Respondent:
(Opponent) DSM Gist B.V.
Wateringseweg 1
P.O. Box 1
NL-2600 MA Delft (NL)

Representative: van Heuvel, Margreet
DSM, N.V.
Patents and Trademarks
Martinus Nijhofflaan 2
P.O. Box 1
NL-2600 MA Delft (NL)

Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 24 November
1999 concerning maintenance of European patent
No. 0 545 958 in amended form.

Composition of the Board:

Chairman: L. Galligani
Members: F. L. Davison-Brunel
C. Rennie-Smith

Summary of facts and submissions

- I. European patent No. 0 545 958 entitled " A process for hydrolyzing hemicellulose by enzymes produced by *Trichoderma reesei*" was granted with 11 claims based on the International application PCT/FI91/00265 published under No. WO 92/03 541.

Granted claims 1 and 2 read as follows:

"1. A process for hydrolyzing hemicelluloses, especially xylans, in wood or in fibres, or isolated from these, characterized by utilization of an enzyme preparation isolated from *Trichoderma reesei*, containing an endo- β -xylanase I with a pI value of 5.5 and a molecular weight of 19 kDa and/or an endo- β -xylanase II with a pI value of 9.0 and a molecular weight of 20 kDa."

"2. The process according to claim 1, characterized by using an enzyme preparation produced by the fungus *Trichoderma reesei*, by a strain derived from that or by any other host strain, to which the genes encoding *T.reesei* xylanases I and/or II as defined in claim 1 have been transferred."

Dependent claims 3 to 11 related to further features of the process of claim 1.

- II. An opposition was filed requesting revocation of the patent under Article 100(a) EPC (lack of novelty and inventive step) and Article 100(b) EPC (insufficiency of disclosure). In the course of opposition, the Patentees filed a main and five auxiliary claim requests. The Opposition Division decided that the only request which complied with the requirements of the EPC was an amended version of the fifth auxiliary request

filed during the oral proceedings from which claim 12 (relating, in particular, to a method for improving the bleachability of cellulose pulps involving host strains to which the *T.reesei* xylanase genes had been transferred ie. involving genetically engineered microorganisms) was deleted, this claim being objectionable under the terms of Article 83 EPC.

III. The Appellant (Patentee) filed an appeal, paid the appeal fee and submitted the statement of grounds for the appeal.

Its main and auxiliary requests I to IV on appeal were the same as those considered by the Opposition Division.

In all these requests, claim 1 relates to a process for hydrolyzing hemicelluloses. Claim 18 of the main request and of auxiliary request I reads as follows:

"18. The process according to claim 1, 11 or 13, characterized by using an enzyme preparation produced by the fungus *Trichoderma reesei*, by a strain derived from that or by any other host strain, to which the genes encoding *T.reesei* xylanase I as defined in claim 1 or 13 and/or xylanase II as defined in claim 1 or 11 have been transferred."

Claim 2 of auxiliary requests II, III and IV reads as follows:

"2. The process according to claim 1, characterized by using an enzyme preparation produced by the fungus *Trichoderma reesei*, by a strain derived from that or by any other host strain, to which the genes encoding *T.reesei* xylanases I and/or II as defined in claim 1 have been transferred."

- IV. The Respondent (Opponent), in answer to the statement of grounds of appeal argued that the Opposition Division decision was correct.
- V. The Board sent with the summons to oral proceedings a communication pursuant to Article 11(2) of the Rules of Procedure of the Boards of Appeal, pointing out various issues to be discussed at oral proceedings, in particular, the sufficiency of disclosure in relation to processes for hydrolyzing hemicellulose involving recombinant micro-organisms (cf. points 10, 11 and 14 of the communication).
- VI. By a letter dated 5 December 2002, the Respondent informed the Board that it would not attend oral proceedings.
- VII. With letter dated 16 December 2002, the Appellant withdrew its request for oral proceedings and informed the Board that it would not attend the oral proceedings.
- VIII. The Board cancelled the oral proceedings appointed for 15 January 2003.
- IX. The Respondent's arguments raised during opposition proceedings concerning the reproducibility of a process for hydrolyzing hemicelluloses involving recombinant micro-organisms may be summarised as follows:

The opposed patent did not disclose such a process in a manner sufficiently clear and complete. The patent specification did not provide any teachings as to how these genes were to be obtained, let alone how they were to be transferred into, and expressed in, any other host strain. These teachings could not be held to be part of the common general knowledge. In fact, the *T.reesei* genes encoding xylanases I and II did not

become available until after the priority date of the opposed patent.

- X. The Appellant's position on this issue may be summarised as follows:

Before the priority date, information on the isolation of several other genes of *T.reesei* and how they could be transferred and expressed in another host was available. The cloning of xylanase I and II genes as described in 1993 and 1992, respectively, was done using normal molecular biology methods and the knowledge of molecular biology of *T.reesei* available at the priority date (1990). Thus, a person skilled in the art was able to isolate the xylanase genes and to transfer them to other host organisms without undue burden.

- XI. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or of any one of the auxiliary requests on file.

The Respondent requested that the appeal be dismissed.

Reasons for the decision

1. The main request and auxiliary requests I to IV on appeal are the same requests as were considered at first instance. Auxiliary request V is that on the basis of which the Opposition Division maintained the patent. The Respondent did not appeal this decision. In accordance with decision G 9/92 (OJ EPO 1994,875), "if the patent proprietor is the sole appellant against an interlocutory decision maintaining a patent in amended form, neither the board of appeal nor the non-appealing

opponent as party to the proceedings as of right under Article 107, second sentence, EPC may challenge the maintenance of the patent as amended in accordance with the interlocutory decision". Thus, only the main and first four auxiliary requests may be considered by the Board.

2. In its interlocutory decision dated 24 November 1999, the Opposition Division concluded, in particular, that the requirement of sufficiency of disclosure was not fulfilled in relation to the subject-matter of a claim relating to a process for hydrolysing hemicelluloses involving recombinant micro-organisms and that only the deletion of such a claim could result in the maintenance of the patent in amended form (cf. section II, supra). Such a claim is now present in all the requests before the Board (cf. section III, supra): it corresponds mutatis mutandis to claim 2 as granted (cf. section I, supra). Thus, the Board finds it expedient, to address firstly the issue of sufficiency of disclosure, although the main, first and fourth auxiliary requests were rejected by the Opposition Division under Article 123(2) EPC, and the second and third auxiliary requests were rejected under Article 100(a) EPC (lack of novelty).

Article 83 EPC: sufficiency of disclosure

3. Article 83 EPC requires that the claimed invention be disclosed "in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art". According to the case law of the boards of appeal, the skilled person has to have at his/her disposal, either in the specification or on the basis of common general knowledge, adequate information leading necessarily and directly towards success (T 226/85, OJ EPO 1988, 336).

4. In the present case, in order to perform the invention claimed in either claim 18 or claim 2 of all the Appellant's pending requests, the skilled person must be able to obtain the genes encoding the *T.reesei* xylanases as the claimed processes involve the transfer of these genes to various host strains.

5. The sole passage in the patent specification (page 2, lines 46 to 48) mentioning the xylanase encoding *T.reesei* genes reads as follows: "*The desired proteins can also be produced using Trichoderma reesei strains which have been genetically modified to produce large amounts of one or both of these proteins or with other genetically modified production organisms, to which genes encoding one or both of these T.reesei enzymes have been transferred.*" No general outline is given of the experimental steps to be taken to isolate these genes, let alone specific technical details. No reference is made to the common general knowledge which would be used for cloning, nor to any prior art document disclosing cloned *T.reesei* genes.

6. The Appellant argued that, at the priority date, the skilled person interested in obtaining the xylanase genes would undoubtedly be aware that many *T. reesei* genes had already been cloned and of the manner in which that had been done. The Board, however, does not consider that information relative to the cloning of other *T. reesei* genes is adequate to lead necessarily and directly to the cloning of xylanase genes and, in particular, of the genes encoding xylanase I and/or II referred to in the claims. Indeed, in order to be able to perform the cloning of any specific gene without undue burden, even using well-tried cloning techniques, information is necessary which is **specific to the gene**

to be cloned: starting strain, partial sequence of the encoded protein, suitable host strain, appropriate screening methods etc... As already indicated, such information is completely absent in the present case.

7. The Appellant also pointed out that the cloning of the xylanase genes was described shortly after the filing date of the present patent and that it required nothing out of the ordinary, thus implying that this cloning was a matter of routine which did not need to be explained. In the Board's judgment, the fact that cloning was accomplished later only demonstrates that some scientists were subsequently able to make the correct specific choices regarding the technical features mentioned in the previous paragraph. This is not the same as showing that, at the claimed date of the invention, such cloning was a matter of routine. In any event, if a disclosure is seriously insufficient in that it provides no guidance for performing a particular aspect of the invention, a reference to later documents showing how such performance was accomplished at a later date is manifestly incapable of curing the insufficiency.
8. It is, thus, concluded that the claimed invention relating to the process for hydrolyzing hemicellulose involving the use of recombinant micro-organisms is not sufficiently clearly and completely disclosed for it to be carried out by a person skilled in the art. Therefore, the requirements of Article 83 EPC are not fulfilled.
9. This conclusion is in line with the findings in decision T 639/95 of 21 January 1998. In this earlier case, the gene encoding polyhydroxybutyrate synthetase was crucial for putting the claimed invention into practice. Neither the gene itself nor the enzyme had

been disclosed before the priority date. The application did not describe any vector containing that gene. The protocol for its isolation was given in very general terms. The information incorporated by reference into the patent specification was considered incomplete. The Board in question decided that the requirements of Article 83 EPC were not satisfied.

10. As already mentioned in paragraph 2 above, all the requests before the Board contain claims relating to a process for hydrolyzing hemicellulose involving recombinant micro-organisms. Accordingly, none of them is allowable under Article 100(b) EPC. Thus, since the appeal must fail on that issue there is no need to consider the other findings of the Opposition Division.

Order

For these reasons, it is decided that:

1. The appeal is dismissed

The Registrar:

A. Wolinski



The Chairman:

L. Galligani