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Bezeichnung der Erfindung:
Title of invention:
Titre de l'invention : A process for the rapid development of hybrid plants and commercial production of hybrid seed

Klassifikation / Classification / Classement : A01H 1/02

ENTSCHEIDUNG / DECISION

vom / of / du 10 November 1988

Anmelder / Applicant / Demandeur : Lubrizol Genetics Inc.

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence : Hybrid plants/LUBRIZOL

EPÜ / EPC / CBE Article 53(b); Article 84

Schlagwort / Keyword / Mot clé : "Essentially biological processes" - "Plant variety" "product-by-process-claim, hybrid seeds or plants"

Leitsatz / Headnote / Sommaire

I Whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved (cf. point 6 of the reasons).

II Hybrid seed and plants from such seed, lacking stability in some trait of the whole generation population, cannot be classified as plant varieties within the meaning of Article 53(b) EPC (cf. point 14 of the reasons).

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Case Number : T 320/87 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 10 November 1988

Appellant : LUBRIZOL GENETICS INC.
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Decision under appeal : Decision of Examining Division 125 of the European Patent Office dated 4 May 1987 refusing European patent application No. 81 303 287.7 pursuant to Article 97(1) EPC

Composition of the Board :

Chairman : P. Lançon
Members : U. Kinkeldey
C. Payraudeau
E. Persson
G. Szabo

Summary of Facts and Submissions

I. European patent application 81 303 287.7, filed on 16 July 1981, claiming priority from three prior applications filed on 17 July 1980, and published on 27 January 1982 with the publication number 44723, was refused by the decision of the Examining Division of 4 May 1987. The decision was based on independent Claims 1, 10 and 17 which related to processes for rapidly developing hybrids and commercially producing hybrid seeds in general (Claims 1 and 10) or belonging to the genus Brassica (Claim 17).

II. The ground for refusal was that the subject-matter of Claims 1, 10 and 17 constituted essentially biological processes for the production of plants for which a patent should not be granted pursuant to Article 53(b) EPC. It was stated in the decision of the Examining Division that the "quantity" of human intervention in a biological process was not decisive in this respect. Rather, the "quality" of the human intervention had to be decisive in determining whether a process was biological in its essence or not.

According to the decision it had never been disputed that at least the classical breeders' methods were considered as essentially biological, although the quantity of human control and interference might be large in these classical methods. Some conditions were said to be common in all classical breeding processes, namely the steps of selection, crossing and propagation, the crossing being by sexual combination of two selected individuals and resulting in a statistical population which follows Mendel's laws with respect to their phenotypical characteristics.

A process fulfilling the mentioned conditions should be considered as biological in its essence and would not be patentable. There was no doubt that the processes according to Claims 1, 10 and 17 were ruled by the mentioned conditions and thus fell under the exception of Article 53(b) EPC.

III. An appeal was lodged on 8 July 1987 and the respective fee was paid on the same day. The statement of the grounds of the appeal was filed on 14 September 1987.

During oral proceedings held on 10 November 1988 a new set of 25 claims was filed including Claims 20 to 25 relating to products. Amended independent Claims 1, 8 and 13 correspond to former Claims 1, 10 and 17 respectively.

Claims 1, 20 and 21 have the following wording:

1. A process for rapidly developing hybrids and commercially producing hybrid seeds, comprising:

   (a) selecting a first heterozygous parent plant and selecting a second parent plant;

   (b) crossing said first parent plant with said second parent plant to obtain original-parent-derived hybrids that are phenotypically uniform;

   (c) cloning said first parent plant to produce a first cloned parental line;

   (d) crossing plants of said first cloned parental line with said second parent plant or with a second parental line produced therefrom to

obtain hybrid seeds which yield hybrids that are phenotypically uniform, provided that when said second parent plant is heterozygous and a second parental line produced therefrom is used in the crossing of step (d), said second parental line must be produced by cloning; and

(e) repeating steps (c) and (d) as required to obtain hybrid seed that yields phenotypically uniform hybrid plants and, optionally, producing phenotypically uniform hybrid plants from the seed.

20. Hybrid seed that yields plants that are phenotypically uniform, said seed having been produced by a process comprising:

(a) selecting a heterozygous first parent plant and selecting a second parent plant;

(b) crossing said first parent plant with said second parent plant to obtain original-parent-derived hybrids that are phenotypically uniform;

(c) cloning said first parent plant to produce a first cloned parental line;

(d) crossing plants of said first cloned parental line with said second parent plant or with a second parental line produced therefrom to obtain hybrid seeds which yields hybrids that are phenotypically uniform, provided that when said second parent plant is heterozygous and a second parental line produced therefrom is used

in the crossing of step (d), said second parental line must be produced by cloning, and

(e) repeating steps (c) and (d) as required to obtain hybrid seed that yields phenotypically uniform hybrid plants and, optionally, producing phenotypically uniform hybrid plants from the seed.

21. Phenotypically uniform hybrid plants produced from hybrid seed according to Claim 20.

Emphasis is added in Claim 1 by the Board to indicate features added to the claim earlier on file. Independent process claims and 8 and 13 have been amended by insertion of the corresponding features.

IV. In the statement of grounds and during the oral proceedings the Appellant submitted substantially the following arguments:

(a) The exclusion of "essentially biological" processes from patentability in Article 53(b) EPC stood as an exception to the general principle that processes were patentable subject-matter. Exceptions to broad statutory principles were to be narrowly construed. In the same Article, it was specifically stated that the "essentially biological" concept was not to be so broadly construed as to extend to microbiological processes and the products thereof. Clearly, the exclusion could not apply automatically to all processes involving the production of plants or animals; if it did, there would be no need for the words "essentially biological" in Article 53(b) EPC. Thus, the mere fact that plants were produced in the

present invention did not automatically render such a process "essentially biological".

(b) The fact alone that a living organism was used in a process or prepared or modified by a process had never been considered to render it "essentially biological", (cf. European patents 10 393, 30 575 and Decision T 49/83, "Propagating material/CIBA GEIGY", OJ EPO 1984, 112, of the Technical Board of Appeal 3.3.1).

(c) The "quality" of technical intervention in the process of the present invention was far more than routine manipulation of a known and naturally occurring biological event.

(d) Not only the biological or non-biological characteristics of individual process steps, but also characteristics of the end result, i.e. the product as the effect of the process had to be taken into consideration. Furthermore the characteristic results of the process, which were repeatable year after year, were substantially different from those provided by naturally occurring selection and crossing events and by classical breeding processes. The latter could only provide reproducible results by use of parent plants which were homozygous.

(e) Article 53(b) EPC, excluding "plant varieties" from patentability, had been adopted in part to prevent overlap between the protection provided by patents and that provided by plant breeders' rights laws. Products obtained by the claimed processes and the claimed products themselves could not be protected by plant breeders' rights laws because they were hybrid populations and not varieties; therefore, there was

no possibility of overlapping or double protection. To deny patent protection in the present case was to leave the process and the resulting claimed products unprotectable. Yet, the process had the potential to yield valuable crop improvements. The process was expensive to carry out owing to maintenance, micropropagations and optionally tissue culture methods. To leave this technology unprotected was to risk its being unexploited, which was contrary to the public interest.

V. The Appellant requested that the decision under appeal be set aside and that the patent be granted on the basis of Claims 1 to 25 as submitted during the oral proceedings.

Reasons for the Decision

1. The appeal complies with Art. 106 to 108 and Rule 64 EPC and is admissible.

Amendments (Art. 123(2) EPC)

2. The limitation to "heterozygous" parents in the new process claims as one of the selected parent plants according to step (a) of Claims 1 and 13 and the last feature of Claim 8 is disclosed in the specification as a whole, since the special advantage of the claimed processes that heterozygous parents can be used irrespective of the degree of heterozygosity is therein emphasised (cf. page 6, last paragraph and page 9, first paragraph).

The features of the newly added process step (e) in independent Claims 1, 8 and 13 are disclosed for example on page 23, paragraphs 2 and 3 and page 25, paragraph 2.

As regards the new product claims only filed shortly before the oral proceedings, the Board agreed to consider them in view of the special circumstances of the case. These claims, directed to hybrid seed and plants grown from such seed, as being the products directly obtained by one of the three independent process claims are supported by the specification as a whole which describes in detail the mentioned processes which result in the repeated production of said seeds and plants. Specifically seeds and plants are mentioned on pages 1b, lines 18-23; page 6, lines 12-16; page 8, lines 4-8 and 29; page 42, lines 30-36; page 43, paragraph 7 and page 55, paragraph 6.

The amendment of independent process Claims 1, 8 and 13 and newly filed product Claims 20 to 25 are thus allowable with regard to Article 123(2) EPC.

Support and Clarity (Art. 84 EPC)

3. The product claims are drafted as "product-by-process" claims. It has been recognised by a Technical Board of Appeal that claims for products defined in terms of a process of manufacture are admissible provided they fulfil the requirements for patentability and there is no other information available in the application which could enable the Applicant to define the product satisfactorily by reference to its composition, structure or some other testable parameter (cf. T 150/82, "Claim categories/IFF" OJ EPO 7/1984, 209). Since in the present case the claimed products are not individually definable biological entities, which could be characterised by their physiological or morphological features, there is no way of defining the hybrid seeds and plants other than by the processes of their production.

Process claims (Art. 53(b) EPC)

The question of "essentially biological" processes

4. As stated in paragraph II above, the application was refused on the ground that the claimed processes were considered as "essentially biological" within the meaning of Article 53(b) EPC and thus excluded from patentability.

5. Article 53(b) EPC represents in this respect an exception to the general provision of Article 52(1) EPC according to which European patents shall be granted for any inventions, which are susceptible of industrial application, provided they are new and involve an inventive step. The exception is modelled on Article 2(b) of the Strasbourg Patent Convention of 27 November 1963. There is in the preparatory documents no clear guidance as to the interpretation of the concept of "essentially biological". It has in this respect to be born in mind that at the time when the exception was drafted, the knowledge of the potential development in the field of biotechnology was rather limited.

6. Like any exception to a general rule of this kind the exclusion of "essentially biological" processes for the production of plants (or animals) has to be narrowly construed. This is underscored by the fact that this exclusion does not apply to microbiological processes or the products thereof, as also stated in Article 53(b) EPC. The Board takes the view that whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result

achieved. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being "essentially biological". Human interference may only mean that the process is not a "purely biological" process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of a quantitative or qualitative character.

7. The principal aim of the invention is rapidly to produce high purity hybrids and hybrid seeds in increased yield, thus providing a method for large scale commercial production. In the claimed processes (Claims 1 to 19), parent plants with desired characteristics are selected, test-crossed, marked and stored. The hybrids resulting from the crosses are then evaluated for desired traits and phenotypical uniformity and that pair of parent plants which provided the desired hybrids is selected. At least the heterozygous parent is multiplied by cloning and the crossing of the said pair of parent plants is repeated as often as desired to provide the hybrids on a large scale. This process ensures a repeatable and rapid way for developing desired and new plant hybrids and a high yield seed production irrespective of whether or not the parent plants were homozygous.

8. In analysing the claimed processes, it appears that their essence lies in the particular manner of the combination of specific steps which allows use of a heterozygous parent and nevertheless ensures in a repeatable way a rapid development of selected and desired hybrid plants and seeds. The totality and the sequence of the specified operations do neither occur in nature nor correspond to the classical breeders processes. Crossing and selection events in nature are influenced by complex, various and non-predictable circumstances. It is consequently highly

unlikely that a desired and identical repetition of a certain crossing, providing in a controlled way a selected first propagation generation, can ever occur in nature. One important reason for the uncertainty of the crossing results is the so-called diploidy, i.e. the fact that in higher organisms like plants each gene is represented two-fold. A certain feature, represented by this gene, may then be found in a certain plant in a homozygous form, which means that both genes are identical for a given character. If there are differences between both genes, said plant is heterozygous as far as this gene is concerned. In nature there is therefore a mixture of homozygous and heterozygous features. There is an unpredictable segregation of these genes during crossings in nature. One of the main aims of all breeding procedures is to determine whether one certain plant is homozygous or heterozygous and to produce homozygous plants. These are breeding true for the character in question, when they are crossed with themselves or with a similar homozygote. Only when homozygosity is provided, a certain generation as a crossing result can be reproduced repeatedly. There are, however, a lot of disadvantages connected to homozygosity, for example low vigor and thus low seed yields.

9. The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed. In some cases the effect of this can be seen in the result. In the present case, which presents a multistep process, each single step as such may be characterized as biological in a scientific sense. However, instead of the traditional approach of creating a single new crossing first and trying to propagate the individual result afterwards, the specific arrangement of the steps as presented above under

paragraph 8 provides a process with a reversed sequence: it multiplies the parent plants by cloning and then crosses the cloned, and thus derived, parent lines on a large scale repeatably to provide the desired resulting hybrid population. This arrangement of steps is decisive for the invention and permits the desired control of the special result in spite of the fact that at least one of the parents is heterozygous. The facts of the present case under appeal clearly indicate that the claimed processes for the preparation of hybrid plants represent an essential modification of known biological and classical breeders processes, and the efficiency and high yield associated with the product in the present case show important technological character.

10. In all these circumstances, the claimed processes cannot be considered as "essentially biological" within the meaning of Article 53(b) EPC. Consequently, the exception to patentability in this Article does not apply in the present case to the processes covered by Claims 1, 8 and 13 presently on file.

Product claims (Art. 53(b) EPC)

The question of "plant varieties"

11. As to product Claims 20 to 25 the question arises as to whether or not the subject-matter of these claims is in conflict with Article 53(b) EPC, directly with regard to the claimed plants or implicitly with regard to the claimed hybrid seeds. In other words: are the products to be considered as "plant varieties" within the meaning of that provision, which excludes their patentability.

12. The term "variety" is not defined in the European Patent Convention at all. There is further no generally

recognised taxonomic definition for "variety" as there is for "species" or "genus".

In the case of the particular exception to patentability with regard to plant varieties, the legal history of Article 53(b) EPC makes it clear that plant varieties were excluded from patent protection under the EPC mainly because several of the Signatory States had developed special legal protection for plant breeding at national and international level (UPOV Convention) and were of the opinion that such special protection was better adapted to meet the interests of plant breeders.

13. In the above mentioned decision of the Technical Board of Appeal (see paragraph IV(b)) the Board analysed the concept of "plant varieties" in Article 53(b) EPC in the light of the corresponding provisions in the UPOV Convention. It arrived at the conclusion that the term "plant varieties" means a multiplicity of plants which are largely the same in their characteristics (i.e. "homogeneity") and remain the same within specific tolerances after every propagation or every propagation cycle (i.e. "stability") (see paragraph 2 of the Reasons for the Decision). Thus, possession of both these characteristics of "homogeneity" and "stability" would be a prerequisite for a "plant variety". This Board sees no reason for taking a different view in the present case.

14. When analysing the subject-matter of product Claims 20 to 25, defined by general processes in which at least one of the parent plants used as a source for the whole processes is heterozygous with respect to a certain trait and therefore will never breed true, it appears that the claimed hybrid seeds or plants, considered as a whole generation population, are not stable in the sense of the above definition and therefore cannot be considered as a

"variety". As emphasized by the Appellants during the whole procedure, stability in the sense of the above definition is not aimed at, let alone guaranteed. On the contrary, the invention relies on going back repeatedly to the parent plants for further propagation by cloning because the hybrids resulting from the crossing of the parent plants, one of which is heterozygous, do not provide plants which, when further sexually propagated, remain stable with respect to certain desired features. Even if the totality of the hybrid generation resulting from the crosses of the cloned selected parent plants were to comprise single individual plants which would be stable for a certain trait when further crossed and propagated, this fact does not in itself contradict the stated non-stability of the population taken as a whole. Furthermore, such single individual plants are not to be construed as embraced within the subject-matter of the product claim. The Board therefore takes the view that the present hybrid seed and plants from such seed, lacking stability in some trait of the whole generation population, cannot be classified as plant varieties within the meaning of Article 53(b) EPC. The exception to patentability in the said Article does therefore not apply to the subject-matter of new Claims 20 to 25.

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 Claims 1 to 25 as submitted during the oral proceedings.

The Registrar: The Chairman:

F.Klein P.Lançon