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**Datasheet for the decision
of 12 May 2010**

Case Number: T 1854/07 - 3.3.04

Application Number: 00943766.6

Publication Number: 1185161

IPC: A01H 5/10

Language of the proceedings: EN

Title of invention:

Oil from seeds with a modified fatty acid composition

Patentee:

CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS

Opponent:

Greenpeace e.V.

Headword:

Oil from seeds/CONSEJO SUPERIOR

Relevant legal provisions:

EPC Art. 53(b), 83, 123(2)

EPC R. 26(4)

Relevant legal provisions (EPC 1973):

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Keyword:

"Exclusion from patentability according to Art. 53(b) for
plant varieties (no)"

"Sufficiency of disclosure (yes)"

"Added matter (no)"

Decisions cited:

G 0001/98

Catchword:

-



Case Number: T 1854/07 - 3.3.04

DECISION
of the Technical Board of Appeal 3.3.04
of 12 May 2010

Appellant: Greenpeace e.V.
(Opponent) Große Elbstraße 39
D-22767 Hamburg (DE)

Representative: Schnekenbühl, Robert ML
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Respondent: CONSEJO SUPERIOR DE INVESTIGACIONES
(Patent Proprietor) CIENTIFICAS
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
17 September 2007 concerning maintenance of the
European patent No. 1185161 in amended form.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: R. Gramaglia
M. Wieser

Summary of Facts and Submissions

- I. European patent No. EP-B-1 185 161 (application No. 00 943 766.6, published as WO-A-00/74469) having the title "Oil from seeds with a modified fatty acid composition" was granted with 25 claims.
- II. Notice of opposition was filed by the opponent requesting the revocation of the European patent on the grounds of Article 100(a) in conjunction with Article 53(b) EPC.
- III. The opposition division maintained the patent on the basis of auxiliary request IIB filed during the oral proceedings, of which claims 1 and 11 read as follows:
- "1. Sunflower seeds that contain an oil having an oleic acid content of more than 5% and less than 65% by weight based upon the total fatty acid content, a linoleic acid content of more than 1% and less than 65% by weight based upon the total fatty acid content, a palmitic acid content of more than 20% and less than 40% by weight based upon the total fatty acid content, a stearic acid content of more than 3% and less than 15% based upon the total fatty acid content, characterized in that the palmitoleic acid content is less than 4% based upon the total fatty acid content, and the asclepic acid content is less than 4% based upon the total fatty acid content, obtainable by crossing the high stearic line CAS-3, deposited on 14 December 1994 with the ATCC under deposit accession number ATCC-75968 with a high palmitic line to introduce the stearyl desaturase enzymatic activity of the high stearic line in the high palmitic line, and

selecting seed of F2 generations in which the amount of palmitoleic and the amount of asclepic acid are decreased to less than 4% based upon the total fatty acid content."

"11. Seeds according to any one of claims 1-10, obtainable by crossing sunflower seeds of the mutant sunflower line IG-1297M deposited on 20 January 1998 with ATCC under deposit accession number ATCC-209591 with the mutant sunflower line CAS-3, deposited on 14 December 1994 with the ATCC under deposit accession number ATCC-75968."

Dependent claims 2 to 10 related to specific embodiments of the seeds according to claim 1. Claim 12 addressed an oil extracted from seeds as claimed in claims 1-11. Claim 13 and 14 were directed to a plant, whereas claim 15 related to the progeny of the plants. Claims 16 and 17-23 related to a method for preparing the oil and uses of the oil, respectively.

IV. The following documents are cited in the present decision:

- D1 Fernández-Martínez J.M. et al., *Euphitica*, Vol. 97, pages 113-116 (1997);
- D3 Cantisán S. et al., *Plant Physiol. Biochem.*, Vol. 38, No. 5, pages 377-382 (2000);
- D4 Martínez-Force E. et al., *Planta*, Vol. 207, pages 533-538 (1999);

D6 Serrano-Vega M.J. et al., *Lipids*, Vol 40. No. 4, pages 1-6 (2005).

- V. The appellant (opponent) filed an appeal against the decision of the opposition division.
- VI. Oral proceedings were held on 12 May 2010, during which the respondent filed a new main request, differing from the claims of auxiliary request IIb in that the wording in claim 1

"in which the amount of palmitoleic and the amount of asclepic acid are decreased to less than 4% based upon the total fatty acid content"

has been amended to read

"in which the amount of palmitoleic acid is decreased to less than 4% based upon the total fatty acid content and the amount of asclepic acid is decreased to less than 3% based upon the total fatty acid content".

- VII. The submissions by the appellant, insofar as they are relevant to the present decision, can be summarized as follows:

Article 123(2) EPC

- The language "with a high palmitic line" in claim 1 was not supported by the application as filed, as page 7, line 32 of the published WO application as filed merely referred to the high palmitic line CAS-12.

Article 83 EPC

- The invention was not reproducible over the whole scope claimed.

Article 53(b) EPC

- Claim 1 referred to an essentially biological process for the protection of plants which was excluded from patentability according to Article 53(b) EPC.
- Rule 23b(4)(a) EPC 1973 (now Rule 26(4)(a) EPC) and decision G 1/98 (see point 3.1 of the reasons) made it clear that the transfer of a single trait (i.e. the claimed phenotype) into plants resulted in patentable plants, whereas the transfer of a trait based on the interaction of several genetic components, as occurred by simple crossing, resulted in non-patentable plants. Consequently, plant inventions were only patentable when the single genetic components underlying the claimed trait (i.e., the underlying DNA(s)) could be identified and transferred between species. In the present case, the claims related to non-patentable plant varieties because the claimed trait (the fatty acid profile) was the result of the **entire** genotype or combination of genotype together with epigenetic effects and this trait could only be stably transmitted as a **whole** and not as a single transferable technical feature or genetic building block, and the DNA(s) underlying the claimed trait could be neither identified nor transferred between species. In view of this, decision G 1/98 was exclusively concerned

with plant varieties as products of recombinant gene technology and this decision was not applicable in the present case, dealing with plants (seeds) produced by classical plant breeding methods consisting of crossing and selection and accordingly directed to plant varieties which were excluded from patentability by Article 53(b) EPC.

- Rule 26(4)(b) EPC and decision G 1/98 also implied that a single phenotypic trait (e.g. the fatty acid profile) was sufficient for a plant to fall under the definition of a plant variety provided (i) this trait allowed the plant to be distinguished from any other plant grouping and (ii) this trait was stably passed on during propagation. All of these requirements were met by the presently claimed subject-matter, which was therefore to be regarded as excepted from patentability according to Art. 53(b) EPC. This is because the progeny of a plant with a defined phenotype (such as the sunflower variety CAS-3) would also constitute a variety as the desired characteristics were inheritable over several generations and it was not necessary that the plant be homogenous in all its characteristics. Hence crossing the CAS-3 line with a "high palmitic" sunflower line and selecting seeds of plants of the F2 generation, as stated in claim 1, inevitably resulted in a plant variety.

VIII. The submissions by the respondent (patentee) can be summarized as follows:

Article 123(2) EPC

- The passage on page 7, line 35 to page 8, line 2 of the published WO application as filed made it clear that any high palmitic line could be used.

Article 83 EPC

- Post-published document D6 showed that other "high palmitic" lines were able to cross with the CAS-3 line to yield the claimed seeds.

Article 53(b) EPC

- Rule 26(4)(b) EPC stipulated that a variety was defined as an entire plant grouping that had to be able to be propagated unchanged in every morphological feature (e.g. same height, leaf and seed shape, flower colour, etc), including biochemical ones.
- Even if the claimed feature was the result of more than one genetic element or even the interplay of multiple genetic elements, this was not an indication that claim 1 related exclusively to a plant variety. Thus, in the definition of variety the entire genetic constitution or the complete genotype was to be considered.
- The appellant's definition of the term variety was at odds with decision G 1/98, which made it clear that plants with one common technical feature could be patented when this feature was a transgene. If

this was not the case, it would not be possible to obtain patent protection for plants.

- Although patent claims usually relate to only one or a few characteristics or traits which should be stably present, this does not mean that all the other traits remain the same upon propagation.

- It was not at all certain that the parent lines recited in claim 1 such as CAS-3 met the requirements of Rule 26(4)(a) and (c) EPC.

- In the plants/seeds as presently claimed only a part of the genotype was responsible for the technical feature claimed (a change in the fatty acid composition of the sunflower plant). As shown in documents D3 and D4, the trait as presently claimed was determined by a limited number of enzymes and genes encoding them and not by a complete genetic constitution. This technical feature could be bestowed upon many different sunflower lines and the claim was thus not limited to varieties.

IX. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 1185161 be revoked.

The respondent (patentee) requested that the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 23 of the main request filed at the oral proceedings.

Reasons for the Decision

Article 123(2) EPC

1. The appellant argues that the broadening to "high palmitic line" in claim 1 is not supported by the published WO application, which on page 7, line 32 merely refers to the high palmitic line CAS-12.

However, the passage on page 7, line 35 to page 8, line 2 of the published WO application makes it clear that the principle of introducing the mutated SAD gene from the CAS-3 line into "high palmitic mutants" (plural emphasized by the board) rather than the specific line ("CAS-12"), is the critical aspect, providing thus support for the use of any high palmitic line. Moreover, Table 1 on page 2 of the published WO application refers to CAS-5, another high palmitic mutant, exhibiting a high "16:0" (palmitic acid) content.

2. The amended wording in claim 1 "in which the amount of palmitoleic acid is decreased to less than 4% based upon the total fatty acid content and the amount of asclepic acid is decreased to less than 3% based upon the total fatty acid content" finds a basis on page 4, lines 32-38 of the published WO application.

Article 83 EPC

3. The appellant argued that the invention was not reproducible over the whole scope claimed, emphasizing that attempts to select mutants departing from 30.000 seeds failed (see page 115 of document D1).

However, the attempts pointed out by the appellant deal with obtaining high oleic acid mutants, not the CAS-3 line (which has been deposited), or the "high palmitic line", both referred to in claim 1. As regards the former, the CAS-3 line had been deposited and was thus available to the skilled person. As regards the "high palmitic line", the skilled person was able to arrive without undue burden at these high palmitic lines. According to Example 3 of the patent (see paragraph [0029]), it is indeed possible to select a "high palmitic line" (such as IG 1297-M having more than 20% palmitic acid) by departing from only 5.000 X-ray irradiated seeds. Another such high palmitic line is "CAS-5" listed in Table 1 in paragraph [0006] of the patent (see also Table 2 in document D1 and post-published document D6, lines 4-5 of the "Abstract"). Table 1 on page 3 of document D6 also lists "high palmitic lines" CAS-18 and CAS-25.

In view of the foregoing, the board concludes that no objection under Article 83 EPC has been made out.

Article 53(b) EPC

4. For the purpose of the present decision, although claims 1 and 11 are directed to sunflower seeds, the latter will be interchangeably considered as plants, given that plants may be grown from seeds, which represent one stage in the life cycle of the plant.
5. Claim 1 refers to a product defined in terms of the process by which it is produced. Such "product by

process" claim remains a product claim irrespective of the process it refers to.

Appellant's argument, that claim 1 refers to an essentially biological process for the protection of plants which is excluded from patentability according to Article 53(b) EPC, must therefore fail.

6. For the following consideration of the requirements of Article 53(b) EPC, the board has to draw the parties' attention to the exact wording of this Article, which reads:

"European patents shall not be granted in respect of:

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof".

7. As the Enlarged Board of Appeal observed in decision G 1/98 OJ EPO 2000, 111; point 3.3.1, "[w]hereas the exclusion for processes is related to the production of plants, the exclusion for products is related to plant varieties. The use of the more specific term 'variety' within the same half-sentence of the provision relating to products is supposed to have some meaning. If it was the intention of the legislator to exclude plants as a group embracing in general varieties as products, the provision would use the more general term plants as used for the processes."

In point 3.10 of decision G 1/98 the Enlarged Board states "[t]hat Article 53(b) EPC defines the borderline

between patent protection and plant variety protection. The extent of the exclusion for patents is the obverse of the availability of plant variety rights. The latter are only granted for specific plant varieties and not for technical teachings which can be implemented in an indefinite number of plant varieties. This is not a question of arithmetical logic but based on the purpose of plant variety rights to protect specific products which are used in farming and gardening."

8. One of the questions (question 2) referred to the Enlarged Board of Appeal and answered by it in decision G 1/98 (supra) read:

"Does a claim which relates to plants but wherein specific plant varieties are not individually claimed ipso facto avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?"

The answer of the Enlarged Board to this question was the following:

"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."

9. The appellant's major argument in this appeal was that decision G 1/98 was exclusively concerned with plant varieties as products of recombinant gene technology and was therefore not applicable in the present case. The claims in the present case referred to plants (seeds) produced by classical plant breeding methods

consisting of crossing and selection and were accordingly directed to plant varieties which were excluded from patentability by Article 53(b) EPC.

According to the appellant's interpretation of decision G 1/98 (supra) the Enlarged Board has decided that plants defined by the introduction (e.g. via a transgene) of a single identifiable trait (i.e. the claimed phenotype) were patentable whereas patenting was prohibited when the plants were the result of the interaction of several genetic components (including whole genomes), as occurs in traditional plant breeding by methods based on crossing and selection. The appellant concluded that the Enlarged Board considered plants to be patentable only when the genetic basis of their characterising trait (the underlying DNA) could be indentified, i.e. when the trait could be transferred between species.

10. The board cannot agree with the appellant's interpretation of decision G 1/98 (supra) and the conclusions drawn therefrom.
- 10.1 The decision (in point 3.1) cites the exact definition given for a "plant variety" in Article 1(vi) of the UPOV Convention 1991, which is identical in substance to the definition given in Article 5(2) of the EC Regulation on Community Plant Variety Rights and in Rule 26(4) EPC (former Rule 23b(4) EPC), which reads:

"(4) 'Plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for

the grant of a plant variety right are fully met, can be:

- (a) defined by the expression of the characteristics that result from a given genotype or combination of genotypes,
- (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- (c) considered as a unit with regard to its suitability for being propagated unchanged."

10.2 The decision (see page 17, first paragraph) goes on to conclude that:

"The reference to the expression of the characteristics that results from a given genotype or combination of genotypes is a reference to the entire constitution of a plant or a set of genetic information."

The decision then states that "[i]n contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed.....It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part."

10.3 Decision G 1/98 is not concerned with methods or steps for obtaining a new plant, be it a variety or not, but

exclusively with the issue whether this new plant is a variety or not. This becomes evident from the answer given by the Enlarged Board in response to question (4) referred to it, which answer reads:

"The exception to patentability in Article 53(b), 1st half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability."

10.4 Thus, although it is evident that the actual technical situation underlying decision G 1/98 refers to a plant produced by recombinant gene technology, in the present board's view the decision does not contain any basis for the assumption that the findings of the Enlarged Board of Appeal, particularly its answer to question (2) referred to it (see point 8 above), only apply to genetically manipulated plants.

On the contrary, decision G 1/98 makes clear beyond doubt that, whether or not a plant is considered to be a plant variety depends only on whether or not it meets the criteria set out in the definition in Rule 26(4) EPC (former Rule 23b(4) EPC). The method for its production, be it by recombinant gene technology or by a classical plant breeding process, is not relevant for answering this question. It is not called into question that a plant variety may be the product of crossing and selection (see decision G 1/98, page 16, first paragraph) but, contrary to the appellant's view, it cannot be derived from decision G 1/98 that a plant by definition is not a variety when the claimed phenotype

has been obtained by introduction of a transgene, whereas it is automatically a variety when the plant having the desired phenotype is achieved in a more traditional way, for example by mutagenesis or by crossing and selection.

11. The presently claimed sunflower plants (seeds) are characterised by having a preferred fatty acid profile, mainly characterised by a high content of the desired oleic acid and a low content of the undesired palmitoleic acid. According to claim 1, they are obtained by a process including crossing the defined and deposited "high stearic line" CAS-3 with a "high palmitic line", and selecting seeds of plants of the F2 generation. According to claim 11 the "high palmitic line" is the defined and deposited breeding line IG 1297-M.

12. According to the appellant, the claimed phenotypic trait (the fatty acid pattern) is not a result of a single transgene but of the interaction of a plurality of genetic components, or even of the entire genotype or combination of genotypes together with epigenetic effects and could only be stably transmitted by these as a whole and not as a single identifiable and transferable technical feature or genetic building block.

This would have the consequence that the plants (seeds) obtained by the process referred to in claim 1 meet all criteria of the definition of a plant variety given in Rule 26(4) EPC (former Rule 23b(4) EPC).

13. The board disagrees with the appellant's proposition. The trait as presently claimed (a change in the fatty acid composition of the sunflower plant) is determined by a limited number of enzymes (and DNAs encoding them) rather than by a complete genetic constitution (see the abstract of document D3 -"Two enzymatic activities are found to be involved"- and the Abstract and Fig. 1 on page 537 of document D4). This part of the genotype which is responsible for the claimed trait can be bestowed upon many different sunflower lines. The lower stearoyl-ACP-desaturase gene from CAS-3 can indeed be introduced into "high palmitic" sunflower lines thus reducing the levels of palmitoleic and asclepic acids (see paragraph [0022] of the patent). Example 4 of the patent and post-published document D6 show that this trait can be bestowed upon different "high palmitic" sunflower lines.

The genetic equipment defining one specific trait of a plant (seed), namely its fatty acid pattern which is regulated by a limited number of enzymes, does not constitute its "genotype", which defines its entire genetic makeup. The claimed plants (seeds) are not therefore "defined by the expression of the characteristics that result from a given genotype or combination of genotypes" (Rule 26(4)(a) EPC).

14. Following a different line of argument, the appellant maintained that a strict reading of Rule 26(4)(b) EPC had to lead to the conclusion that a single phenotypic trait (e.g. in the present case the claimed fatty acid profile) was sufficient for the plant to fall within the definition of plant variety, provided the single phenotypic trait allowed the plants to be distinguished

from any other plant grouping and the single phenotypic trait was stably passed on during propagation.

In the light of the board's findings in point 13 above this argument is also without merit.

15. It remains to be established whether carrying out the method recited in claim 1 (crossing the CAS-3 line with a "high palmitic" sunflower line, and selecting seeds of plants of the F2 generation) inevitably results in a plant variety, as the appellant argues.
16. The parent CAS-3 line is a sunflower breeding line. The respondent pointed out that an application for variety protection was not successful.

While a consensus seems to have existed between the parties during the opposition procedure that a "breeding line" contains more phenotypic variation than a plant variety (see paragraph 26.1 of the decision under appeal), in the oral proceedings before the board of appeal, the appellant took the view that a breeding line (in German "Linie") and a variety (in German "Sorte") defined the same entity with the only exception that a variety was registered and a breeding line not. No evidence was provided for this assumption.

The only further information relating to CAS-3 appears from the declarations of Juan Fernandez-Perez and Ricardo R. Siciliano Giner filed by the respondent on 26 March 2007, stating that this line was not uniform.

Therefore, in the light of the evidence on file, the board has no reason to assume that the parent CAS-3 line is a plant variety.

The "high palmitic" line referred to in claim 1 is not restricted to any particular deposited line or variety. Thus the claim allows the use of any sunflower provided it has a high palmitic acid content. There is also no requirement in the claim that the genetic background of the high palmitic lines be the same as that of the high stearic line (CAS-3). Therefore, the only possible way in which the claimed progeny could result in a variety or group of varieties is if the stabilisation of the desired phenotype through backcrossing led to phenotypic homogeneity. In the present case, the wording of the claim ("selecting seed of the F2 generation") only requires a single backcross. There is no evidence before the board that this single backcross would result in a plant variety.

17. In claim 11 the "high palmitic" parent line is defined as being the deposited line IG 1297-M. This line does not possess the same genetic background as CAS-3, and is not uniform (see the declarations referred to in point 16 supra). There is no evidence before the board, either, that a single backcross, as required by the claims would result in a plant variety.

18. Accordingly, the board arrives at the decision that both claims 1 and 11 do not individually claim a plant variety even though they may embrace plant varieties. Therefore, following decision G 1/98 (supra) the subject-matter of these claims, as well as that of

claims 2 to 10 and 13 to 15, is not excluded from patentability under Article 53(b) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claims 1 to 23 of the main request as filed at the oral proceedings and the description as granted.

The Registrar:

The Chairman:

P. Cremona

C. Rennie-Smith