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Date

30. 11. 06

Reference L/DU62/ems/4	Application No./Patent No. 00943766.6 - 2406 / 1185161
Applicant/Proprietor CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS	

Summons to attend oral proceedings pursuant to Rule 71(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will be public, will take place before the opposition division

on 28.03.07 at 09.00 hrs in Room 3468
at the EPO, Bayerstr. 34, PschorrHöfe, D-80335 München

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 10/2000, 456).

If you do not appear as summoned, the oral proceedings may continue without you (R. 71(2) EPC). Your attention is drawn to Rule 2 EPC, regarding the language of the oral proceedings, and to the OJ EPO 9/1991, 489, concerning the filing of authorisations for company employees and lawyers acting as representatives before the EPO.

The final date for making written submissions and/or amendments (Rule 71a EPC), is 29.01.07.

You are requested to report in good time beforehand to the porter in the EPO foyer. Room 3473 and 3474 are available as waiting rooms. Parking is available free of charge in the underground car park. However, this applies only in the case of accessing the car park via the entrance "Zollstrasse".

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Chairman:
Bilang J

For the Opposition Division



Annexes:
Confirmation of receipt (Form 2936)
Rule 2 EPC (EPC Form 2043)
Communication (EPO Form 2906)



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Summons to Oral proceedings

- 1: This communication accompanies a summons to oral proceedings, as requested by the Patentee should the opposition division come to decision other than maintaining the Patent as granted. The communication sets out the essential issues to be discussed as said oral proceedings.
2. The Patent EP1 185 161 was published and granted on 01.09.2004. It corresponds to European application number EP00943766 filed on 05.06.200 and claims priority from US application 326500 dated 13.03.2002. It is entitled "Oil from seeds with a modified fatty acid composition". The patent proprietor (P) is Consejo Superior de Investigaciones Cientificas of Seville, Spain.
3. A notice of Opposition has been filed against this patent by Greenpeace e.V. (O) of Hamburg, Germany, received on 27.05.2005.
4. The extent of opposition is the patent as a whole. The grounds for opposition raised by O are Art. 100(a) in conjunction with Art. 53b EPC.
5. O requests that the Patent be revoked in its entirety.
6. P has replied to the notice of opposition with a letter dated 16.01.2006. P requests that the opposition is rejected and that the Patent be maintained as granted or failing that on the basis of claims 1-25 in which claim 17 has been amended, filed as an auxiliary request.
7. O has substantiated his objections as summarised below:
Claims 1-10 and 14-16 relate to plant varieties which are excepted from patentability according to Art. 53(b) EPC.
O argues that the claims are directed exclusively to plant varieties characterised by a set of features that are determined by a particular genotype or combination of genotypes. The combination of complex characteristics (oil profile) is determined by a the entire genotype or combination of genotype together with epigenetic effects and can only be stably transmitted by these as a whole.
8. D1 and D2 authored by the inventors of the patent in suit make it clear that the claimed oil profile is not only the result of particular mutations but the particular genetic background in which they occur.



9. P has responded to the objections as follows:
The claims 1-10 and 14-16 do not relate to plant varieties. In the plants as presently claimed only a part of the genotype is responsible for the technical feature (fatty acid profile) claimed. **This technical feature can be bestowed upon many different varieties** and the claim is thus not limited to varieties. This statement is supported by post published documents which show that "only a part of the genotype is responsible for that feature". Only a limited number of enzymes and genes encoding them were found to be responsible for the claimed traits and not a complete genetic constitution. Moreover, these genes can be transferred to other sunflower lines. Thus, the invention does not claim a variety and is not limited to a variety but the teaching is applicable to plants in general.
10. O has also objected to claims 11 and 17 as relating to essentially biological processes for the production of plants.
11. P argued that claim 11 was not a process but a product claim. With respect to claim 17, step a) inherently includes a step of human intervention. In the auxiliary request claim 17 as granted is modified by the inclusion of mutagenesis steps in part a).

Preliminary and non-binding opinion of the opposition division.

12. **Extent of opposition.**

The opponent has not used the standard forms provided by the EPO to file the opposition, but has stated in the letter of opposition dated 24.05.05 that the patent should be revoked in its entirety. Reasoning is provided only for the ground of opposition Art. 53b EPC.

The opposition division is of the opinion that the extent of opposition is the patent as a whole, since if this were not the case the request to revoke the patent as a whole could never be followed.

13. Art. 53b EPC states that European patents shall not be granted in respect of plant varieties.
Rule 23b EPC states that "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 results 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
14. The exception of plant varieties from patentability under the EPC was examined in detail in the decision of the enlarged Board of Appeal G1/98. Here the board concluded "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".
15. The opposition division now has to answer the question whether the subject-matter of the present claims is directed to specific plant varieties or if it relates to plants in a broader sense.
16. When considering the case giving rise to G1/98, the Board (Reasons 3.1) makes the statement that "in assessing the subject-matter of a claim [with respect to Art. 53b], the underlying invention has to be identified. In this respect, it is relevant how generic or specific the claimed invention is."
17. Applied to the present case, study of the description reveals that the only examples of sunflower seeds with the oil profile set out in claim 1 are those disclosed in the specific breeding method set out in Example 4, which relies on the use of particular deposited parent plants IG-1297M and CAS-3. CAS-3 is a mutant generated by chemical mutagenesis of a named sunflower seed RDF-1-532 (see example 1). IG-1297M is a mutant generated by X-ray mutagenesis from an unnamed parent (see example 3).
18. Claim 1 on the other hand defines the sunflower seeds only by their fatty acid profile, a phenotypic feature, without any reference to the underlying genotype. Since the genetic features leading to this phenotype were not known, the only way to carry out the invention as claimed is by use of the particular deposited seeds of the parental lines.



19. Thus the answer to the question "how generic or specific is the claimed invention?" is that it is specifically restricted material derived from particular deposited lines.
20. There are consequences of this answer for assessment of the requirements of the EPC under a number of Articles. Thus, the grounds for opposition as raised by O will be expanded by the opposition division of its own motion, in accordance with Art. 114(1) EPC, in those cases where the objection is more properly raised under a different ground.
- Art. 100b EPC**
21. Art. 100b EPC implements the requirements of Art 83 EPC for granted patents. Thus, the European patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. According to the Guidelines, C-III, 6.4 and established practice of the Boards of Appeal (see Case Law Book, page 147, final complete paragraph), the requirements of Art. 83 EPC are not met if the disclosure is insufficient to enable the skilled person to carry out the "invention" over **the whole of the broad field claimed**.
22. As is apparent from the discussion above, it appears that the presently claimed subject-matter can only be carried out by using the deposited sunflower lines. All remaining claimed subject-matter cannot be carried out because, amongst other reasons, the nature of the mutation(s) leading to the claimed phenotype was/were not known. Moreover, these were generated by a random, and thus inherently unrepeatable, mutagenesis process. No means of introducing the specific mutations, which do not rely on access to the deposited plant lines, exist. Thus, the subject-matter of claims 1-10 and 14-16 does not meet the requirements of Art. 83 EPC. Moreover, claim 17 also falls with the above objection since, as discussed above, they depend on a mutagenesis step which is inherently random and not repeatable.
- Art. 53b EPC - Plant Varieties**
23. An alternative or complementary objection may be raised under Art. 53b . In a case where the **only** sufficiently disclosed subject-matter in a claim *de facto* consists of plant varieties, the claim can be said to contravene Art. 53b even if, *prima facie*, it appears more broadly drafted. This may indeed hold for present



Bescheid/Protokoll (Anlage)		Communication/Minutes (Annex)		Notification/Procès-verbal (Annexe)	
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claims 1-11 and 14-16 for the reasons already set out above.

To fall within the exception according to Art. 53b EPC, the claimed subject-matter must be restricted to plant varieties (see G1/98). The claimed subject-matter must belong to "any plant grouping i) within a single botanical taxon of the lowest known rank - *in the present case sunflower-*

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 results from a given genotype or combination of genotypes, - *in the present case, the genotype does indeed define the characteristics-*

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, -*this condition is met by the distinguishing oil profile and possibly by other features of the original plant material-* and

(c) considered as a unit with regard to its suitability for being propagated unchanged.

This depends on whether the originally used sunflower seeds were those of a variety. It is unlikely that the mutagenesis will have itself caused instability to such an extent as to take an existing variety out of the stability criterion: -The opposition division is not in a position to determine whether the originally used plant material was a variety or even if the seeds used in examples 1 and 3 were of the same type. The Patentee is requested to provide the opposition division with the information necessary to reach a decision on this issue, i.e. what was the nature of the originally used seed material?

24. **Art. 53b EPC - Essentially biological processes for the production of plants** are also excepted from patentability. Rule 23b(5) EPC explains 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."

The subject-matter of claim 17 as granted is a process for the production of plants consisting entirely of natural phenomena. Thus, it falls within the exception.

Claim 11 on the other hand relates to plants and has been dealt with above.

25. Auxiliary request 1: It remains to be discussed whether the claim 17 including a mutagenesis step is to be seen as essentially biological or not. In considering this matter it should be noted that in the preparatory documents leading to the EPC, it is stated that processes for producing new plants by irradiation of the plants



themselves or the seeds with isotopes would not be excepted from patentability (see T356/93, Reasons 25).

26. **Claims 12, 13 and 20-25 directed to oil and it uses.** The opposition division considers that these claims *prima facie* lack inventive step (Art. 56 EPC) and raises this objection of its own motion according to Art. 114(1) EPC.
- The closest prior art for claims to sunflower oil having the particular fatty acid profile of claim 12 will be that sunflower oil known in the prior art which has the closest fatty acid profile. This is likely to be an oil derived from one of the sunflower lines mentioned on pages 3-4 of the present patent under the heading "Background of the Invention".
- The difference between these oils will therefore be a difference in the levels of one or more fatty acids, including high palmitic and stearic acid and low palmitoleic and asclepic acid content. The problem to be solved can be seen as provision of a sunflower oil that meets the requirements of the food industry in terms of high thermostability and plasticity to be spread.
- This problem appears to be solved by the oil that is the subject-matter of claims 12 and 13.
- However the solution is considered obvious. The desire to move away from hydrogenated fats in food industry applications requiring oils with high thermostability and plasticity to be spread was well known in the art. The problems of conventional sunflower oil for these purposes were also well known, as was the potential solution, i.e. increasing the levels of the saturated palmitic and stearic fatty acids. Thus, the skilled person faced with the above problem would have considered increasing the percentage of either or both palmitic and stearic acids in sunflower oil.
- It is noted that the claimed oil is not restricted to that obtained directly from sunflower seeds and can also be obtained by other means. For instance simple mixing of the constituent fatty acids, in this case palmitic and stearic acids into a conventional sunflower oil would lead to an oil falling within the claim. Such mixing is considered to lack any inventive merit.