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DECISION of 30 June 2004

Case Number: T 0579/01 - 3.3.4

Application Number: 95202975.9

Publication Number: 0771523

IPC: A01H 1/02

Language of the proceedings:

#### Title of invention:

A cytoplasmic male sterile vegetable plant cell of the compositae family and also a method for obtaining such a plant

#### Patentee:

Enza Zaden, De Enkhuizer Zaadhandel B.V.

#### Opponents:

Florimond Desprez Groupe Limagrain Holding

#### Headword:

Cytoplasmic male sterile plants/ENZA ZADEN

## Relevant legal provisions:

EPC Art. 123(2), 123(3), 83, 54, 56, 69(1) EPC R. 23b, 23c, 23d, 23e

#### Keyword:

"Main request: added subject-matter (no); extension of protection (no); sufficiency of disclosure (yes); novelty (yes); inventive step (yes)"

#### Decisions cited:

T 0059/87, T 0049/89, T 0402/89, T 0019/90, T 0604/01

## Headnote:

Under certain circumstances the amendment of a "cell of a plant" claim to a "plant" claim is not contrary to the requirements of Article 123(3) EPC. (See points 8 to 13 of the reasons).



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Boards of Appeal

Chambres de recours

Case Number: T 0579/01 - 3.3.4

DECISION

of the Technical Board of Appeal 3.3.4 of 30 June 2004

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted 15 March 2001 revoking European patent No. 0771523 pursuant

to Article 102(1) EPC.

Composition of the Board:

Chairwoman: U. M. Kinkeldey Members: R. E. Gramaglia

S. U. Hoffmann

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## Summary of Facts and Submissions

- The appeal is against the decision of the opposition division revoking European patent No. 0 771 523 (application No. 95202975.9), which had been opposed by opponents 01 and 02, all requesting the revocation of the European patent on the grounds of Article 100(a), (b) and (c) EPC. Independent claims 1 and 7 as granted read as follows:
  - "1. A cell of a vegetable plant belonging to the Compositae family, the cytoplasm of which is provided with mitochondria comprising DNA which at least partially originate from a different species of the Compositae family, and which is the carrier of stably expressable cytoplasmic male sterility (CMS), said cell comprising species-specific chloroplast and nuclear genome which are normal for the vegetable plant.
  - 7. Process for producing a vegetable plant belonging to the <u>Compositae</u> family comprising the steps of providing the cytoplasm thereof with mitochondria having DNA which at least partially originate from a different species of the <u>Compositae</u> family, and which is the carrier of stably expressable cytoplasmic male sterility (CMS), as well as providing the cytoplasm thereof with species-specific chloroplast and nuclear genome."

Claims 2 to 6 were addressed to specific embodiments of the cell of claim 1.

II. By its decision the opposition division held that the claims then on file did not satisfy, *inter alia*, the

requirements of Article 123(2) EPC because the expression "stably expressable" in the independent claims represented added subject-matter. The opposition division did not consider the issues of novelty, inventive step and sufficiency of disclosure.

- III. During the oral proceedings held on 30 June 2004 appellant submitted a new main request (claims 1 to 7), a new first auxiliary request (claims 1 to 6) and a new second auxiliary request (sole claim) in replacement of any previous claim request. Claims 1 and 7 of the new main request read as follows:
  - "1. A vegetable plant belonging to the <u>Compositae</u> family, the cytoplasm of which is provided with mitochondria comprising DNA which at least partially originates from a different species of the <u>Compositae</u> family, and which is the carrier of stably expressable cytoplasmic male sterility (CMS), whose cells comprise species-specific chloroplast and nuclear genome which are normal for the vegetable plant.
  - 7. Process for producing a vegetable plant belonging to the <u>Compositae</u> family comprising the step of providing the cytoplasm thereof with mitochondria having DNA which at least partially originates from a different species of the <u>Compositae</u> family, and which is the carrier of stably expressable cytoplasmic male sterility (CMS), as well as providing the cytoplasm thereof with species-specific chloroplast and nuclear genome, wherein
  - the vegetable plant has been selected from the group consisting of <u>Cichorium intybus (L.) var. foliosum</u> (Hegi), Cichorium endivia (L.), Lactuca sativa (L.),

Scorzonera hispanica (L.), Cynara scolymus (L.), and Taraxacum officinale (L.); and

- the other species of the <u>Compositae</u> family has been selected from the group consisting of <u>Helianthus spp.</u>, <u>Cirsium spp.</u>, <u>Chrysanthemum</u>, <u>Senecio</u>, <u>Centaurea</u>, <u>Sonchus</u>, <u>Hiëracium</u>, <u>Tagetes</u>, <u>Dahlia and Aster</u>; and - use is made of irradiation for inactivating the donor nucleus."

Claims 2 to 6 were addressed to specific embodiments of the vegetable plant of claim 1.

- IV. The following documents are cited in the present decision:
  - (D1) Rambaud C. et al., Theor. Appl. Genet., Vol. 87, pages 347-352 (1993);
  - (D2) Rambaud C. & Vasseur J., C.R. Acad. Agric. Fr., Vol. 80, No. 7, pages 63-67 (1994);
  - (D3) Rambaud C. et al. in "Quel avenir pour l'amélioration des plantes?", Ed. AUPELF-UREF, John Libbey Eurotext, Paris, pages 483-489 (1994);
  - (D5) FR-A-2 628 601;
  - (D6) Köhler et al., Mol. Gen. Genet., Vol. 227, pages 369-376 (1991);
  - (D7) Rambaud C. et al., Plant Breeding, Vol. 116, pages 481-486 (1997);

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(D8) Galun E. & Aviv D., Methods in Enzymology, Vol. 118, pages 595-611 (1986);

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- (D9) Rambaud C. et al., Agronomie, Vol. 10, pages 767-772 (1990);
- (D10) Rambaud C. et al., Euphytica, Vol. 62, pages 63-67 (1992);
- (D13) Vedel F. et al., Plant Physiol. Biochem., Vol. 32, No. 5, pages 601-618 (1994);
- (D14) Yesodi V. et al., Mol. Gen. Genet., Vol. 255, pages 106-114 (1997).
- V. The submissions in writing and during oral proceedings by the appellant (patentee), insofar as they are relevant to the present decision are summarised as follows:

Added subject-matter (Article 123(2) EPC)

- The expression "stably expressable CSM" in claims 1 and 7 found a basis in the application as filed.
- The Mendelian rules relating to dominance / recessiveness did not apply to mitochondrial (mt) DNA (see documents (D11), D13) and (D14)). Rather, any cytoplasm-coded property (e.g., the "stably expressable CSM" of claims 1 and 7) was maternally

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inherited and thus transmitted to all progeny (document (D11)).

Claim 7 was no broader than the disclosure of the application as filed and found a basis on page 2, line 32 (the introduction of CSM into a vegetable plant).

Extension of scope of protection (Article 123(3) EPC)

- The amendment of "a cell of a vegetable plant" (granted claims) to "a vegetable plant" (claims of the new main request) did not extend the protection conferred, but solely limited it.
- A vegetable plant belonging to the Compositae family was nothing more than a plurality of cells as claimed previously.
- Plants generally consisted of a plurality of diploid cells, while only the reproductive organs of plants could comprise haploid cells, i.e. pollen and egg cells. The male sterile vegetable plant according to the invention thus predominantly consisted of cells comprising all claimed features of the previous claims, i.e. "the cytoplasm of the cells is provided with mitochondria comprising DNA which at least partially originates from a different species of the Compositae family, and which is the carrier of stable expressable cytoplasmic male sterility (CMS), and the cells are provided with species-specific chloroplast and nuclear genome which are normal for the vegetable plant".

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- Although the plant might comprise other types of cells as well (i.e. egg cells), the cell as claimed previously would always be present in a plant, since a cell could not be seen apart from a plant.
- The protection which would be conferred by the claims directed to the cell would always have extended to those cells forming part of a plant. Thus, such a plant wherein the cells were contained, notwithstanding the presence of other cell-types, would have been encompassed by the claims on the cell.
- In addition, as the plant cell was generally a totipotent cell, it was possible to regenerate a plant from one cell, thus showing that the plant indeed consisted of a plurality of the cells covered by the previous claims.
- Claims relating to the vegetable plant, which corresponded to the claims as originally filed, actually gave a better definition of the present invention, as the invention related to a property which was only phenotypically visible in the plant, and not in the cell itself, even though it was present in its genetic information.

## Sufficiency of disclosure

- The patent in suit (see Examples 1 to 7) gave plenty of details enabling the skilled person to perform the invention for chicory, endive and lettuce as acceptors and sunflower as donor, while explicitly disclosing various other vegetable plants as

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acceptor, as well as various other donor types. The skilled person was able to obtain substantially all embodiments falling within the ambit of the claims.

- A definition of CSM was given in documents (D5) and (D6) relating to CSM in sunflowers.

## Novelty

- The authors of documents (D1) to (D3) did not succeed in obtaining stably expressible CMS, nor 100% pure plants as far as the chloroplast and nuclear genome was concerned, as required by present claim 1.
- According to document (D1) (see page 348, second column, lines 35-ff and page 351, first column), only a few plants out of 600 regenerants obtained showed some form of male sterility and only one plant could be used for obtaining seeds. This plant was also unstable as far as male sterility was concerned.
- This was in line with the conclusions arrived at in document (D2) (see English summary) and document (D3) (see paragraph "Caractérisation des plantes obtenues"), which again related to the same failed attempt to obtain male sterile plants of the Compositae family.
- As for post-published document (D7), it had to be disregarded. But once taken into account, it showed that even the fourth generation of the plants as described in documents (D1) to (D3) was not stable

with respect to mitochondrial DNA and the CMS property (see Abstract, "...genetic instability...").

- Further, the terminology used in documents (D1) to (D3) was "heterokaryocytes" or "heterocaryons", suggesting the presence of both a sunflower and a chicory nucleus (and cytoplasm).

## Inventive step

- The closest prior art was represented by either of documents (D1) to (D3) relating to a failed attempt to obtain 100% pure stably expressible CMS plants of the Compositae family.
- None of the prior art documents suggested how to overcome the problem of obtaining 100% pure male sterile plants endowed with stably expressable CMS, without any negative aberrations in flower morphology and/or plant type. This problem had been solved by applying the method described in the patent in suit making use of, inter alia specific inactivation steps of the donor nucleus and acceptor mitochondria.
- VI. The submissions in writing and during oral proceedings by the respondents (opponents 01 and 02), insofar as they are relevant to the present decision, are summarised as follows:

Added subject-matter (Article 123(2) EPC)

The expression "stably expressable CSM" in claims 1 and 7 (see the wording "...is the carrier of stably - 9 - T 0579/01

expressable cytoplasmic male sterility (CMS)") had no basis in the application as filed.

- The fact that the mt DNA profile was "stably transmitted" throughout progeny lanes 2 to 5 after 5 backcrosses (see the legend to Fig. 2) did not mean that said CSM was linked to CSM, let alone "expressable".
- The legend to Fig. 2 related to a specific example (<u>Helianthus</u> and <u>Cichorium</u>) which could not be generalized without infringement of Article 123(2) EPC.
- Claim 7 was an inadmissible generalisation of the Examples in the application as filed, limited to particular species and involving protoplast fusion only.

#### Article 123(3) EPC

 Interpreting a claim to a cell as covering a plant was not necessarily a broadening under Article 123(3) EPC.

## Sufficiency of disclosure

- It represented undue burden for the skilled person to establish whether a plant exhibited "stably expressable CSM" since no definition of this concept was given in the patent in suit.
- Obtaining CSM plants was a question of chance and undue burden.

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- The skilled person was not able to obtain substantially all the embodiments falling within the ambit of the claims. Document (D1) showed that it was not always possible to obtain male sterile chicory (see page 351, 1-h column, lines 11 to 13).

## Novelty (Article 54 EPC)

- The subject matter of claims 1 to 7 lacked novelty over documents (D1), (D2) and (D3), which described stable male sterile chicory "cybrids" obtained by intergenic protoplast fusion of chicory with CMS sunflower, the features in claim 1 "stably expressable cytoplasmic male sterility (CMS)" and "the cell comprises species specific chloroplast and nuclear genome which are normal for the vegetable plant" being implicitly disclosed in these documents.
- Document (D7) (post-published 1997), cited as expert opinion, confirmed that fourth generation plants from CT41/1 (i.e. the same plants disclosed in documents (D1 to (D3)) only had the mitochondrial genome rearranged (see page 484, col. 2, paragraph under "Discussion"), while possessing a normal chicory nuclear (see document (D2), page 66(7): "...possédant 2n = 18 chromosomes comme la chicorée) and chloroplastid genome as required by present claim 1 (see "whose cells comprise species specific chloroplast and nuclear genome which are normal for the vegetable plant").
- Claim 7 was anticipated by the process described in document (D1) for obtaining male sterile chicory

plants comprising the steps of (i) isolating chicory mesophyll protoplasts (acceptor) and hypocotyl protoplasts derived from male sterile sunflower; (ii) fusion of these protoplasts; (iii) culture of the fused protoplasts and (iv) culture of the plants from the fused protoplast, as illustrated in more details in documents (D9) and (D10) (steps (i), (ii) and (ii)).

#### Inventive step

- The closest prior art was represented by documents (D1) to (D3). The problem to be solved was to obtain 100% pure male sterile plants endowed with stably expressable CMS. However, this problem had not been solved by the patent in suit.
- The technique yielding the claimed plants, i.e. protoplast fusion and X ray irradiation was already known and obvious from document (D13) (see page 612) and document (D8) (see page 596, first full paragraph).
- It was obvious to stabilize the plant by backcrossing and arrive at the claimed subjectmatter. Table 2 of document (D7) showed that after 4 backcrossings only 1.9% of the flowers was fertile (i.e. the flowers had 98.1 % purity): only two further backcrossings were needed to reach 100% purity.
- VII. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of

claims 1 to 7 of the new main request or

claims 1 to 6 of the new first auxiliary request or

the sole claim of the new second auxiliary request

all filed during the oral proceedings on 30 June 2004.

The respondents (opponents 01 and 02) requested that the appeal be dismissed.

#### Reasons for the Decision

The appeal is admissible.

New Main Request

Rule 57a EPC

2. The claims of the new main request comply with the requirements of Rule 57a EPC. Granted claim 1 directed to "a cell of a vegetable plant" had been objected to under Article 123(2) EPC during opposition proceedings and the amended-subject matter now claimed is suitable to address this objection.

Added subject-matter (Article 123(2) EPC)

"Stably expressable CSM"

3. The respondents argue that the expression "stably expressable CSM" in claims 1 and 7 has no basis in the

application as filed. There is indeed no explicit wording "stably expressable CSM" in the application as filed. The question thus arises of whether this feature is implicitly disclosed. In the board's view, it can be derived from page 23, lines 12 to 14 of the application as filed which reads "As a result of maternal heredity, all cytoplasm-coded properties, such as CSM, will be present in all progeny". This means that the cytoplasmcoded CSM trait is transmitted throughout the progeny at the DNA level. Moreover, the legend to Fig. 2 on page 17 of the application as filed shows that the CSM trait is stably transmitted as DNA information throughout the progeny. In fact, Fig. 2 illustrates the mt DNA profile (hybridization with the specific mt DNA probe pEZMT22) of the acceptor (Cichorium), the donor (Helianthus) and the fusion product. In lanes 1 to 5 of Fig. 2 is also shown the mt DNA profile of 5 plants which are "backcrosses" (progeny) of the fusion products (the mother) and Cichorium (the pollinator). According to the legend to Fig. 2, the mt DNA profile underwent a change only during the transition from the fusion product to the first progeny (lane 1) but the mt DNA profile thus changed was "stably transmitted" throughout progeny lanes 2 to 5, i.e. it was intact after 5 backcrosses.

4. The question now arises whether "stably transmitted CSM" implies also "stably expressable CSM", which the respondents deny. They argue that the fact that the mt DNA profile is "stably transmitted" throughout progeny lanes 2 to 5 after 5 backcrosses (see the legend to Fig. 2) does not mean that said mt DNA profile is linked to CSM, let alone "expressable".

However, the application as filed (see bottom of page 2) also teaches that one has to select a plant which is "phenotypically cytoplasmic male sterile", i.e. wherein CSM has "manifested itself" (ibidem). This choice is critical since "all progeny of this male sterile plant possesses this unchanged property [because of cytoplasmic heredity of CSM]" (see page 2, line 37 to page 3, line 2). The plant phenotype to be selected is illustrated in Fig. 6 and on the right of Fig. 7 of the application as filed, showing CMS chicory flowers wherein the CSM trait (phenotype) is clearly expressed, as the anthers are not there (the anthers being the male organ of the flower), whilst the rest of the flower is normal.

Moreover, the passage on page 5, lines 20 to 24 provides instructions for selecting these "phenotypically cytoplasmic male sterile" plants from the regenerants by analysis of mitochondrial, chloroplast and genomic DNA, followed by phenotypic evaluation of the plant properties.

In conclusion, once the skilled person follows the instructions given in the application as filed, he/she will of necessity select a plant having a "stably transmitted" (cf the mt DNA stability shown in Fig. 2) and "expressed" CSM phenotype. There is also no evidence before the board that once such a plant is selected, the maternally inherited CSM phenotype will not turn up in all the progeny, the more so as the "Mendelian rules" (dominance/recessiveness) have no bearing in the context of mitochondrial DNA (see documents (D11), (D13) and (D14)). Therefore, "stably transmitted CSM" implies "stably expressable CSM", the

presence of which in claims 1 and 7 at issue has thus an implicit basis in the application as filed.

#### Process claim 7

6. Contrary to the respondents' view, the application as filed is limited neither to protoplast fusion (see page 2, lines 24 to 28: "the cytoplasm of such a vegetable plant is provided with mitochondria comprising DNA which at least partially originate from a different species of the <a href="Compositae">Compositae</a> family..") nor to particular plant species (see page 4, line 32 to page 5, line 28). Therefore, claim 7 does not represent an inadmissible generalisation of the Examples in the application as filed.

Furthermore, the features which have been added to claim 7 as granted in new amended claim 7 ("wherein ...nucleus") were not objected to by the respondents. The board is satisfied that claims 4, 6 and 7 and the passage at page 4, lines 36 to 37 of the application as filed provide a basis for these amendments.

7. In view of the above findings, the board concludes that no case has been made out that the claims of the new main request do not satisfy the requirements of Article 123(2) EPC.

Extension of the scope of protection (Article 123(3) EPC)

8. Claims 1 to 6 of the new main request are directed to a "vegetable plant", while the subject matter of granted product claims 1 to 6 was "a cell of a vegetable plant".

- 9. Article 123(3) EPC provides that during opposition proceedings the claims of the European patent may not be amended in such a way as to extend the protection conferred upon grant. The board considers that the object of Article 123(3) EPC is to prevent any procedural situation where an act which does not infringe the patent as granted becomes an infringing act as a result of an amendment after grant (cf also T 59/87, OJ EPO 1988, 347, reasons point 2; T 604/01 of 12 August 2004, reasons point 2.3). In accordance with the established case law of the Boards of Appeal (cf. T 49/89 of 10 July 1990, reasons point 3.2.2; T 402/89 of 12 August 1991, reasons point 2), the board holds that the legal notion "protection conferred" in Article 123(3) EPC refers to the totality of protection established by the claims as granted and not necessarily to the scope of protection within the wording of each single claim as granted. Under Article 123(3) EPC, the patentee is generally allowed to redraft, amend or delete the features of some or all claims and is not bound to specific terms used in the claims as granted as long as the new wording of the claims does not extent the scope of protection conferred as a whole by the patent as granted (and does not violate the requirements under Article 123(2) EPC). Thus, in order to assess any amendment under Article 123(3) EPC after grant, it is necessary to decide whether or not the totality of the claims before amendment in comparison with the totality of the claims after amendment extends the protection conferred.
- 10. In the present case, independent claim 1 and dependent claims 2 to 6 of the new main request are directed to a

"vegetable plant", while the respective claims as granted were directed to a "cell in a vegetable plant". Evidently, a plant is an object different to a cell, both as a physical phenomenon and as a biological entity. This might indicate that the subject matter of the claims related to these objects is different too. However, in applying the above-mentioned principles, the starting point for the question of whether or not the requirements under Article 123(3) EPC are fulfilled are not the amended expressions or terms of the individual claim but the extent of protection conferred by all granted claims in comparison to the extent of protection conferred by the new claims.

- 11. In the understanding of the skilled person the term "a cell of a plant", not being qualified as "isolated", includes various physiological and morphological states of such a cell, including both differentiated and undifferentiated states. Undifferentiated states of plant cells include those states as e.g. existing in a cell culture or callus (see example 5 of the patent). Differentiated states of plant cells include those states as existing in a (developing) plant, e.g. in a whole plant regenerated from a plant cell (see example 5 of the patent in suit).
- 11.1 The board therefore concludes that cells in the different states in which they exist in a (developing) plant fall within the protection conferred by the claim to the "cell of a vegetable plant" as granted and the protection conferred by such claim also extends to such cells in a plant.

- 11.2 Furthermore, the biological notion "cells of a plant" encompasses such differentiated cells which are morphologically and functionally organised to constitute a plant. This implies that also morphologically and functionally organised aggregates of plant cells, e.g. plants, fall within the protection conferred by the granted claim to a "cell of a plant".
- 11.3 It still needs to be decided whether any plant as subject matter of claim 1 of the new main request falls within the protection conferred by a claim to "a cell of a plant". Claim 1 as granted recites "a cell of a vegetable plant ..., the cytoplasm of which ...". In this respect the board notes that the reference to the cytoplasm characteristics contained in the granted "cell" claim refers to the "cell" as claimed and not to "the cell's plant", i.e. the claim does not require the plant of this cell to consist exclusively of cells as defined in the claim as granted. Accordingly, the board concludes that the protection conferred by the "cell" claim as granted also extends to such plants which contain cells as granted, but not exclusively consist of such cells.
- 11.4 It remains to be examined whether the "plant" now claimed is characterised by the same genetic features as recited in the granted claim to "a cell of a plant". The cytoplasm of the cell of a plant of claim 1 as granted is "provided with mitochondria comprising DNA which at least partially originate from a different species of the Compositae family, and which is the carrier of stably expressable cytoplasmic male sterility (CMS), said cell comprising species-specific chloroplast and nuclear genome which are normal for the

vegetable plant". The board notes that the vegetable plant of new claim 1 - via the cytoplasm of the cells it comprises - is provided with the very same genetic features.

- 11.5 In view of the above considerations, the amendment of the "cell" claim (granted claim) to the "plant" claim (new main request), i.e. selecting specific organisational aggregates that comprise the cells as previously claimed, does not extend the protection conferred as compared with the granted claims. Hence, in the present case the amendment of the "cell of a plant" claim to a "plant" claim is not contrary to the requirement of Article 123(3) EPC.
- 12. The above conclusion on the compliance of the amendment in the claims of the new main request with Article 123(3) EPC is based on the legal provisions set by the EPC. The board notes however that this position would be supported if one took into account legislative developments in Europe in respect of the legal protection of biotechnological inventions.
- On 6 July 1998, the European Union issued Directive 98/44/EC on the legal protection of biotechnological inventions (OJ EPO 1999, 101; hereafter "Directive"). With decision of 16 June 1999, the Administrative Council of the EPO amended the Implementing Regulations of the European Patent Convention in line with certain provisions of the Directive namely inter alia new Rules 23b to 23e EPC (OJ EPO 1999, 437).
- 12.2 In recital (13) of the Directive, the Community legislator expresses its intention to include in the

Community's legal framework for the protection of biotechnological inventions principles applying inter alia to the scope of protection conferred by a patent on a biotechnological invention. Accordingly, the Directive deals with the issue of "scope of protection" in four Articles of its Chapter II.

- 12.3 When considering the question of whether or not the subject matter of a claim is allowable under Article 123(3) EPC, the board is of the opinion that an adequate answer may be found by considering the scope of protection of a claim in the light of Article 69(1) EPC. While the implementation of Rule 23b to 23e EPC by the Administrative Council was regarded as relating to those provisions of the Directive which are directed to issues relating to granting requirements (Notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the EPC, OJ EPO 1999, 573, see points 5 and 6) - the EPO being an authority only dealing with this matter - the board finds it of assistance to address those provisions of the Directive which deal with the scope of protection of claims to biological material, the question here at issue.
- As far as products are concerned, Article 8.1 of the Directive provides that the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. Furthermore, Article 9 specifies in relation to genetic information that the protection conferred by a patent on a product

containing or consisting of genetic information shall extend to all material (save as to the human body) in which the product is incorporated and in which the genetic information is contained and performs its function.

- 12.5 The board considers that the "cell of a plant" as subject matter of claim 1 as granted is
  - biological material possessing specific characteristics as a result of the invention within the meaning of Article 8.1 of the Directive; and
  - a product containing genetic information within the
     meaning of Article 9 of the Directive.

Accordingly, the protection conferred by a patent on such a cell pursuant to Articles 8.1 and 9 of the Directive extends to all material in which the product is incorporated and in which the genetic information is contained and performs its function.

- 12.6 The board is satisfied that the plant of claim 1 of the new main request constitutes biological material derived from the cell of claim 1 as granted through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
- 12.7 Likewise, the plant as claimed in the new main request constitutes material in which the product (the cell) is incorporated and in which the genetic information is contained and performs its function. The genetic information relevant for the assessment under Article 9

of the Directive is "DNA which at least partially originate from a different species of the <a href="Compositae">Compositae</a> family, and which is the carrier of stably expressable cytoplasmic male sterility (CMS)" and "species-specific chloroplast and nuclear genome which are normal for the vegetable plant". The functions of this genetic information are being "carrier of stably expressable cytoplasmic male sterility (CMS)" and furthermore "providing genome and chloroplast functions" which are "normal" in the cellular context. The board considers that both functions of the genetic information can be accepted to be performed in the plants as subject matter of the "plant" claim of the new main request.

- 12.8 Furthermore, the board considers that the protection conferred by Article 8.1 and 9 of the Directive to the "vegetable plant" of claim 1 of the new main request does not extend the protection of the patent beyond the protection conferred by the "cell of a vegetable plant" of claim 1 as granted.
- 12.9 Therefore, the board considers that the protection conferred by claim 1 of the main request falls exclusively within the protection conferred by Articles 8.1 and 9 of the Directive to claim 1 as granted.
- 13. Accordingly, in the board's opinion Articles 8.1 and 9 of the Directive 98/44/EC, provide ancillary support for the finding in points 11 to 11.5 above that, in the present case, the amendment of the "cell of a plant" claim to a "plant" claim does not violate Article 123(3) EPC.

#### Sufficiency of disclosure

- 14. There is an implicit basis for the wording "stably expressable CSM" in present claims 1 and 7 in the application as filed as stated above in connection with Article 123(2) EPC (see points 2 to 4). For the purpose of Article 83 EPC the expression "stably expressable CSM" can thus be treated as having the same definition derivable from the application as filed. Therefore, contrary to the respondents' position, it does not represent undue burden for the skilled person to establish whether a plant exhibits "stably expressable CSM" and to select a plant exhibiting "stably expressable CSM", e.g. by picking up a regenerant having the exact nuclear and chloroplast genome of e.g. chicory and whose mt DNA behaves as shown in Fig. 2 of the patent (stable CSM progeny), while discarding undesired regenerants wherein "the mt genome has still not stabilized" (see page 351, 1-h column of document (D1)).
- 15. It is true that obtaining 100% pure CSM plants according to the present claims 1 and 7 is a question of chance, as the respondents argue. However, the prior art techniques disclosed by documents (D1) to (D3) merely yielded (also by chance) a 98% pure unstable CSM plant, i.e. whose progeny "R4" still had 1.9% fertile flowers and unstable mt DNA after the fourth backcrossing (see the Abstract: "...genetic instability..." and Table 2 of post-published document (D7) as expert opinion). Consequently, the relevant question to be answered in the context of sufficiency of disclosure is whether or not the patent in suit provides the technical information/means necessary for

increasing the selective pressure from 98% pure CSM plants (by chance) towards a 100% pure CSM plants (by chance). The answer is in the affirmative (see point 14).

- The respondents further argue that claim 1 cannot be practised within its whole broadness. However, the patent in suit (see examples 1 to 7) gives plenty of details enabling the skilled person to perform the invention for chicory, endive and lettuce as acceptors and sunflower as donor, while explicitly disclosing various other vegetable plants as acceptor, as well as various other donor types. Thus, the board is satisfied that the skilled person is able to obtain substantially all embodiments falling within the ambit of the claims, which are already limited to the Compositae family. The respondents did not demonstrate the contrary (see e.g. decision T 19/90, OJ EPO, 1990, 476).
- 17. The passage on page 351, 1-h column, lines 11 to 13 of document (D1), in the respondents' opinion demonstrates that it is not always possible to obtain male sterile chicory according to present claim 1. However, document (D1) also warns that "fusion partners for the production of male sterility need to be phylogenetically distant to generate sufficient mt rearrangements" (ibidem, lines 13 to 16). The skilled person, who is deemed to be aware of the above restriction, would thus avoid phylogenetically close partners.
- 18. In view of the above findings, the board concludes that the claims of the new main request satisfy the requirements of Article 83 EPC.

#### Novelty

#### Claim 1

- Document (D1) discloses a method for obtaining male 19. sterile chicory plants by fusion of chicory protoplasts with protoplasts derived from male sterile sunflower plants. The board observes that only a few plants out of 600 regenerants obtained exhibited some form of male sterility, that only one plant could be used for obtaining seeds (see page 348, second column, lines 35 to 55), and that this plant was unstable as far as the male sterility trait was concerned (see page 351, first column, lines 17 to 32: "...is likely to take a long time to stabilize"). This finding is in line with the teaching of document (D2) (see English summary: "....has shown an instability of the mitochondrial genome") and document (D3) (see page 488: "en 3e génération, le genome mt avait tendance à se stabiliser"), which again relate to the same failed attempt to obtain stable male sterile plants of the Compositae family.
- 20. The respondents maintain that the cybrids disclosed in documents (D1) to (D3) have a normal chicory nuclear (2n = 18 chromosomes as chicory) and chloroplastid genome as the plants defined in present claim 1.

  However, in the board's view, the presence of specific sunflower chromosomes (or parts thereof) in the ultimate fusion product, the cybrids, is proven by the fact that, after regeneration into complete plants, these fusion products are in general characterized by an abnormal morphology, e.g. in the flowers which may

exhibit complete sterility (see e.g. Table I on page 487 of document (D3)). This view finds support in the terminology ("heterokaryocytes" or "heterocaryons") used in documents (D1) to (D3), which suggests the presence of both a sunflower and a chicory nucleus (and cytoplasm). Furthermore, none of documents (D1) to (D3) demonstrates by flowcytometric analysis or by hybridization with DNA probes as in the patent in suit that the obtained primary regenerants and their respective progeny have the nuclear and chloroplast genome of chicory, an essential feature of the claims under consideration.

- 21. The respondents also rely on post-published document (D7) as expert opinion for arguing that the fourth progeny of a male sterile cybrid CT41/1, obtained from protoplast fusion between chicory and sunflower as disclosed in documents (D1) to (D3) have a normal chicory nuclear and chloroplastid genome as required by present claim 1. However, even if post-published document (D7) could be taken into account, it would confirm the view the board has come to that even the fourth generation of the plants as described in documents (D1), (D2) and (D3) is not stable with respect to mitochondrial DNA and the CMS property (see abstract, line 9: "...the genetic instability of this genome.").
- 22. In conclusion, the authors of documents (D1) to (D3) did not succeed in obtaining stably expressable CMS, nor 100% pure plants as far as the chloroplast and nuclear genome was concerned. Thus, none of documents (D1) to (D3) discloses fusion products with "stably expressable CMS and a species specific chloroplast and

nuclear genome which are normal for the vegetable plant" as required by claim 1 at issue. Therefore, the subject-matter of this claim is novel over the disclosure of the mentioned documents.

#### Claim 7

- 23. It is the respondents' view that claim 7 is anticipated by the process described in document (D1) for obtaining male sterile chicory plants, as illustrated in more details in documents (D9) and (D10). However, document (D1) fails to disclose the use of irradiation for inactivating the donor nucleus (see last step of claim 7). Thus present claim 7 does not cover the prior art method of document (D1).
- Thus, none of the objections to the novelty issue raised by the respondents are convincing, and the board comes to the conclusion that the subject-matter of claims 1 (and dependent claims 2 to 6) and 7 of the new main request is novel.

#### Inventive step

25. The parties and the board agree that the closest prior art is represented by either of documents (D1) to (D3). As emphasized in points 19 to 21 supra these documents relate to a failed attempt to obtain 100% pure stably expressible CMS plants of the Compositae family. The objective technical problem to be solved is thus seen in reaching this goal. This problem is solved by applying the method of present claim 7 which exerts a high selection pressure toward obtaining the 100% pure stably expressible CMS plants of the Compositae family.

- 26. The respondents deny that the patent in suit actually solves the above problem. However, it cannot be disputed that the legend to Fig. 2 of the patent demonstrates that the mt DNA profile is "stably transmitted" throughout progeny lanes 2 to 5, i.e. it is kept intact after 5 backcrosses of the claimed CSM Compositae plants. Fig. 6 and the right of Fig. 7 of the patent in suit show that the claimed plants exhibit CMS chicory flowers wherein the CSM trait is expressed by forming no anthers, whilst otherwise the flower is normal. The board concludes that the above problem has been solved, which is also in accordance with the board's finding in points 14 to 17 relating to sufficiency of disclosure.
- 27. In the board's judgement, none of the prior art documents suggests how to overcome the problem of obtaining 100% pure male sterile Compositae plants endowed with stably expressible CMS, without any negative aberrations in flower morphology and/or plant.
- It is true, as the respondents argue, that the specific techniques underlying the process yielding the claimed plants, such as protoplast fusion and X ray irradiation were already known from document (D13) (see page 612) and document (D8), (see page 596, first full paragraph). However, these measures were taken in a different context, e.g. for suppressing the cell nucleus division capability in general. More importantly, there was no suggestion in any of the prior art documents to combine all these expedients for resolving the specific problem referred to above. In fact, the board observes that in spite of all these techniques being available before

the publication of document (D1) to (D3), neither the authors of documents (D1) to (D3), nor anybody else had applied this technique and achieved some progress in arriving at 100% pure male sterile Compositae plants endowed with stably expressible CMS, without any negative aberrations in flower morphology and/or plant type. Table I on page 487 of document (D3) indeed shows that the backcrosses of the third generation still had 2.2% fertile flowers, which could still contaminate a whole cultivation field. There was thus a blockage which had to be overcome, as stated in document (D13), page 613, r-h column: "the molecular basis of the CSM trait is not understood".

29. It is the respondents' view that arriving at the claimed subject-matter was obvious in view of the known stabilizing effect of backcrossing (see Table 2 of document (D7), wherein only 1.9% of the flowers was fertile (i.e. the flowers had 98.1 % purity) after 4 backcrossings). However, this assumption is contradicted by the passage on page 484, r-h column, line 4 from the bottom to page 485, l-h column, line 1 of document (D7): "After four generations...the mitochondrial genome of chicory approaches an equilibrium", according to which it is not possible to reach 100% purity by further backcrossing.

#### Conclusion

30. The subject-matter of claim 7 cannot be derived in an obvious manner from the prior art. This conclusion has to be extended to the Compositae plants of claims 1 to 6. For any of this claimed subject-matter to be carried out, one must have available the process recited in

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claim 7. Thus, since inventive step can be acknowledged for the process of claim 7, it can be acknowledged for all these other claims of the main request as well.

## 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 maintain the patent on the basis of

claims 1 to 7 of the new main request submitted during the oral proceedings

and a description to be adapted thereto.

The Registrar:

The Chairwoman:

P. Cremona

U. M. Kinkeldey