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**Datasheet for the interlocutory decision
of 31 May 2012**

Case Number: T 1242/06 - 3.3.04

Application Number: 00940724.8

Publication Number: 1211926

IPC: A01H 5/10

Language of the proceedings: EN

Title of invention:

Method for breeding tomatoes having reduced water content and product of the method

Patentee:

State of Israel - Ministry of Agriculture

Opponent:

Unilever N.V.

Headword:

Tomatoes II/STATE OF ISRAEL

Relevant legal provisions:

EPC Art. 53(a), (b), (c), 64(2), 84, 100(a), 123(2), (3), 164(2)

EPC R. 26(4), (5), 27(b), (c), 28(c), 43(2), 80

Rules of Procedure of the Boards of Appeal (RPBA) Art. 13

Directive 98/44 EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Biotech Directive) Art. 2(3), 6(2)(c)

Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg Convention) Art. 2(b)

Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights (CPVR Regulation) Art. 5(2), (3), 13(2), (6)

UPOV Convention 1991 Art. 1(vi), 14(1), (2), (5)(b)

TRIPS Agreement Art. 28.1(a), (b)

French Intellectual Property Code Art. L613-5-3
German Patent Law § 11 No. 2a

Relevant legal provisions (EPC 1973):

EPC Art. 53(a), (b), 54, 64(2), 100(a), 112, 123(2), (3),
EPC R. 23b(4), (5), 23c(b)

Keyword

"Exclusion of essentially biological processes for the
production of plants - possible effect on allowability of
product claim for plants or plant material - important point
of law - referral of questions to the Enlarged Board of
Appeal"

Decisions cited:

G 0005/83, G 0002/88, G 0010/91, G 0001/95, G 0001/98,
G 0001/03, G 0002/06, G 0001/07, G 0001/08, G 0002/08,
G 0002/10, T 0083/05, T 0263/05, T 0275/05, T 1384/06,
T 1854/07

European Court of Justice C-34/10 of 18 October 2011 (*Oliver
Brüstle v Greenpeace e.V.*)

Headnote:

Headnote follows.



Case Number: T 1242/06 - 3.3.04

INTERLOCUTORY DECISION
of the Technical Board of Appeal 3.3.04
of 31 May 2012

Appellant I: State of Israel - Ministry of Agriculture
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Appellant II: Unilever N.V.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
29 May 2006 concerning maintenance of European
patent No. 1211926 in amended form.

Composition of the Board:

Chairman: R. Gramaglia
Members: B. Claes
R. Moufang

Summary of Facts and Submissions

I. Appeals were lodged by the patent proprietor (appellant I) and the opponent (appellant II) against the interlocutory decision of the opposition division according to which European patent No. 1 211 926 could be maintained in amended form on the basis of auxiliary request IIIb then on file.

II. The independent claims 1, 15 and 16 of the granted patent read:

"1. A method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of:

crossing at least one *Lycopersicon esculentum* plant with a *Lycopersicon* spp. to produce hybrid seed;
collecting the first generation of hybrid seeds;
growing plants from the first generation of hybrid seeds;

pollinating the plants of the most recent hybrid generation;

collecting the seeds produced by the most recent hybrid generation;

growing plants from the seeds of the most recent hybrid generation;

allowing plants [*sic*] to remain on the vine past the point of normal ripening; and

screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin.

15. A tomato fruit characterized by a capability of natural dehydration while on a tomato plant, natural

dehydration being defined as wrinkling of skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said natural dehydration being generally unaccompanied by microbial spoilage.

16. A tomato fruit characterized by an untreated skin which permits dehydration of the fruit so as to obtain wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage."

Claims 2 to 14 were method claims dependent on claim 1.

- III. In its notice of opposition, appellant II had *inter alia* raised a ground for opposition pursuant to Article 100(a) EPC 1973 in connection with Article 53(b) EPC 1973. It maintained that both the method and the product claims of the patent were directed to subject-matter excluded from patentability, being essentially biological processes for the production of plants or being plant varieties.
- IV. In the oral proceedings before the opposition division the proprietor requested that the patent be maintained in amended form on the basis of a main request or any of auxiliary requests I, II and IIIb. Concerning the **main request**, the opposition division decided that the subject-matter of claim 1 (which was identical to claim 1 as granted apart from a correction of the wording "allowing plants to remain ..." to "allowing fruit to remain ...") was excluded from patentability by Article 53(b) and Rule 23b(5) EPC 1973. **Auxiliary request I** was refused for the reason that its further

amended independent method claim 1 did not meet the requirements of Article 123(2) and (3) EPC 1973.

The claims of **auxiliary request II** were restricted to two independent product claims and read:

"1. A tomato fruit of the species *Lycopersicon esculentum* which is naturally dehydrated, wherein natural dehydration is defined as wrinkling of skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said natural dehydration being generally unaccompanied by microbial spoilage.

2. A tomato fruit of the species *Lycopersicon esculentum* characterized by an untreated skin, dehydration of the fruit and wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage."

The opposition division found that these claims were allowable *inter alia* under Article 53(b) and Rule 23b(4) EPC 1973 since their subject-matter was not limited to a single variety, but that they did not comply with the requirement of novelty (Article 54 EPC 1973).

Auxiliary request IIIb differed from auxiliary request II only in that in both claims the tomato fruit was further characterised as being a "raisin-type" tomato fruit. This request was found to comply with all the requirements of the EPC.

- V. With its grounds of appeal appellant I requested that the decision under appeal be set aside and the patent maintained on the basis of claims 1 to 17 of the main request, which was identical to the main request before the opposition division, or on the basis of one of newly filed auxiliary requests I to V (auxiliary request V being identical to auxiliary request IIIb before the opposition division). With a letter dated 16 July 2007, appellant I filed a further new auxiliary request VI. Auxiliary requests I to III contained both method claims and product claims, auxiliary requests IV to VI only product claims.
- VI. With its grounds of appeal, appellant II requested that the decision under appeal be set aside and the patent revoked. In addition, refund of the appeal fee was requested on the ground that the opposition division had committed a substantial procedural violation by admitting appellant I's auxiliary request IIIb into the procedure.
- VII. On 19 September 2007 first oral proceedings before this board, albeit in a different composition, took place, restricted to the issue of a possible referral under Article 112 EPC 1973. In an interlocutory decision issued on 4 April 2008, the board referred three questions of law to the Enlarged Board of Appeal. All questions related to the interpretation of the process exclusion contained in Article 53(b) EPC, namely to the circumstances under which processes for the production of plants have to be regarded as "essentially biological". The Enlarged Board of Appeal answered the referred questions in its decision G 1/08 of 9 December 2010.

VIII. In preparation for a second oral proceedings appointed by the board in its present composition, the parties filed further submissions. The board also received third-party observations pursuant to Article 115 EPC.

IX. Appellant I amended its claim requests by filing a new main request and auxiliary requests I to III with a letter dated 7 September 2011, as well as auxiliary requests IV and V with a further letter dated 28 October 2011. All of the requests were restricted to product claims:

The **main request** was identical to auxiliary request II before the opposition division (see Section IV, above) and its two independent claims had been included in several of the claim requests previously filed with the grounds of appeal.

Auxiliary request I was identical to auxiliary request IIIb before the opposition division (see Section IV, above).

Auxiliary request II was identical to previous auxiliary request VI submitted with the letter dated 16 July 2007 (see Section V, above) and differed from auxiliary request I in that in both claims the word "product" was inserted after "[a] raisin-type tomato fruit".

Auxiliary request III differed from the main request in that in both claims the word "harvested" was inserted before "tomato fruit".

Auxiliary request IV differed from the main request in that at the end of both claims the wording "wherein said tomato fruit is from a plant obtainable by a breeding method which involves the crossing of *Lycopersicon esculentum* with *Lycopersicon hirsutum*" was introduced.

Auxiliary request V differed from the main request in that at the end of both claims the following wording was introduced:

"wherein said tomato fruit is from a plant obtainable by a method for breeding tomato plants that produce tomatoes with reduced fruit water content, said method comprising the steps of:
crossing at least one *Lycopersicon esculentum* plant with a *Lycopersicon hirsutum* plant to produce hybrid seed;
collecting the first generation of hybrid seeds;
growing plants from the first generation of hybrid seeds;
pollinating the plants of the most recent hybrid generation;
collecting the seeds produced by the most recent hybrid generation;
growing plants from the seeds of the most recent hybrid generation;
allowing fruit to remain on the vine past the point of normal ripening; and
screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin."

X. By a letter dated 3 November 2011, appellant II requested that the board refer further questions of law to the Enlarged Board of Appeal. The questions proposed focused on the patentability of claims directed to plants, fruits or seeds where, as appellant II maintained, the claim would *de facto* provide patent protection for essentially biological processes as defined in decision G 1/08.

XI. The second oral proceedings took place on 8 November 2011. In the course of the proceedings appellant I submitted a new auxiliary request I.

Claim 1 of this request was identical to claim 1 of the main request filed with letter of 7 September 2011 (see Section IX, above). Claim 2 was amended to read:

"2. A **dehydrated** tomato fruit of the species *Lycopersicon esculentum* characterized by an untreated skin, **which permits said** dehydration of the fruit **so as to obtain** wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage."
(emphasis added by the board)

XII. Appellant I requested that the decision under appeal be set aside, and that the patent be maintained in amended form on the basis of the main request filed with the letter dated 7 September 2011 or, in the alternative, on the basis of auxiliary request I filed at the oral proceedings or on the basis of any of auxiliary requests II to VI, the latter having been filed as auxiliary requests I to III with the letter dated 7 September 2011, and as auxiliary requests IV and V filed with the letter dated 28 October 2011.

Appellant II requested that the decision under appeal be set aside, the patent revoked and the appeal fee reimbursed, and, if the board did not intend to revoke the patent, that the questions of law submitted at the oral proceedings be referred to the Enlarged Board of Appeal.

The questions proposed by appellant II for referral were:

"1. Is a claim which is not directed to an essentially biological process per se as defined in Art. 53(b) EPC and G01/08 patentable, if such claim would render inoperative the exclusion from patentability as defined in G01/08?

2. Is a claim patentable if such claim is directed to a plant, fruit, seed or any other part of an essentially biological process as defined in Art. 53(b) and G01/08, if such claim would render inoperative the exclusion from patentability as defined in G01/08?

3. If such claim is patentable which other requirements are there to be met?

4. If such claim is unpatentable which other requirements need to be met to escape the exclusion from patentability as defined in G01/08?"

XIII. At the end of the oral proceedings the chairman announced the board's decision that appellant I's main request was refused, that, with respect to new auxiliary request I, the debate was closed in relation

to the requirements of Rule 80, Article 123(2) and (3), Article 84 and Article 53(b) EPC, and that the proceedings would be continued in writing. He also announced the board's intention to refer questions of law to the Enlarged Board of Appeal.

XIV. Further third-party observations relating to the interpretation of Article 53(b) EPC were received after the oral proceedings.

XV. The arguments of appellant I made during these appeal proceedings and relevant for the present decision can be summarised as follows.

Main request

Rule 80 EPC

- The product claims were amended in order to defend them against novelty attacks. Therefore, the amendments were occasioned by a ground for opposition.

Article 123(2) EPC

- The application as filed disclosed on page 3, line 10 that the invention *inter alia* related to "tomatoes having reduced water content". It was thus directly and unambiguously derivable for a skilled person that the invention also related to tomato fruits in which the "capability of natural dehydration" was realised, and to tomato fruits in which the dehydration permitted by the untreated skin was carried out.

Article 123(3) EPC

- The feature "capability of natural dehydration while on a tomato plant" of granted claim 15 and the feature "which permits dehydration of the fruit" of granted claim 16 both defined the claimed fruit by a range starting from fully hydrated fruit and including fruit with a gradually reduced water content. Also the endpoint, i.e. the most dehydrated tomato, would have a residual water content which could be further reduced under suitable conditions. Thus, fruits as defined in claims 1 and 2 fell under claims 15 and 16 as granted because they would still retain the capability of natural dehydration and permit dehydration, respectively.

- Even if one hypothetically assumed that there could be a tomato fruit that had such a low water content that further natural dehydration was no longer feasible, such fruit was also covered by the claims as granted. In particular, claim 16 as granted characterised the claimed tomato fruit by the presence of an untreated skin which permitted dehydration of the fruit. The tomato fruits of claim 2 had such a skin. Otherwise, providing them in a dehydrated form while the skin was untreated would be impossible.

Auxiliary request I

Admissibility of auxiliary request I

- The amendments made to claim 2 overcame the objections against claim 2 of the main request. While the limiting feature that the tomato fruit had to be dehydrated was kept, the wording of new claim 2 otherwise reverted to that of claim 16 as granted in order to preserve the interdependency of the features relating to the untreated skin, the dehydration of the fruit and the wrinkling of the skin.

Article 123(2) and (3) EPC

- Claim 2 was based on claim 16 as originally filed combined with the disclosure on page 3, line 10. It limited the scope of protection compared to that of granted claim 16.

Articles 84 EPC

- A skilled person could identify an *L. esculentum* tomato plant and its fruit by using the established taxonomic traits of this species. These traits were for example discernible from taxonomic keys for *Lycopersicon* and closely related *Solanum* species. The respective feature thus had a clear meaning to a skilled person.
- It was common general knowledge that an initial interspecific hybrid between a cultivated line and a wild relative attained the characteristics of

the cultivated line after several rounds of selfing and back-crossing, by the successive dilution of wild germplasm during this process.

- The requirements of Rule 43(2) EPC did not apply in opposition appeal proceedings.

Article 53(b) EPC

- In view of the procedural developments in parallel case T 83/05, it was surprising that Article 53(b) EPC had now again become an issue of relevance with respect to the product claims. All the more so since the opponent had dropped this issue during the opposition proceedings and had not reiterated it in its grounds of appeal.
- Both the product and method aspects of the exception to patentability pursuant to Article 53(b) EPC had already been dealt with by the Enlarged Board of Appeal in decisions G 1/98 and G 1/08 respectively. It followed from the principles laid down in G 1/98 that the claims should be allowed. The board, albeit in a different composition, had already recognised this in its first interlocutory decision (see point 17 of the reasons).
- Although it could be argued that the conclusions in G 1/08 led to a somewhat paradoxical legal situation which might need further clarification, a second referral would unnecessarily prolong the proceedings and had no basis in Article 112 EPC. The board should not decide on the issue of

Article 53(b) EPC without first deciding on the other patentability requirements.

- There existed other technical fields in which situations arose where methods were not patentable whereas the products were. For example, methods for treatment of the human body by therapy were excluded from patentability although medicaments could be patented.

XVI. The arguments of appellant II made during these appeal proceedings and relevant for the present decision can be summarised as follows.

Main request

Rule 80 EPC

- Claim 1 no longer recited the technical feature "characterized by a capability of natural dehydration while on a tomato plant". Claim 2 no longer contained the phrases "which permits" and "so as to obtain", thereby deleting the causal relation between the fruit skin and a functional feature thereof. None of these amendments were occasioned by grounds of opposition.

Article 123(2) EPC

- The person skilled in the art reading the passages on page 4, lines 21-29, and page 9, lines 20-27 and the product claims of the published application had no reasonable grounds to assume that the features "capability of natural

dehydration while on a tomato plant" and "untreated skin which permits ..." were optional. The pending claims omitted these features and therefore contravened Article 123(2) EPC.

Article 123(3) EPC

- The amendment of the feature which characterised the tomato fruit of claim 1 as having the "capability of natural dehydration while on a tomato plant" to a tomato fruit "which is naturally dehydrated" extended the protection conferred.

- Claim 2 now also encompassed tomato fruits of which the untreated skin did not permit dehydration of the fruit. This extended the protection conferred.

Auxiliary request I

Admissibility of auxiliary request I

- The facts and arguments which the amendment of claim 2 in auxiliary request I attempted to take into account had been on file before. This request could therefore have been submitted earlier than at the very late stage of the second oral proceedings before the board. The request was moreover surprising and caused clarity problems.

Article 84 EPC

- The use of the term "Lycopersicon esculentum" was unclear. The patent in suit related to a cross starting from *L. esculentum* and *L. hirsutum* to create new plants which could be backcrossed to *L. esculentum*. It was not clear which of the resulting plants belonged to the species *L. esculentum*.
- The wording "dehydrated" as used in claim 2 lacked clarity within the meaning of Article 84 EPC. In particular, it could not be determined whether or not the notion "partially dehydrated" also fell under the meaning of "dehydrated".
- The two independent claims contravened Rule 43(2) EPC, as their overlapping scope created ambiguities concerning the scope of protection conferred.

Article 53(b) EPC

- The exclusion of essentially biological processes by virtue of Article 53(b) EPC was an exclusion per se and therefore had to be addressed before the examination of other patentability requirements such as sufficiency of disclosure, novelty and inventive step.
- Although the wording of the claims related to the fruit of a plant, the Enlarged Board had found in decision G 1/98 that it was not the wording but the substance of a claim which was decisive in

assessing the subject-matter to which the claim was directed. The invention underlying the claims in the present case were specific *Lycopersicon esculentum* plants.

- The claimed subject-matter could only be obtained by a cross of two specific tomato plants and the subsequent selection of tomato plants with the desired phenotype which was "a selectable inherited trait" (see page 5, lines 1 and 2 of the patent description). Paragraph [0027] of the patent description reported that when the F4 generation was backcrossed to different *L. esculentum* lines all plants showed the desired phenotype of dehydrated tomatoes. Thus the trait was stable and suitable for being propagated unchanged. Accordingly, the claimed subject-matter was necessarily a plant variety within the meaning of Rule 26(4) EPC.

- In its decision G 1/98 (see points 3.7 and 3.8 of the reasons) the Enlarged Board of Appeal had provided two requirements for claimed plants to escape the exclusion of plant varieties. First, the invention had to be in the field of genetic engineering. Second, the invention underlying the claimed subject-matter should be so generally applicable to all appropriate plants that the inventor would not be able to obtain appropriate protection by means of plant breeders' rights. The invention underlying the present case was neither in the field of genetic engineering nor generally applicable; rather, it was limited to *L. esculentum*, i.e. the only tomato species used

in the food industry. Furthermore, there was no indication that the claimed tomatoes would not be eligible for protection under the plant breeders' right system. Accordingly, the claims contravened Article 53(b) EPC as they were directed to a plant variety.

- The classical breeding process of the patent, which was not patentable for the reasons given in decision G 1/08, was inseparably linked to the claimed dehydrated tomatoes, as it comprised the step of using the (harvested) tomato fruit to provide the seeds for a next generation in the breeding process. In addition, the harvested fruit was used for selecting the desired trait. Thus, allowing the tomato fruit claims would nullify the effect of the process exclusion contained in Article 53(b) EPC and its interpretation in decision G 1/08 of the Enlarged Board. Patent protection would then still *de facto* be provided for classical breeding processes. Furthermore, it was of no relevance whether, based on post-published knowledge about the *cwp* gene, tomato fruits falling under the claims might be obtained using non-essentially biological processes.

- In point 5.3 of the reasons in decision G 1/98, the Enlarged Board merely answered the question whether plant varieties obtained by recombinant gene technology escaped the exclusion of plant varieties by virtue of Article 53(b) EPC. This point did not address the question of patentability of claims to plants which were obtained by essentially biological processes. In

point 6 of the same decision, the Enlarged Board explicitly declined to comment on the exclusion of essentially biological processes. Thus, an attempt to extrapolate the Enlarged Board's comments in point 5.3 to resolve an issue that it did not want to comment on had to fail, and any interpretation of them which came to the conclusion that the fruit claims might be allowable could not be reconciled with the later decision G 1/08.

Reasons for the Decision

Main request

Rule 80 EPC

1. The main request is identical to auxiliary request II before the opposition division (see Sections IV and IX, above). Its two claims contain amendments when compared with the independent product claims 15 and 16 of the patent as granted. In both claims the tomato fruits are now defined as belonging to the species *Lycopersicon esculentum*. Furthermore, in claim 1 the feature "characterized by a capability of natural dehydration while on a tomato plant" contained in granted claim 15 has been replaced by the feature "which is naturally dehydrated", and in claim 2 the wording "characterized by an untreated skin which permits dehydration of the fruit so as to obtain wrinkling of the skin" which was contained in granted claim 16 has been replaced by the wording "characterized by an untreated skin, dehydration of the fruit and wrinkling of the skin."

2. The above amendments were, as the procedural history shows, introduced by appellant I in order to overcome novelty objections raised by appellant II. These objections were based on prior art allegedly disclosing, on the one hand, tomato fruits capable of natural dehydration and, on the other hand, dehydrated bush tomatoes. The board is therefore satisfied that the amendments were occasioned by a ground of opposition under Article 100 EPC and therefore comply with Rule 80 EPC.

Article 123(2) EPC

3. The application as filed comprised claims which were identical to claims 15 and 16 as granted. Also insofar as these claims have now been amended in the main request, their subject-matter was originally disclosed. In particular, it follows from the first sentence of the summary of the invention (page 3, lines 8 to 10 of the published application) that the invention seeks to provide tomatoes with reduced water content, i.e. tomatoes in which the capability of natural dehydration is realised. The application also discloses the further features appearing in the amended claims such as being "of the species *Lycopersicon esculentum*" (see page 4, lines 1-2, and page 5, lines 15-26 of the published application, where backcrossing with *Lycopersicon esculentum* plants is disclosed as a preferred embodiment), "untreated skin" (see page 4, line 27 and page 9, line 21) and "wrinkling of the skin" (see page 3, line 28, page 5, line 12 and page 6, line 11 and 29 of the published application).

4. Accordingly, claims 1 and 2 of the main request comply with the requirements of Article 123(2) EPC.

Article 123(3) EPC

5. Insofar as the amended claims specify that the claimed tomatoes have to be of the species *Lycopersicon esculentum*, the scope of protection of the claims as granted has been narrowed. However, the question arises whether the further amendments of claims 1 and 2 extend the scope of protection over that of the patent as granted and therefore infringe Article 123(3) EPC.
6. With respect to claim 1, the board considers that the amended feature "which is naturally dehydrated" does not extend the protection conferred. Claim 15 as granted (see Section II, above) characterised the tomatoes as having the "capability of natural dehydration while on a tomato plant". In the board's understanding, this claim encompasses not only fruits in which the capability of dehydration is going to be realised in the future, i.e. tomatoes which are not yet dehydrated, but also fruits in which the capability has already been realised, i.e. dehydrated tomatoes.
7. The amendments in claim 2 are similar insofar as they limit the claimed subject-matter to dehydrated tomato fruits. However, by characterising the fruits through three independent features (untreated skin, dehydration of the fruit and wrinkling of the skin), they omit the interdependency between these features that was contained in claim 16 as granted (see Section II, above). This omission has the consequence that, as correctly argued by appellant II, claim 2 of the main

request no longer requires the fruit skin to permit dehydration of the fruit so as to obtain wrinkling of the skin. Accordingly, in this aspect of the definition of the tomato fruit, the scope of protection of claim 2 is broader than the scope of protection provided by any of the claims of the patent as granted.

8. The board concludes that only claim 1 of the main request, but not its claim 2, complies with the requirements of Article 123(3) EPC. Therefore the main request is not allowable.

Auxiliary request I

Admissibility

9. Auxiliary request I was only filed during the second oral proceedings. The admissibility of this request therefore has to be considered in the light of Article 13 of the Rules of Procedure of the Boards of Appeal (RPBA), taking into account the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.
10. The filing of the request was a reaction to the board's announcement that claim 2 of the main request extended the scope of protection as granted (see point 8, above). In this aspect the board did not endorse the opposition division's decision which had found the claims of then auxiliary request II to comply with Article 123(3) EPC.
11. Compared to the main request, auxiliary request I only contains amendments in claim 2 (see Section XI, above). The wording of that claim still requires the tomato

fruit to be dehydrated but otherwise reverts to the wording of claim 16 as granted, thereby preserving the interdependency of the features relating to the untreated skin, the dehydration of the fruit and the wrinkling of the skin.

12. These amendments are neither complex nor difficult to understand and assess. They address and overcome the objection under Article 123(3) EPC in view of which the main request was refused, and they do not raise any additional issue that would take the other party or the board by surprise. Thus the board, using its discretion under Article 13(1) RPBA, admits auxiliary request I into the proceedings.

Rule 80 EPC and Article 123(2), (3) EPC

13. The reasons why claim 1 of auxiliary request I (which is identical to claim 1 of the main request) fulfils the requirements of Rule 80 EPC as well as those of Article 123(2) and (3) EPC have already been set out (see points 1-6, above). They also apply *mutatis mutandis* to amended claim 2 of auxiliary request I. In particular, the board considers that characterising the claimed tomato fruits as "dehydrated" does not extend the scope of protection of claim 16 as granted, which encompasses fruits that were dehydrated as a consequence of having an untreated skin permitting dehydration.

Article 84 EPC

14. Since Article 84 EPC is not a ground for opposition, lack-of-clarity objections based on it have to be

- examined in opposition proceedings only insofar as they are directed against amendments made by the proprietor in the course of those proceedings.
15. The introduction of the feature "of the species *Lycopersicon esculentum*" in claims 1 and 2 does not cause a lack of clarity. Describing plants by scientific species denominations in accordance with accepted international nomenclature is very common in botany in general and in the breeding profession in particular. Such denominations have a clear technical meaning to the skilled person even if in certain situations, in particular with respect to the F1 generation of an interspecies cross, difficulties in drawing the precise borderline between the species involved may arise in practice.
 16. Appellant II further raised a clarity objection against the insertion of the feature "dehydrated" in claims 1 and 2, arguing that it could not be determined whether a partially dehydrated tomato fruit would fall under this term. However, since the claims do not specify any degree of dehydration, it is apparent that they cover not only completely dehydrated but also partially dehydrated fruits. The board furthermore notes that claims 15 and 16 as granted already contained the term "dehydration" so that it may even be questioned whether, in view of the principles mentioned above (see point 14), the issue of clarity is open to scrutiny in this respect at all.
 17. Appellant II furthermore argued that the presence of two independent claims contravened Rule 43(2) EPC, as the overlapping scope created unclarity concerning the

scope of protection. However, as explained in more detail in decision T 263/05 (OJ EPO 2008, 329, points 5.11 to 5.20 of the reasons), this Rule is an administrative provision which has to be applied in the examination of patent applications, but not in opposition proceedings. In addition, the board considers that, since the patent as granted already contained two independent product claims with possibly overlapping scope of protection, the alleged lack of clarity was not caused by amendments made in the opposition proceedings.

18. The board therefore concludes that none of the amendments introduced into claims 1 and 2 of auxiliary request I contravenes Article 84 EPC.

Article 53(b) EPC

General

19. With respect to the area of plant breeding, Article 53(b) EPC contains two exceptions from patentability. It prohibits the patenting of, on the one hand, plant varieties and, on the other hand, essentially biological processes for the production of plants. When this board handed down its first interlocutory decision, both the proprietor's main request and auxiliary request I then on file contained process claims directed to methods for breeding tomato plants as well as product claims directed to tomato fruits and tomato plants. Since the board considered that the interpretation of the process exclusion contained in Article 53(b) EPC needed clarification in

the light of Rule 26(5) EPC, it referred corresponding questions to the Enlarged Board of Appeal.

20. In view of the responses given by the Enlarged Board in its decision G 1/08 of 9 December 2010, appellant I deleted the process claims so that the claim requests now on file are restricted to product claims directed to tomato fruits or tomato fruit products (see Section IX, above). Nevertheless, appellant II is of the opinion that the remaining product claims are still directed to subject-matter excluded from patentability by Article 53(b) EPC. Its main lines of argument are firstly that the claims are directed to plant varieties which are excluded from patentability, and secondly that allowing these claims would counteract the process exclusion of Article 53(b) EPC as interpreted in decision G 1/08, thereby frustrating the legislator's aim not to provide patent protection for the excluded plant breeding processes.

Procedural aspects

21. When filing its notice of opposition, appellant II challenged both process and product claims of the granted patent as not complying with Article 53(b) EPC 1973. In particular, it argued that the claimed tomato fruit had to be regarded as concerning an excluded plant variety. Thus, as also noted by appellant I in its response to the notice of opposition, the ground for opposition under Article 100(a) EPC 1973 in connection with the product exclusion under Article 53(b) EPC 1973 was specifically raised already at the beginning of the opposition procedure.

22. During the oral proceedings before the opposition division, appellant II did not maintain this objection when confronted with the newly introduced auxiliary requests II and IIIb then on file (which contained only product claims directed to tomato fruits). Nevertheless, the opposition division dealt with the objection in substance (see page 7 of its decision) by stating that claims 1 and 2 of auxiliary request II were not limited to a single plant variety and were therefore allowable under Article 53(b) and Rule 23b(4) EPC 1973.
23. Under these circumstances the objection under Article 100(a) EPC in conjunction with Article 53(b) EPC against product claims relating to tomato fruits cannot be regarded as a fresh ground of opposition which may be introduced in the appeal proceedings only with the proprietor's consent according to decisions G 10/91 (OJ EPO 1993, 420) and G 1/95 (OJ EPO 1996, 615) (see also T 275/05 of 20 March 2007, point 1 of the reasons).
24. Although appellant II did not pursue the above objection in its grounds of appeal or in the response to the appellant I's grounds of appeal, it raised the objection again in the course of the first oral proceedings before this board (which took place more than four years before the second oral proceedings) and requested that questions of law relating to the interpretation of the product exclusion contained in Article 53(b) EPC be referred to the Enlarged Board of Appeal. Furthermore, in its written submissions in the aftermath of the Enlarged Board's decision G 1/08, appellant II presented several arguments as to why the product claims contained in appellant I's requests

should be regarded as non-patentable under Article 53(b) EPC. Since appellant I therefore had ample opportunity to consider this objection and the supporting arguments brought forward by appellant II, the board, using its discretion under Article 13(1) RBPA, admits and examines the objection in the present appeal procedure.

The concept of plant varieties

25. Both the European legislator (see Article 2(3) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ EPO 1999, 101, hereinafter "Biotech Directive", and Rule 26(4) EPC) as well as the Enlarged Board of Appeal in its decision G 1/98 (OJ EPO 2000, 111) have contributed to clarifying the meaning of the term "plant varieties" contained in Article 53(b) EPC. According to the definition provided by Rule 26(4) EPC, "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. Identical or very similar definitions are contained in the international and European legislative framework for the protection of plant breeders' rights (see Article 5(2) Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights,

hereinafter "CPVR Regulation") and Article 1(vi) UPOV Convention 1991).

26. In accordance with the decision G 1/98 (*supra*, points 3.1 and 3.8 of the reasons), the reference in Rule 26(4) (a) EPC to the expression of the characteristics that results from a given genotype or combination of genotypes is to be understood as a reference to the entire constitution of a plant or a set of genetic information. The concept of plant variety requires plant groupings defined by their whole genome, not merely by individual characteristics. The Enlarged Board has therefore held that a claim to transgenic plants that are characterised merely by specific recombinant DNA sequences is not directed to a plant variety. The relevant passages in decision G 1/98 (*supra*) read as follows:

"In 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. As described in more detail in the referring decision, the claimed transgenic plants in the application in suit are defined by certain characteristics allowing the plants to inhibit the growth of plant pathogens (Reasons, point 11, Annex I, point 8). The taxonomic category within the traditional classification of the plant kingdom to which the claimed plants belong is not specified, let alone the further characteristics

necessary to assess the homogeneity and stability of varieties within a given species. Hence, it would appear that the claimed invention neither expressly nor implicitly defines a single variety, whether according to the definition of 'plant variety' in Article 1(vi) of the UPOV Convention 1991, or according to any of the other definitions of 'plant variety' mentioned above. This also means that it does not define a multiplicity of varieties which necessarily consists of several individual varieties. In the absence of the identification of specific varieties in the product claims, the subject-matter of the claimed invention is neither limited nor even directed to a variety or varieties."

27. In the present case, the subject-matter of the claims of auxiliary request I is not directed to whole tomato plants, but to dehydrated tomato fruits. The question thus arises whether for that reason alone the claimed subject-matter might escape the exclusion of plant varieties. However, a plant variety may be represented not only by whole plants but also by propagating material such as seeds and by parts of plants. It is noted that Article 5(3) CPVR Regulation defines "variety constituents" as "entire plants or parts of plants as far as such parts are capable of producing entire plants". In addition, Article 13(2) CPVR Regulation defines the rights of the holder of a Community plant variety right as covering specific acts in respect of variety constituents or harvested material of the protected variety. The UPOV Convention 1991 defines the scope of the breeders' right primarily by enumerating certain acts in respect of the propagating material of the protected variety, but

extends these rights under certain conditions also to acts relating to harvested material (see Article 14(1) and (2) UPOV Convention 1991). The board therefore concludes that claims which, as in the present case, are directed to plant fruits which contain seeds and which are therefore to be regarded as plant parts capable of producing entire plants may well in general fall under the patent exclusion of plant varieties contained in Article 53(b) EPC.

28. The plant grouping to which the claimed tomatoes belong is restricted to plants belonging to the species *Lycopersicon esculentum*. Thus it is not as broad and generic as the plant grouping in the case underlying the decision G 1/98 (*supra*) where the claimed subject-matter was transgenic plants that, while being characterised by specific recombinant DNA sequences, could belong to completely different taxonomic categories within the traditional classification of the plant kingdom.
29. However, even a plant grouping of which the members all belong to a single plant species such as *Lycopersicon esculentum* is not necessarily a plant variety. There are currently several thousands of tomato varieties grown for various purposes, each tomato variety being based on an entire set of genetic information and having a number of specific features e.g. with respect to leaf type, plant type, plant height, plant size, season, fruit shape, skin colour, flesh colour, taste and resistance to plant diseases and pests. In contrast, in the present case the claimed tomatoes are not defined by a multitude of characteristics resulting in

- a given genotype, but only by one particular trait, i.e. (natural) dehydration.
30. The board is aware that a single trait may be sufficient to make a given plant grouping distinguishable from another very similar plant grouping not having that trait and thus provide a basis for the grant of a plant breeders' right for that specific plant grouping if it qualifies as a new variety (which may be an essentially derived variety, see Article 14(5) (b) UPOV 1991 and Article 13(6) CPVR Regulation). Nevertheless, a single trait is in general not sufficient to define a plant variety without providing, apart from an indication of the species, any other indication about the actual genotype of the plant grouping. As already pointed out (point 26, above), the concept of plant variety requires plant groupings to be defined by their whole genome and not merely by a particular individual characteristic. It is therefore not sufficient that, as maintained by appellant II in the present case, the specific trait is inserted into the tomato plants in a stable manner so that it can be inherited by future generations.
31. The board acknowledges that the description of the patent in suit uses at some places the term "tomato varieties", e.g. by stating that the development of tomato varieties with the trait of natural dehydration is highly valuable to the tomato industry (see paragraph [0010] of the description) or that selected plants may be crossed with other *Lycopersicon esculentum* cultivars to create varieties that incorporate characteristics other than reduced fruit water content (see paragraph [0024] of the description).

Furthermore, as described in Examples 1 and 2, specific *Lycopersicon esculentum* breeding lines were used in the breeding programme for developing naturally dehydrated tomatoes. Nevertheless, the subject-matter of the claims under consideration is not restricted to tomatoes of any of those specific varieties or breeding lines. The claims leave completely open what further characteristics the claimed naturally dehydrated tomato fruits and the plants on which they grow may have.

32. According to the patent description, the tomato fruits of the invention were developed by crossing and selection, i.e. "classical" plant breeding methods. However, this does not have the automatic consequence that they have to be regarded as a plant variety. The question as to whether a plant grouping constitutes a plant variety does not depend on how it was obtained, i.e. whether it was produced by genetic engineering technology or by more traditional breeding techniques based on crossing and selection. This was made clear by the Enlarged Board of Appeal in the following passage of its decision G 1/98 (*supra*) in point 5.3 of the reasons (see also T 1854/07 of 12 May 2010, point 10.4 of the reasons):

"As already emphasised by the referring Board, it does not make any difference for the requirements under the UPOV Convention or under the Regulation on Plant Variety Rights, how a variety was obtained. Whether a plant variety is the result of traditional breeding techniques, or whether genetic engineering was used to obtain a distinct plant grouping, does not matter for the criteria of distinctness, homogeneity and stability and the examination thereof. This means that the term

'plant variety' is appropriate for defining the borderline between patent protection and plant breeders' rights protection irrespectively of the origin of the variety."

No extension of the exclusion of plant varieties to plants in general

33. Having ascertained that the claimed invention at issue was neither limited nor even directed to a variety or varieties, the Enlarged Board in its decision G 1/98 (*supra*) carefully considered in great depth the further issue as to whether the exclusion of plant varieties negatively affected the allowability of claims which included plant varieties as possible embodiments, i.e. whether it prohibited the patenting of subject-matter which, whilst not directed to a plant variety, embraced plant varieties.
34. The Enlarged Board found that there was no general principle according to which a claim would become automatically non-patentable if it encompassed an embodiment which did not comply with the requirements of the EPC. This principle applied only in certain contexts, in particular when examining novelty or inventive step, but not in others (e.g. when examining the requirement of sufficiency of disclosure or the exception to patentability pursuant to Article 53(a) EPC 1973).
35. The Enlarged Board furthermore considered that the legislative reason for excluding plant varieties in Article 53(b) EPC 1973 was to delimit patents and plant breeders' rights as the two forms of protection for

plant innovation, taking into account the ban on dual protection in the UPOV Convention in its version of 1961. It had been the legislator's intention to consider plant breeders' rights and patents as a single comprehensive system, so that the two forms of protection together permitted neither overlapping nor gaps in the protection of eligible subject-matter. Inventions ineligible under the plant breeders' rights system were thus intended to be patentable under the EPC provided they fulfilled the other requirements of patentability. The extent of the exclusion for patents was the obverse of the availability of plant variety rights.

36. The Enlarged Board concluded that it was not sufficient, for the exclusion of Article 53(b) EPC 1973 to apply, that one or more plant varieties were embraced by the claims. Thus, 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. The Enlarged Board's conclusion is corroborated by Rule 27(b) EPC which was introduced into European patent law as Rule 23c(b) EPC 1973 in the course of implementation of the Biotech Directive and which states that biotechnological inventions shall also be patentable if they concern plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety.
37. The Enlarged Board underpinned its legal analysis by emphasising that the broadly claimed subject-matter in the case underlying the referral, i.e. transgenic plants characterised by specific recombinant DNA

sequences, could not be protected by a plant breeders' right and that the inventor in the genetic engineering field would not obtain appropriate protection if he were restricted to specific varieties. Notwithstanding these particular arguments made in view of the specific technology involved, the Enlarged Board did not limit its above conclusion to situations where inventions based on genetic engineering are claimed.

38. Rather, the core of its reasoning was the consideration that the exclusion of plant varieties serves only to exclude from patentability those plant inventions which can be protected by plant breeders' rights. To extend the product exclusion contained in Article 53(b) EPC generally to a plant invention which is not directed to a plant variety would be difficult to reconcile with this legislative purpose and could lead to undesirable gaps of protection. Whether the invention is in the area of genetic engineering (as in the case underlying decision G 1/98, *supra*) or in the field of more traditional plant breeding, as in the present case, should therefore not make any difference when considering the effect of the exclusion of plant varieties on the patentability of the claimed subject-matter (see also decision T 1854/07, *supra*, point 10.4 of the reasons).
39. The present board therefore takes the view that, if it only had to consider the exclusion of plant varieties in Article 53(b) EPC, the subject-matter of the claims of auxiliary request I would not be excluded from patentability.

Impact of the process exclusion on claimed subject-matter

40. However, the above conclusion does not yet terminate the analysis of the objections raised by appellant II under Article 53(b) EPC (see point 20, above). The board still has to address the further argument that, irrespective of the interpretation of the exclusion of plant varieties, it would be wrong to allow the claimed subject-matter to be patented, since this would render the exclusion of essentially biological processes for the production of plants completely ineffective, thereby frustrating the legislative purpose behind the process exclusion in Article 53(b) EPC.
41. The meaning and the scope of this process exclusion were considered in detail in decision G 1/08 (*supra*) on referral in the present case. Although Rule 26(5) EPC (which was introduced into European patent law as Rule 23b(5) EPC 1973 in the framework of implementation of the Biotech Directive) attempts to define the term "essentially biological process for the production of plants", the Enlarged Board considered this provision as unclear and self-contradictory. Since Rule 26(5) EPC did not provide any useful guidance on the interpretation of the above term, the latter had to be interpreted on its own authority.
42. The Enlarged Board came to the conclusion that any non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genome of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC. Excluded processes

are characterised by the fact that the traits of the plants resulting from the crossing are determined by the underlying natural phenomenon of meiosis which is responsible for the genetic make-up of the plants produced (see decision G 1/08, *supra*, point 6.4.2.3 of the reasons). A process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genome of plants or of subsequently selecting plants. An exception has to be made only with respect to processes which contain within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces or modifies a trait in the genome.

43. In view of the above ruling, the deletion of all the method claims in appellant I's present claim requests (see Sections IX and XI, above) did not come as a surprise. It follows from the principles stated in decision G 1/08 (*supra*) that the method claims in the patent as granted and in appellant I's claim requests at the time when the case was before the Enlarged Board fell under the process exclusion of Article 53(b) EPC. For they were based on and contained steps of sexually crossing the whole genome of plants and of subsequently selecting plants by screening for reduced fruit water content, and none of them appeared to contain an additional step of a technical nature which by itself introduced or modified a trait in the genome.

44. Appellant II took the view, however, that the deletion of the method claims was not sufficient to escape the

process exclusion of Article 53(b) EPC. Its line of argument can be summarised as follows. As a matter of legislative policy, it would not make any sense to exclude, on the one hand, essentially biological processes for the production of plants from patentability and to allow, on the other hand, patents on plants which, according to the disclosure of the invention, are produced by an excluded process. The legislator's reasons for excluding these processes had to be respected and necessarily implied the exclusion of plants or plant parts that are produced by essentially biological processes. To hold otherwise would lead to an inconsistent legal framework. The EPC should not be interpreted in such a self-contradictory way even in the absence of an explicit provision excluding the products of essentially biological plant production processes.

45. The argument that allowing the product claims in the present case would be inconsistent with the legislator's decision to exclude the processes specified in Article 53(b) EPC may, in the board's view, be underpinned by considering the respective scope of protection conferred by product and process claims. According to established principles of patent law, the protection conferred by a product claim is absolute (see decision G 2/88, OJ EPO 1990, 93, point 5 of the reasons) and the patent proprietor has in particular the right to exclude others from making or using the patented product (see decision G 2/06, OJ EPO 2009, 306, point 25 of the reasons; Article 28.1(a) TRIPS Agreement and the corresponding provisions of the national laws of the contracting states). In contrast, the protection conferred by a process claim for making

a product is narrower since it basically covers only the use of the process and the products directly obtained by it (see Article 64(2) EPC, Article 28.1(b) TRIPS Agreement). Hence, a claim to a product provides the patent proprietor with protection that generally encompasses the protection provided by a patent claim for the process of making the product.

46. If in the present case the product claims of auxiliary request I were allowed, any act of making and using the claimed dehydrated tomato fruits would in principle fall under the prerogative of the patent proprietor. This would have the consequence that the proprietor could prevent others from using the essentially biological plant breeding method which is taught in the description of the patent and which was the subject-matter of the deleted method claims. In fact, if one takes into account the features of the breeding method as defined in claim 1 as granted ("breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of: crossing [...]; growing plants from the first generation of hybrid seeds; [...] growing plants from the seeds of the most recent hybrid generation; allowing plants [*sic*] to remain on the vine past the point of normal ripening; and screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin"), it appears that this method cannot be performed without producing and using the tomato fruits claimed in auxiliary request I.

47. In view of the above considerations, the question arises whether allowing the product claims in the present case would effectively negate the legislator's

intention as identified in decision G 1/08 (*supra*, see point 6.4.2.3 of the reasons) "to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties". Disregarding the process exclusion in the examination of product claims altogether would have the general consequence that for many plant breeding inventions patent applicants and proprietors could easily overcome the process exclusion of Article 53(b) EPC by relying on product claims providing a broad protection which encompasses that which would have been provided by an excluded process claim. At least *prima facie* this would appear to be at odds with a purposive construction of Article 53(b) EPC.

Issue not settled by decision G 1/98 and Rule 27(b) EPC

48. In the board's view, decision G 1/98 (*supra*) did not deal with this line of argumentation, either explicitly or implicitly. It is true that the Enlarged Board came to the conclusion that a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC 1973, even though it may embrace plant varieties (see point 36, above). However, the reasons underlying this conclusion only concerned the meaning and the scope of the exclusion of plant varieties. The issue of a possible impact of the process exclusion in Article 53(b) EPC 1973 on claims for plants or plant material was not addressed. This can be explained by the fact that the case underlying the referral leading up to decision G 1/98 (*supra*) concerned transgenic plants that were produced by modern genetic technology, rather than by a breeding method based on crossing and selection.

49. In a similar vein, Rule 27(b) EPC is understood by the board as aiming at restricting the scope of the product exclusion in Article 53(b) EPC, not of the process exclusion. If the legislator had intended to clarify that products obtained by essentially biological plant production processes, other than a plant variety, should not be excluded from patentability, then this could have been expected to be expressed in Rule 27(c) EPC (according to this provision, products obtained by means of a microbiological or other technical process other than a plant or animal variety are to be regarded as patentable). However, this was not done. The board furthermore considers that, in the light of Article 164(2) EPC, it appears questionable whether a provision of the Implementing Regulations could mitigate an effect which a provision of the Convention would have if interpreted on its own authority.

Interpretation of other process exclusions - the example of Rule 28(c) EPC

50. The case law shows that there are situations where an exclusionary provision referring to specific processes or uses may have an impact on the allowability of product claims. According to Rule 28(c) EPC, European patents shall not be granted in respect of biotechnological inventions which concern the uses of human embryos for industrial or commercial purposes. In its decision G 2/06 (*supra*) the Enlarged Board concluded that this provision forbids the patenting of claims directed to products which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the

destruction of the human embryos from which said products are derived, even if the said method is not part of the claims. The patent applicant's counter-argument that, in order to fall under the prohibition of Rule 28(c) EPC, the use of human embryos must be claimed was dealt with in point 22 of the reasons for the decision as follows:

"However, this Rule (as well as the corresponding provision of the Directive) does not mention claims, but refers to 'invention' in the context of its exploitation. What needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed. Before human embryonic stem cell cultures can be used they have to be made. Since in the case referred to the Enlarged Board the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention falls under the prohibition of Rule 28(c) [...]. To restrict the application of Rule 28(c) [...] to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim."

51. The corresponding provision of the Biotech Directive was interpreted in a similar manner by the European Court of Justice (ECJ) in its decision C-34/10 of 18 October 2011 (Oliver Brüstle v. Greenpeace e.V.). In response to the third question referred to it by the German Federal Supreme Court, the ECJ concluded that Article 6(2)(c) Biotech Directive excluded an invention

from patentability where the technical teaching which was the subject-matter of the patent application required the prior destruction of human embryos or their use as base material, whatever the stage at which that took place and even if the description of the technical teaching claimed did not refer to the use of human embryos. In the ECJ's view, not to include in the scope of the exclusion technical teaching claimed, on the ground that it does not refer to the use of human embryos, would make the provision concerned redundant by allowing a patent applicant to avoid its application by skilful drafting of the claim.

52. The board is aware that, due to the different legislative purposes of the patentability exceptions under Article 53(a) and (b) EPC, the above considerations do not necessarily apply *mutatis mutandis* to the interpretation of the process exclusion of Article 53(b) EPC. Nevertheless, they demonstrate that situations exist where an exclusion referring to specific processes (according to the Enlarged Board's case law "uses" are regarded as a sub-class of processes, see e.g. decision G 5/83, OJ EPO 1985, 64, point 11 of the reasons) may negatively affect the allowability of product claims.

Arguments against a negative effect of the process exclusion on product claims

53. The board considers that the following interrelated lines of argument against extending the effect of the process exclusion in Article 53(b) EPC to product claims need to be addressed:

- Issues of patentability (including the applicability of an exclusionary provision) should be determined strictly in relation to the subject-matter of the claim to be examined.

- The subject-matter of product claims is different from that of process claims, so that it is justified to treat them differently when determining what is patentable and what is not.

- The difference in subject-matter should not be smoothed out by taking into account the scope of protection or the proprietor's prerogatives conferred by the claims, since this would amount to an impermissible mixing of two bodies of rules, i.e. those concerned with the patentability of inventions and those concerned with patent infringement.

The following considerations are of relevance for addressing these lines of arguments.

54. As pointed out in the Enlarged Board's decision G 2/88 (*supra*, points 2.2 and 2.6 of the reasons), the subject-matter of a claimed invention involves two aspects: first, the category or type of the claim, and second, the technical features, which constitute its technical subject-matter. Basically two types of claim have to be distinguished, namely claims to a physical entity (e.g. product, apparatus) and claims to a physical activity (e.g. method, process, use), although there are no rigid demarcation lines between the various possible forms of claims. Consequently, the subject-matter of a process claim for the production of

plants (which relates to a physical activity) and that of a product claim for plants or plant parts (which relates to physical entities) are not identical.

55. The difference of subject-matter between product and process claims is *inter alia* of importance when the patentability requirements of novelty and inventive steps are examined. While a product claim can only be allowed when the claimed product is new and inventive, a claim to a manufacturing process for a product may comply with the requirements of novelty and inventive step even where the product to be manufactured does not fulfil these requirements itself. Since an invention underlying a product claim therefore has to have an "inventive quality" which is not the same as that of an invention underlying a process claim, it may be argued that, when framing the exclusionary provision of Article 53(b) EPC, the legislator made a deliberate differentiation by excluding only certain plant breeding processes, but not all the products produced by those processes.
56. However, the process exclusion itself does not distinguish between processes which lead to new and inventive plants and those processes which do not. Rather, it excludes them all. This uniform approach is reflected in the legislative history, during which it was explained that the (essentially) biological processes for the production of plants or animals should include those which may produce known varieties as well as those which may produce new ones (see decision G 1/08, *supra*, point 6.4.2.2 of the reasons). It appears furthermore that, when new and inventive subject-matter is developed in the context of a plant

breeding invention based on the natural phenomenon of meiosis, it will very often be possible to formulate process and product claims which both comply with the requirements of novelty and inventive step. The argument of a distinctive inventive quality of product inventions justifying their general allowability notwithstanding the general non-allowability of process claims therefore does not seem to be convincing in the present context.

57. In decision G 1/98 (*supra*), in the context of its answer to the referred question 3, the Enlarged Board dealt with an issue which may be considered to be the obverse of the present core issue: it analysed a possible impact of the product exclusion in Article 53(b) EPC 1973 on the examination of process claims, namely the question as to whether, in view of Article 64(2) EPC 1973, the exclusion of plant varieties should be a bar to process claims when the products directly obtained by such processes were or covered plant varieties. The Enlarged Board gave a negative answer to this question and pointed out that the protection of the product obtained by a patented process was of particular importance in situations where product protection was not available. Thus, when a claim to a process for the production of a plant variety is examined, Article 64(2) EPC 1973 should not be taken into consideration.
58. It is apparent that the protection conferred by Article 64(2) EPC on any process for the production of a plant variety is limited to the variety directly obtained by the process and thus considerably narrower than the protection which would be conferred by a

product claim to the variety. As emphasised by the Enlarged Board in decision G 1/98 (*supra*) in point 4 of the reasons, the protection of the product obtained by a patented process has nothing to do with product-by-process claims, which belong to the category of product claims. It may be inferred from this that a legal framework does not lack consistency if it disallows the broader protection conferred by product claims while allowing the narrower protection conferred by process claims.

59. The core issue of the present case, however, is quite different, since not taking into account the process exclusion of Article 53(b) EPC when examining product claims may lead to a situation where the legal framework disallows the narrower protection conferred by claims on essentially biological plant production processes while allowing the generally broader protection conferred by product claims. The Enlarged Board's above-mentioned finding in decision G 1/98 (*supra*) can therefore not simply be extrapolated to the present case.

60. European patent law clearly distinguishes between issues of patentability, which are governed by the EPC, and issues of infringement, which are a matter for the legislation of the contracting states. The process exclusion of Article 53(b) EPC belongs to those provisions which determine what can be patented under the EPC. It is not a provision exempting specific activities from the rights conferred by patents and therefore does not completely shield those who use an essentially biological process for the production of plants from infringing patent rights.

61. Already at an early stage in the legislative history of Article 2(b) Strasbourg Convention (on the Unification of Certain Points of Substantive Law on Patents for Invention) and Article 53(b) EPC it was recognised and accepted that technical devices used in an excluded process (e.g. a particular type of instrument for use in a grafting process or a special greenhouse for growing a plant) may perfectly well be patented themselves (see in particular document EXP/Brev 61(8), pages 4-5, as cited in decision T 83/05, OJ EPO 2007, 644, point 40, and summarised in decision G 1/08, *supra*, point 6.4.2.2). The legislator apparently did not see any inconsistency in allowing patent protection for these devices, notwithstanding the consequence that the proprietor's prerogatives may then encompass the use of the patented devices in an excluded process.
62. A similar approach appears to underlie Article 53(c) EPC which, on the one hand, excludes certain surgical, therapeutic and diagnostic methods from patentability and, on the other hand, stipulates that products, in particular substances or compositions, for use in any of these methods are patentable. This has the consequence that, although the exclusion of medical methods by Article 53(c) EPC is commonly explained by the legislator's aim to free the medical profession from possible constraints imposed on them by patents (see e.g. decision G 1/07, OJ EPO 2011, 134, point 3.2.3.2), medical practitioners who use such products in a medical method excluded per se may well infringe patents (see decision G 2/08, OJ EPO 2010, 456, point 6.5, in the context of dosage regimes).

63. It follows from the above that a process exclusion cannot have the general effect of precluding patents on any product that can be used in the excluded process. This also appears to be justified from the point of view of legal policy. As there will normally be a market for lawfully produced and commercialised products to be used in excluded processes (e.g. plant greenhouses or medicaments), those who want to use these products in their professional activities (e.g. plant breeders or medical practitioners) will be able to acquire them. Using these products put on the market with the consent of the patent proprietor will then be exempted from patent infringement pursuant to the doctrine of exhaustion.
64. In the present case, however, a product is claimed which is being **made** (i.e. not only used) when an excluded process is performed. The breeding method disclosed in the patent necessarily implies the production of the claimed tomatoes (see point 46, above). Plant breeders who perform this essentially biological process would fall into the scope of protection of appellant I's patent without being able to invoke the doctrine of exhaustion. They would also be prevented from commercializing the tomatoes obtained through the breeding method. If appellant I's product claims were allowed, then plant breeders would be more severely restricted in performing essentially biological processes than in the above-mentioned situation where (merely) a product to be used in the course of this activity was patented.
65. Summing up, the board is not fully convinced by the arguments reviewed above against considering the

process exclusion of Article 53(b) EPC in the examination of claims for plants or plant material. Serious concerns remain that allowing claims to plant material which, according to the disclosure of the patent, is obtained by means of an essentially biological breeding process would *de facto* frustrate the legislator's intentions in framing the process exclusion, which were emphasised in decision G 1/08 (*supra*), and make the circumvention of the exclusion in many cases a matter of skilful claim drafting, thereby diminishing the consistency and persuasiveness of the legislative framework of the EPC as regards patentable subject-matter.

66. In the board's view, these concerns can equally not be overcome by pointing out that national legislators, insofar as this is permitted under the Biotech Directive, might be able to introduce specific exemptions for plant breeding activities into their national infringement provisions (see e.g. Article L613-5-3 French Intellectual Property Code and § 11 No. 2a German Patent Law). Courts should aim at interpreting the EPC provisions on patentable subject-matter in a consistent manner, wherever possible. To rely on the possibility that inconsistencies might be partially remedied by national infringement provisions appears to the board to be the second-best solution.

Referral under Article 112(1) EPC

67. The board is of the opinion that the issues analysed above under points 40 to 66 raise points of law of fundamental importance and that a decision of the

Enlarged Board on them is required in order to dispose of the present appeals on a correct legal basis.

68. While there are further grounds of opposition in the present appeal procedure which the board has not yet fully examined, the issue as to whether the claimed subject-matter is excluded from patentability conceptually precedes the assessment of other substantive requirements such as novelty or inventive step and is therefore normally determined first. This has also been noted in decision T 1384/06 of 26 June 2007 (see point 5 of the reasons "*[...] it must be investigated whether such subject-matter falls within the category of exceptions to patentability. Obviously, this should be done as the first step in the examination because there is absolutely no point in assessing whether or not a subject-matter which is decided to be an exception to patentability fulfils the requirements for patentability.*").
69. Similarly, it was found in decisions G 1/03 (OJ EPO 2004, 413, point 1.2 of the reasons) and G 2/10 of 30 August 2011 (see point 1 of the reasons) that a referral concerning the conditions under which a disclaimer complies with Article 123(2) EPC is justified since formal allowability is normally examined before substantive requirements.
70. The board notes in addition that the issue of a possible impact of the process exclusion in Article 53(b) EPC on the allowability of product claims does not only arise in view of auxiliary request I; it is also highly relevant for all other pending requests of appellant I.

71. The board has therefore not followed appellant I's suggestion that it proceed with the examination of these other requirements before referring questions of law to the Enlarged Board.
72. The questions of law referred by the board with its first interlocutory decision were limited to the issue as to whether certain plant production processes fall under the process exclusion of Article 53(b) EPC. The Enlarged Board was therefore not provided with the opportunity to address the further issue now at stake.
73. Indeed, when the board took that first interlocutory decision, the current issue had not yet emerged, at least not clearly. Insofar as the decision under appeal and the submissions of the parties dealt with the allowability of the product claims under Article 53(b) EPC, they focused only on the scope of the exclusion of plant varieties. Since the board was - and still is (see point 39, above) - of the opinion that the Enlarged Board had already sufficiently clarified the interpretation of the exclusion of plant varieties in its decision G 1/98 (*supra*), it refrained from following the suggestion made by appellant II in the first oral proceedings to refer an additional question concerning that interpretation.
74. The issue now at stake, i.e. a possible negative effect of the process exclusion contained in Article 53(b) EPC on the allowability of appellant I's product claims, differs from the issues considered by the board in its first interlocutory decision. It has come up as a result of the Enlarged Board's decision G 1/08 (*supra*) which, as summarised above (points 41 and 42), has

given the process exclusion a broad reading, and of the parties' submissions made in the aftermath of that decision. Fully aware of the unusual character of such a course of action, the board therefore decides to refer again questions of law to the Enlarged Board. In formulating them, the board has taken into account the suggestions made by appellant II (see Sections X and XII, above), while submissions by third parties after the closure of the debate on this issue at the end of the oral proceedings have been disregarded.

Order

For these reasons it is decided that:

- I. Appellant I's main request is refused.

- II. The following questions are referred to the Enlarged Board of Appeal for decision:
 1. Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit?

 2. In particular, is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?

 3. Is it of relevance in the context of questions 1 and 2 that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?

The Registrar:

The Chairman:

P. Cremona

R. Gramaglia