Enlarged Board of Appeal EPO, 25 March 2015, Broccoli II - Tomato II (G 2/12 - G 2/13)



PATENT LAW

Product-by-process claim

• protects the product, not the process and is only allowable if (a) it is impossible to define the claimed product other than in terms of a process of manufacture and (b) the claimed product itself meets the patentability requirements

Rules for interpretation of EPC

• EPC contains no general rules for its interpretation, and one must look outside the terms of the Convention itself for such rules. [...]. it is established in the jurisprudence that the principles of interpretation provided for in Articles 31 and 32 Vienna Convention are to be applied when interpreting the EPC. Decisions and opinions given by national courts in interpreting the law may also be taken into consideration

• The starting point of interpretation is thus the wording, i.e. the "objective" meaning, regardless of the original "subjective" intention of the contracting parties. To this end, the provisions are to be read in their context so that they comply with the object and purpose of the European Patent Convention. The preparatory work ("travaux preparatoires") and the circumstances of the conclusion of the EPC serve only as supplementary sources of evidence to confirm the result of the interpretation or if no reasonable meaning can be determined by applying the general rule of interpretation (Article 32 Vienna Convention)

No general notion of an obligatory restrictive construction of exceptions to patentability

• <u>such a narrow interpretation might well result</u> <u>from applying the general principles of</u> <u>interpretation to a specific provision with regard to</u> <u>specific legal and factual circumstances.</u>

Allowable product claim directed to plants or plant material such as plant parts or fruits

• The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts or fruits

Fact that only an essentially biological process or a product-by-process claim is available for the claimed subject matter (other than plant varieties) does not make the claims unallowable

• The fact that the process features of a productby-process claim directed to plants or plant material other than a plant variety define an essentially biological process for the production of plants does not render the claim unallowable.

• The fact that 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 does not render a claim directed to plants or plant material other than a plant variety unallowable.

In the circumstances, it is of no relevance 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.

Source: www.epo.org and epo.org

Enlarged Board of Appeal EPO, 25 March 2015

(W. van der Eijk, I. Beckedorf, C. Floyd, K. Garnett, U. Oswald, J. Riolo, G. Weiss) [Case Numbers: G 0002/13 and G 002/12] DECISION of the Enlarged Board of Appeal of 25 March 2015 G 0002/12

Appellant I (Patent Proprietor): State of Israel -Ministry of Agriculture, Volcani Research Center, P.O. Box 6, IL-50250 Beit Dagan (IL)

Representative : Vossius & Partner, Siebertstrasse 3, D-81675 Mtinchen (DE)

Respondent (Opponent): Unilever N.V., Weena 455, NL-3013 AL Rotterdam,

Representative: Tjon, Hon Kong Guno, Unilever N.V.

(NL), Unilever Patent Group, Olivier van Noortlaan 120 NL-3133 AT Vlaardingen (NL)

G 002/13:

Appellant I: Syngenta Participations AG, Schwarzwaldallee 215, CH-4058 Basel (CH)

Representative: Syngenta International AG, No. 557, WRO 4008-ZI-26, Schwarzwaldallee 215, CH-4058 Basel (CH)

Appellant II: Groupe Limagrain Holding, Rue Henri Mondor, Biopole Clermont Limagne, F-63360 Saint-Beauzire (FR)

Representative: Almond-Martin, Carol, Ernest Gutmann - Yves Plasseraud S.A.S., 88, Boulevard des Belges F-69452 Lyon Cedex 06 (FR) Respondent: Plant Bioscience Limited, Norwich Research Park, Colney Lane, Norwich Norfolk NR4 7UH (GB)

Representative: Williams, Aylsa, D Young & Co LLP, 120 Holborn, London EC1N 2DY (GB)

Referring Decision: Interlocutory decision of Technical Board of Appeal 3.3.04 dated 8 July 2013 in case T 0083/05.

Composition of the Board:

Chairman: W. van der Eijk Members: I. Beckedorf

C. Floyd

- K. Garnett
- U. Oswald
- J. Riolo
- G. Weiss

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SUMMARY OF FACTS AND SUBMISSIONS I. PROCEDURAL ASPECTS

1. Consolidation

By decision of 22 July 2013 the Enlarged Board of Appeal (hereinafter: the Enlarged Board) decided to consider the points of law referred to it by Technical Board of Appeal 3.3.04 (hereinafter: the referring Board) in case T 1242/06 (G 2/12) and in case T 83/05 (G 2/13) in consolidated proceedings in accordance with Article 8 of the Rules of Procedure of the Enlarged Board (hereinafter: RPEBA)

2. Preceding referrals

The current proceedings were preceded by two earlier referrals concerning these two appeal cases. Reference is made to the respective <u>decisions of the Enlarged</u> Board G 2/07 (OJ EPO 2012, 130 - Broccoli) and G

1/08 (OJ EPO 2012, 130, 206 - Tomato)

II. REFERRAL G 2/12

1. The referred questions

By interlocutory decision T 1242/06 dated 31 May 2012 (OJ EPO 2013, 42, hereinafter: referral tomato II), the referring Board referred to the Enlarged Board the following questions:

"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?"

2. The patent in suit

European patent No. 1 211 926 (hereinafter: the tomato patent) was published in European Patent Bulletin 2003/48 of 26 November 2003. It concerns a method

for breeding tomatoes having reduced water content, and the product of the method. The independent claims of the tomato patent as granted 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 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 natu-ral dehydration while on a tomato plant, natural dehydra-tion 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."

3. The appeal proceedings T 1242/06

(1) The proceedings before the referring Board concern appeals filed by the patent proprietor (appellant I, hereinafter: patent proprietor T or patent proprietor in case T 1242/06) and by the opponent (former appellant II, hereinafter: opponent T or opponent in case T 1242/06) against the decision of the opposition division dated 29 May 2006. In that decision, the opposition division had found that the tomato patent, as amended by patent proprietor T pursuant to its auxiliary request IIIb then on file, comprising two independent product claims, and the invention to which it related met the requirements of the EPC.

Opponent T filed an appeal against this decision seeking revocation of the patent, but that appeal was withdrawn during the proceedings before the Enlarged Board by letter of 28 June 2012. With its own appeal, patent proprietor T first de-fended the tomato patent in a form containing both independent

process and product claims.

(2) In its (first) interlocutory decision of 4 April 2008, the referring Board referred three questions of law to the Enlarged Board. 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".

Those questions were answered by the Enlarged Board in <u>its decision G 1/08 (supra)</u>.

(3) In the light of this decision, patent proprietor T 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 in this section point II.4 below).

(4) These amendments then led to the second referral by the Board (see in this section point II.5 below).

4. The patent claims currently on file

(1) The independent claims of the main request (filed with letter of 7 September 2011, being identical to auxiliary request II before the opposition division) read:

"1. A tomato fruit of the species Lycopersicon esculentum which is naturally dehydrated, wherein natural dehy-dration 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."

(2) Auxiliary request I (filed during the oral proceedings of 8 November 2011) comprises claim 1 according to the main request and an amended claim 2 that reads:

"2. A dehydrated tomato fruit of the species Lycopersiconesculentum 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."

(3) Auxiliary request II (filed as auxiliary request I with letter of 7 September 2011) differs from the main request in that at the beginning of both claims the term "*A tomato fruit*" has been changed to "*A raisin-type tomato fruit*".

Auxiliary request II is identical to the claim version that was maintained by the opposition division in the decision under appeal (at that time: auxiliary request IIIb).

(4) Auxiliary request III (filed as auxiliary request II with letter of 7 September 2011) differs from auxiliary request II in that in both claims the word "*product*" has been inserted after "*A raisin-type tomato fruit*".

(5) Auxiliary request IV (filed as auxiliary request III with letter of 7 September 2011) differs from the main request in that at the beginning of both claims the term "*A tomato fruit*" has been changed to "*A harvested tomato fruit*".

(6) Auxiliary request V (filed as auxiliary request IV with letter of 28 October 2011) differs from the m9in 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" has been added.

(7) Auxiliary request VI (filed as auxiliary request V with letter of 28 October 2011) differs from the main request in that at the end of both claims the following wording has been added:

"wherein said tomato fruit is from a plant obtainable by a method for breeding tomato plants that produce toma-toes 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 b extended preservation of the ripe fruit and wrinkling of the fruit skin."

5. The referring decision

(1) In its second interlocutory decision of 31 May 2012, i.e. referral tomato II, the Board refused patent proprietor T's main request because its claim 2 did not comply with the requirements of Article 123(3) EPC, whereas both claims of new auxiliary request I complied with the requirements of Rule 80 and Articles 84 and 123(2) and (3) EPC. Furthermore, it referred the above questions to the Enlarged Board (see point II .1 above).

(2) According to the referring Board, in the proceedings before it important points of law arose because of patent proprietor T's restriction of the claims to mere product claims that were not considered in the first interlocutory decision leading to decision G 1/08 (supra). The referring Board gave the following reasons for making the second referral:

(a) With respect to the area of plant breeding, Article 53(b) EPC prohibited the patenting of, as a first group, plant (or animal) varieties and, as a second group, of essentially biological processes for the production of plants (or animals) (referral tomato II, Reasons, point 19).

(b) When the referring Board handed down its first interlocutory decision, referring to the Enlarged Board questions concerning the interpretation of the process exclusion contained in Article 53(b) EPC in the light of Rule 26(5) EPC, both patent proprietor T'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 plant (referral tomato II, Reasons, point 19).

(c) In respect of the first group of exceptions to patentability, the referring Board held that the subjectmatter of the independent claims according to all patent proprietor T's then current requests was not directed to whole tomato plants, but to dehydrated tomato fruits. Having considered Articles 5(3) and 13(2) Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, Council of Europe, signed in Strasbourg on 27 November 1963 (hereinafter: Strasbourg Convention) and Article 14(1) and (2) UPOV Convention 1991 (International Convention for the Protection of New Varieties of Plants of 2

December 1961 (hereinafter UPOV Convention 1961), as revised on 10 November 1972, ?3 October 1978~ and 19 March 1991 (the current version: UPOV Convention 1991), the referring Board concluded further that such plant fruits were to be regarded as plant parts capable of producing entire plants. However, the referring Board held that the claimed tomato fruits did not come under the patent exclusion of plant varieties contained in Article 53(b) EPC (see referral tomato II, Reasons, points 27 to 33). Considering decision G 1/98 (OJ EPO 2000, 111), the Board took 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 (referral tomato II, Reasons, points 33 to 39).

(d) However, the referring Board saw itself confronted with the issue of whether, irrespective of the interpretation of the exclusion of plant varieties, patenting the claimed subject-matter rendered the exclusion of essentially biological processes, i.e. the second group of exceptions to patentability pursuant to Article 53(b) EPC, completely ineffective, thereby frustrating the legislative purpose behind the process exclusion in Article 53(b) EPC (referral tomato II, Reasons, point 40). If the product claims of auxiliary request I were allowed, any act of making and using the claimed dehydrated tomato by applying the breeding method as defined in claim 1 of the tomato patent as granted would, in principle, fall under the patent proprietor T's right in respect of the patent (referral tomato II, Reasons, point 46). Thus (referral tomato II, Reasons, point 47):

"Disregarding the process exclusion in the examination of product claims altogether would have the general con-sequence that for many plant breeding inventions patent appli-cants 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."

(e) This question of a possible impact of the process exclusion in Article 53(b) EPC on claims for plants or plant material was not answered by decision G 1/98 (supra) or settled by Rule 27(b) EPC. In the referring Board's view, the conclusions reached in decision G 1/98 involved only the meaning and the scope of the exclusion of plant varie-ties and were to be understood against the factual background of the appeal case leading up to decision G 1/98. It concerned transgenic plants produced by modern genetic technol-ogy, rather than by a breeding method based on crossing and selection (referral tomato II, Reasons, point 48). Rule 27(b) EPC was understood by the referring Board as being aimed at restricting the scope of the product exclusion in Article 53(b) EPC. This rule had no - and could have no - influence on the scope of the process exclusion in Article 53(b) EPC (referral tomato II, Reasons, point 49).

(f) However, albeit acknowledging the different legislative purposes of the exceptions to patentability under Article 53(a) and (b) EPC, the referring Board concluded from Article 53(a) EPC, Rule 28 (c) EPC and Article 6 (2) (c) Biotech Directive (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ EU L 213 of 30 July 1998, p. 13 to 21) that situations existed where an exclusion directed at a specific process might negatively affect the allowability of a product claim (referral tomato II, Rea-sons, points 50 to 52).

(g) The referring Board, after having listed the argument against a negative effect of the process exclusion on product claims (referral tomato II, Reasons, points 53 to 66), was of the opinion that a decision of the Enlarged Board on the points of law in respect of the scope of the process exclusion from patentability according to Article 53(b) EPC as regards the allowability of product claims was required in order to dispose of the present appeals on a correct legal basis. It noted that this issue not only arose in respect of auxiliary request I but was also highly relevant for all other pending requests of the patent proprietor T (referral tomato II, Reasons, points 67 to 74).

III. REFERRAL G 2/13

1. The Referred questions

By interlocutory decision T 83/05 dated 8 July 2013 (OJ EPO 2014, A39, hereinafter: referral broccoli II), the referring Board referred to the Enlarged Board the following questions:

"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 plant parts?

2. In particular:

(a) Is a product-by-process claim directed to plants or plant material other than a plant variety allowable if its process features define an essentially biological process for the production of plants?

(b) Is a claim directed to plants or plant material other than a plant variety allowable even if the only method avail-able 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?

4. If a claim directed to plants or plant material other than a plant variety is considered not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability under Article 53(b) EPC, is it possible to waive the protection for such generation by "disclaiming" the excluded process?"

2. The patent in suit

European patent No. 1 069 819 (hereinafter: the broccoli patent) was published in European Patent Bulletin 2002/30 of 24 July 2002. It concerns a method for selective increase of the anticarcinogenic glucosinolates in brassica species.

The independent claims of the broccoli patent as granted read:

"1. A method for the production of Brassica oleracea elevated levels of 4-methylsulfinylbutyl with 3-methylsulfinylpropyl glucosinolates, or glucosinolates, or both, which comprises: (a) crossing wild Brassica oleracea species with Brassica oleracea breeding lines; and, (b) selecting hybrids with levels of *4-methylsulfinylbutyl* glucosinolates, or 3methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in Brassica oleracea breeding lines.

9. An edible Brassica plant produced according to the method of any one of claims 1 to 6.

10. An edible portion of a broccoli plant produced according to the method of any one of claims 1 to 6.

11. Seed of a broccoli plant produced according to the method of any one of claims 1 to 6.

13. A broccoli plant having elevated levels of 3methylsulfinylpropyl glucosinolates, or 4methylsulfinylbutyl glucosinolates, or both; wherein the broccoli plant is a hybrid plant following crossing of broccoli breeding lines with wild species and, the levels 4-methylsulfinylbutyl glucosinolates, or 3of methylsulfinylpropyl glucosinolates, or both, are elevated above that initially found in broccoli breeding lines.

15. A broccoli inflorescence having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4methylsulfinylbutyl glucosinolates, or both; wherein the broccoli inflorescence is obtained from a hybrid plant following crossing of broccoli breeding lines with wild species and, the levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, are elevated above that initially found in broccoli breeding lines.

17. A Brassica plant cell having elevated levels of 3methylsulfinylpropyl glucosinolates, or 4methylsulfinylbutyl glucosinolates, or both; wherein the Brassica plant cell is obtained from a hybrid plant following crossing of broccoli breeding lines with wild species and, the levels of 4-methylsulfinylbutyl glucosinolates, or 3- methylsulfinylpropyl glucosinolates, or both, are elevated above that initially found in broccoli breeding lines."

3. The appeal proceedings T 83/05

(1) The proceedings before the referring Board concern appeals filed by the two opponents (hereinafter: opponents B or opponents in case T 83/05 or opponent B1 and opponent B2) against the decision of the opposition division dated 23 November 2004. In that decision, the opposition division had found that the broccoli patent, as amended by the patent proprietor (hereinafter: patent proprietor B or patent proprietor in case T 83/05) pursuant to its (new) main request then on file, comprising method, product and product-byprocess claims, and the invention to which it related met the requirements of the EPC.

{2) In its (first) interlocutory decision of 22 May 2007, the Board referred two questions of law to the Enlarged Board. Both 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 interlocutory decision furthermore dealt with all other objections raised by opponents B up to then in the course of the appeal proceedings. The Board concluded that none of these other objections precluded maintenance of the patent as amended on the basis of the respondent's main request. The Enlarged Board answered the referred questions in its decision G 2/07 (supra).

(3) In the light of this decision, patent proprietor B submitted a new main request and a new auxiliary request replacing all previous requests; subsequently, patent proprietor B filed a new first auxiliary request making the former first auxiliary request its new second auxiliary request. These new requests are restricted to product and product-by-process claims (see in this section point III.4 below).

(4) These amendments then led to the second referral by the referring Board (see in this section point III.5 below).

4. The patent claims currently on file

(1) The independent claims of the new main request (filed with letter of 29 April 2011) read:

"1. An edible Brassica plant produced according to a method for the production of Brassica oleracea with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, which comprises: a) crossing wild Brassica oleracea species selected from the group consisting of Brassica villosa and Bras-sica drepanensis with broccoli double haploid breeding lines; b) selecting hybrids with levels 4-methylsulfinylbutyl glucosinolates, of or3methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in broccoli double haploid breeding lines; c) backcrossing and selecting plants with the genetic combination encoding the expression of elevated levels of 4- methylsulfinylbutyl glucosinolates, or3-methylsulfinylpropyl glucosinolates, or both; and d) selecting a broccoli line with elevated levels of 4-methylsulfinylbutyl 3methylsulfinylpropyl glucosinolates, orglucosinlates, or both, capable of causing a strong induction of phase II enzymes, where-in molecular markers are used in steps (b) and (c) to select hybrids with genetic combination encoding expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3- methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes." (Claims 2 and 3 of the new main request were directed to an edible portion and to the seed of a broccoli plant produced by a method defined in the same manner as in claim 1.)

"4. A broccoli plant having elevated levels of 3methylsulfinylpropyl glucosinolates, or 4methylsulfinylbutyl glucosinolates, or both, wherein the broccoli plant is a hybrid plant following crossing of broccoli double haploid breeding lines with wild Brassica oleracea species selected from the group consisting of Brassica villosa and Brassica drepanensis and the levels of 3- methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, are between 10 and 100 pmoles per gram of dry weight of said plant.

5. A broccoli inflorescence having elevated levels of 3methylsulfinylpropyl glucosinolates, or 4methylsulfinylbutyl glucosinolates, or both, wherein the broccoli inflorescence is obtained from a hybrid plant following crossing of broccoli double haploid breeding lines with wild Brassica oleracea species selected from the group consisting of Brassica villosa and Brassica drepanensis and the levels of 3-methylsulfinylpropyl glucosinolates, or 4- methylsulfinylbutyl glucosinolates, or both, are be-tween 10 and 100 pmoles per gram of dry weight of the inflo-rescence."

(2) New auxiliary request I (filed during the oral proceedings of 1 March 2013) is identical to the new main request, except that at the end of each claim a "wherein" clause is introduced starting with "wherein the claim does not encompass an essentially biological process for producing" and continuing in claims 1 and 4 with "the plant", in claim 2 with "the portion of a plant", in claim 3 with "the seed of the plant" and in claim 5 with "the inflorescence".

(3) New auxiliary request I (filed during the oral proceedings of 1 March 2013 and identical to the new auxiliary request filed with the letter dated 29 April 2011) differs from the main request only by deletion of claims 1 to 3 and the renumbering of the remaining claims 4 and 5.

5. The referring decision

(1) In its second interlocutory decision of 8 July 2013, the referring Board admitted patent proprietor B's requests (i.e. the main request and the two auxiliary requests) into the appeal proceedings (referral broccoli II, Reasons, point 3). Likewise, the referring Board admitted into the proceedings the objection of opponents Braised under Articles 100(a) and 53(b) EPC against the product claims (referral broccoli II, Reasons, point 12). Furthermore, the Board held that, in respect of the main request, its conclusions concerning the grounds for opposition other than Articles 100(a) and 53(b) EPC laid down in its first interlocutory decision of 22 May 2007 still applied in favour of patent proprietor B (referral broccoli II, Reasons, point 6).

(2) According to the referring Board, in the proceedings before it important points of law arose because of patent proprietor B's restriction of the claims to product claims that were not considered in the first interlocutory decision leading to the decision G 2/07 (supra). In the reasons for the interlocutory decision, the Board referred to the respective reasons for the referral tomato II, because it considered an answer to those referred questions essential for deciding the appeal in case T 83/05 (referral broccoli II,

Reasons, points 13 to 20). In addition, it gives the following reasons for needing to refer modified questions compared to those in referral tomato II:

(a) The reasons for the referring Board not just to stay the proceedings pending answers to the referral in case G 2/12 but to refer additional questions were to ensure a decision of the Enlarged Board on the merits of the questions of law relevant to both referral cases, independent of the procedural fate of the appeal proceedings in case T 1242/06, and to enrich the basis on which the Enlarged Board would take its decision (referral broccoli II, Reasons, points 21 and 22).

(b) Patent proprietor B's claims were directed not to fruits but to plants and plant parts (seed, edible portion, inflorescence) and the referring Board considered these not to fall under the exclusion of plant varieties as stipulated in Article 53(b) EPC and defined by Rule 26(4) EPC (referral broccoli II, Reasons, points 16 and 23).

(c) Furthermore, the point that patent proprietor B's claim requests defined the products by process features needed to be addressed in the additional referred questions (referral broccoli II, Reasons, point 25).

(d) The referring Board understood the clause in the claims according to patent proprietor B's first auxiliary request "*wherein the claim does not encompass an essentially biological process for producing*" the plant, the portion of a plant, the seed of the plant or the inflorescence as an attempt to waive some of its rights in respect of a product patent, such that producing the claimed product by an essentially biological process could no longer be prohibited. Referring to G 1/93 (OJ EPO 1994, 541), the Board doubted that the EPC allowed such a waiver (referral broccoli II, Reasons, points 26 to 28).

IV. THE COURSE OF THE PROCEEDINGS BEFORE THE ENLARGED BOARD

In both referrals the Enlarged Board invited the parties to the proceedings to file observations on the referred questions (G 2/12: decision of 26 June 2012 and communication of 27 June 2012, G 2/13 decision of 22 July 2013 and communication of 23 July 2013) (see in this section point V below). Furthermore, the Enlarged Board invited the President of the EPO to comment in writing on the points of law referred to it (G 2/12: decision of 26 June 2012 and communication of 27 June 2012; G 2/13: decision of 22 July 2013 and communication of 23 July 2013) (see in this section point VI below) and also issued an invitation for third parties to file comments (G 2/12: decision of 26 June 2012 and OJ EPO 2012, p. 468; G 2/13: decision of 22 July 2013 and OJ EPO 2013, p. 412) (see in this section point VII below).

With regard to patent proprietor T's request in case G 2/12 that, as a consequence of opponent T having withdrawn its appeal, the proceedings before the Enlarged Board be terminated, the Enlarged Board issued a communication stating that it did not consider that a procedural situation existed in which these proceedings would have to or could be terminated (communication of 31 January 2013). Patent proprietor

T later withdrew its request for termination of the proceedings (letter of 26 September 2014).

Finally, the Enlarged Board summoned the parties to oral proceedings to be held on 27 October 2014 (order of 23 June 2014) and issued a communication pursuant to Articles 13 and 14(2) RPEBA (communication of 15 July 2014). In this communication, the Enlarged Board informed the parties of its preliminary views and the issues that were likely to be addressed in the oral Proceedings.

V. THE SUBMISSIONS OF THE PARTIES

Patent proprietors T and B and opponents B made comprehensive submissions both in the written proceedings and in the oral proceedings. Their written and oral submissions, insofar as relevant for deciding the two referrals, are summarised as follows:

1. Submissions of the patent proprietor in case T 1242/06

Patent proprietor T addressed in its written and oral submissions the admissibility of the proceedings before the Enlarged Board and the legal questions referred to the Enlarged Board. It filed fourteen documents (El to El4). (1) Patent proprietor T submitted that the referral should be rejected as inadmissible because the criteria of Article 112(1) (a) EPC were not fulfilled. It was already clear from G 1/98 (supra) that only product claims directed to individual plant varieties fell under the exclusion of Article 53(b) EPC. This result had been confirmed by the District Court of The Hague. In the reasoning of its decision of 8 May 2013 (Taste of Nature Holding B.V. v. Cresco Handels B.V.¹, see in this connection point VIII.4 below), the Dutch court had considered that the second group of exclusions pursuant to Article 53(b) EPC referred only to processes. Hence, the referral tomato II did not concern a point of law of fundamental importance. The referring Board could easily decide the appeal case itself by relying upon the interpretation of Article 53(b) EPC given by the Enlarged Board in G 1/98 and by the Dutch court.

(2) If the Enlarged Board took the view that the referral was admissible, <u>decisions G 2/07 and G 1/08</u> should be reviewed in order to rectify their negative effects as discussed by 0. Malek et al., Plant patents an endangered species? - surprising new developments in the tomato case, in epi information 1/2012, 16 (document Ell). Accordingly, the term "essentially biological processes for the production of plants" was to be interpreted as referring only to those essentially biological processes the direct product of which is a plant variety.

(3) Since the wording of the process exclusion in Article 53(b) EPC and its context within the Convention and with regard to the Biotech Directive did not leave any doubt in respect of its limited scope of application to process claims, the referred questions should then be answered in the following way: the first

¹ Editor IPPT: A Dutch language version of this decision can be found at <u>Boek9.nl</u> (subject to subscription).

and third questions were to be answered in the negative and the second in the affirmative.

(4) Since the category of product claims was already addressed in Article 53(b) EPC in respect of plant and animal varieties, a broad interpretation of the process exclusions, to the effect that it extended to product claims, was legally questionable.

(5) When interpreting Article 53(b) EPC, Article 32 Vienna Convention on the Law of Treaties of 23 May 1969 (hereinafter: Vienna Convention) could not be applied on the same level as Article 31 Vienna Convention. Once a clear and satisfactory result has been found by applying the rules of the latter provision there is no room for applying the former.

2. Submissions of the patent proprietor in case T 83/05

The written and oral submissions of patent proprietor B essentially concerned the following aspects.

(1) It requested that the first question be answered in the negative, in which event the subsequent questions did not require an answer or, alternatively, that these subsequent questions be answered in favour of the allowability of a product claim or product-by-process claim as defined in the referral (second and third questions) or in favour of the allowability of "disclaiming" the process steps in the product claim that infringed the process exclusion in Article 53(b) EPC (fourth question).

(2) The Enlarged Board should clarify its earlier **rulings in G 2/07 and G 1/08** because they had led the referring Board to make the second referral. In addition, it should be stressed that, as a general principle, any exclusion from patentability was to be interpreted narrowly and that the process exclusion could not extend to claims other than process claims.

(3) The assessment of patentability was to be based on the subject-matter of a claim. However, the subjectmatter of a claim should not be confused with its scope of protection.

(4) Article 53(b) EPC was to be interpreted in the light inter alia of Article 52(1) and Rule 27(b) EPC. Since Rule 27(b) EPC explicitly provided that patents should be granted for inventions concerning "plants 000 if the technical feasibility of the invention is not confined to a particular plant variety", the answer to the first question followed from the wording of the law itself. This conclusion held true also with a view to the legislative history of Article 53(b) and Rule 27(b) EPC as well as of Article 4 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter: Biotech Directive).

(5) Since, applying the means of interpretation pursuant to Article 31 Vienna Convention, the ordinary meaning of the wording of Articles 52(1), 53(b) and Rule 27(b) EPC was neither ambiguous nor led to a manifestly absurd or unreasonable result, there was room for applying Article 32 Vienna Convention and for supplementary means of interpretation.

(6) Articles 52, 53 and Rule 26(2) EPC clearly distinguished between product and process inventions

in the definition of patentable subject-matter. Consequently, a ruling by the Enlarged Board on process claims in G 2/07 (supra) and G 1/08 (supra) could not be extended to product claims. (7) In G 1/98 (supra, Order, point 2), the Enlarged Board had explicitly concluded that product claims directed to plants were excluded from patentability under Article 53(b) EPC only if they were directed to individual plant varieties. It could be concluded from this restrictive interpretation of the product exclusion (first group of exclusions in Article 53(b) EPC) that the process exclusion (second group of exceptions in Article 53(b) EPC) likewise required a narrow interpretation. As a consequence, the narrow scope of the product exclusion had an impact on the interpretation of process exclusion.

(8) If the first question were answered by the Enlarged Board in the affirmative, it should be possible to except from the subject-matter of the product claim or product-by-process claim the part that was considered to violate the process exclusion under Article 53(b) EPC by way of a disclaimer (see G 2/10, OJ EPO 2012, 376; G 1/07, OJ EPO 2011, 134; <u>G 1/03</u> and G 2/03, OJ EPO 2004, 413 and 448).

3. Submissions of the opponent in case T 1242/06

Apart from withdrawing its appeal by its letter dated 28 June 2012, the former opponent did not file any submissions during the present proceedings before the Enlarged Board. Nor did it attend the oral proceedings.

4. Submissions of the opponents in case T 83/05

(1) Opponent B1 submitted that the first, third and fourth questions were to be answered in the negative, while the second question was to be answered in principle in the affirmative.

(a) Article 31 Vienna Convention was the basis for interpreting Article 53(b) EPC in respect of the exception to patentability of essentially biological processes for the production of plants. Since the means of interpretation provided for in Article 31 Vienna Convention led to a clear, ambiguous and reasonable result, there was no need to apply Article 32 Vienna Convention. Besides, a dynamic interpretation of Article 53(b) EPC was only feasible for defining what is patentable. A dynamic interpretation excluding conventional processes from patentability was provided by the requirement of inventive step. To use a dynamic interpretation for broadening the scope of the process exclusion towards product claims would distort the legislator's intention.

(b) As to the result of interpreting Article 53(b) EPC in accordance with Article 31 Vienna Convention, opponent B1 argued that an extension of the exception to patentability of process claims according to Article 53(b) EPC to product claims lacked any legal basis. Its legislative intent was to be seen in exempting non-:-technical "essentially bio-logical processes", i.e. breeding processes, not in supporting a "freedom-to-operate" notion.

(c) Rule 26(5) EPC, which was to be interpreted in the light of the legislative history of the Biotech Directive,

pointed to interpreting the process exclusion in Article 53(b) EPC in a narrow manner.

(d) <u>Decisions G 2/07 and G 1/08</u> (supra) had already expanded the scope of the process exclusion to processes which as a whole have a technical character. This conclusion, however, was in conflict with Rule 27(b) EPC and the ordinary meaning of the term "essentially biological processes for the production of plants".

(e) Should this broad approach be further advanced by extending the process exclusion in Article 53(b) EPC to technical product inventions that resulted from such excluded processes, nothing would be patentable in the plant ar-ea. Such an outcome would be in stark contradiction to the EPC, its legislative history and the relevant established case law.

(f) Even a "limited" extension to products that could only be obtained by an "essentially biological process" under-mined legal certainty, because new technologies could prove the "only" wrong.

(g) Rather, it was necessary (and sufficient) to apply the general requirements for patenting strictly in relation to plant-related patent applications. This led to denying the patentability of the product-by-process claims sought by the patent proprietor, because patent proprietor B could de-scribe the alleged invention by structural features in order to avoid the use of productby-process type definitions in the claims.

(2) Opponent B2 requested that the first, third and fourth questions be answered in the negative, while the second question be answered in the affirmative.

(a) Opponent B2 submitted that the allowability of product claims directed to plants was essential in order to give the correct scope to the exclusion of "essentially biological processes for the production of plants" in Article 53(b) EPC and not to exceed what the legislator intended.

(b) The scope of the exception to patentability according to Article 53(b) EPC was to be defined by the nature of the products produced by an essentially biological process. If the plant product was itself within the scope of the patent, the essentially biological process for making it was within the scope of the product patent and was protected. Thus, the process exclusion was not a general ban on protection for all such processes, limited only by the exclusion from patentability of plant varieties.

(c) The allowability of general plant claims had the effect of attenuating the impact of the exclusion of essentially biological process claims so that only processes which did not give rise to the patented product were excluded. These processes were typical "improving" breeder's activities.

(d) Given this, opponent B2 argued in favour of the allowability of a plant product claim independent of the process implemented for making that product, even if the process was an essentially biological process. Consequently, there was no need to "waive" protection for this particular process by a "disclaimer".

(e) However, measures should be taken to ensure that the claim did not confer protection on the use of the patented product to generate new, different plants which were outside the scope of the patent. Such measures could take the form of a breeder's exemption in national law, or a waiver of pro-tection in the form of a statement in the patent specification.

VI. THE PRESIDENT'S SUBMISSIONS

The President of the EPO commented in writing and at the oral proceedings on both referrals. His written and oral comments, insofar as relevant for the present decision, are summarised as follows:

1. The President's comments in case G 2/12

The President concluded that Article 53(b) EPC did not have a negative effect on the allowability of product claims to plants. Any extension of an exclusion from patentability in this respect would be a matter for the legislator to decide. His conclusion is based on the following line of argument.

(1) The extent of protection was not to be taken into account in examining the patentability of a claim.

(2) Just as the patentability of a process claim was not affected by the lack of patentability of the direct product, a product-by-process claim was to be examined independently of the process by which the product is defined.

(3) Interpreting Article 53(b) EPC, unlike Article 53(a) EPC, did not include aspects of ordre public or morality. Rather, it was guided by Article 31(1) Vienna Convention alone. The International Convention for the Protection of New Varieties of Plants (UPOV Convention) and the Biotech Directive could be taken into account as supplementary means of interpretation.

(4) Neither the wording nor the travaux preparatoires supported the notion that the exclusion of "essentially biological processes for the production of plants" covered any product of such a process. Its focus lay rather on the exclusion of patent claims the subjectmatter of which was directed to such a process. The legislative intent to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties at that time suggested that Article 53(b) EPC was merely aimed at excluding essentially biological breeding processes sensu stricto.

(5) Applying the process exclusion to plant products generated by selection or plant breeding led to an undesirable inconsistency resulting from the patentability of plant products achieved by genetic modification.

(6) The process exclusion in Article 53(b) EPC was not rendered void by the availability of product claims for plants in general, because this process exclusion still had a significant effect. In cases where an applicant had made an invention whose essence lay in the (excluded breeding) method itself, but where the resulting product was not patentable, e.g. because it was not new, no patent could be granted.

(7) As far as the President, in his written comments, had raised the question of reformatio in peius in general terms with regard to the withdrawal of its appeal by opponent T, he did not pursue this issue in the written and oral proceedings once patent proprietor T withdrew its request to terminate the proceedings before the Enlarged Board.

2. The President's comments in case G 2/13

(1) The President came to essentially the same conclusion as in case G 2/12, namely that Article 53(b) EPC did not have a negative effect on the allowability of product claims to plants. Any extension of an exclusion from patentability in this respect was a matter for the legislator to decide.

(2) Concerning the first three questions, the President essentially reiterated his conclusions submitted in case G 2/12. In respect of the fourth question, the President concluded that there was no legal basis for a "disclaimer" or "waiver" as suggested by patent proprietor B.

VII. THE AMICI CURIAE

(1) Numerous amici curiae briefs were filed by professional representatives, patent attorneys' associations, interest groups, farmers' associations, plant breeders, plant breeders' associations, seed producing associations and firms, scientists, politicians, and private persons. Their submissions articulated divergent views, some of which were expressed by the parties to proceedings as well.

(2) Various submissions rejected the notion that the non-patentability of "essentially biological processes for the production of plants" had a negative impact on the patentability of plants, plant material such as fruits, or plant parts.

(3) Others voiced the view that, in applying the decisions of the <u>Enlarged Board in cases G 2/07</u> (supra) and G 1/08 (supra) as well as Article 4 Biotech Directive, claims directed at products derived from essentially biological processes were excluded from patenting under Article 53(b) EPC.

(4) These views were based on arguments similar to those submitted by the parties to the proceedings and the President and summarised above, as well as on scientific and economic aspects.

(5) A third group of amici curiae briefs expressed general objections against patenting the kind of technologies at issue in the present proceedings. These objections were essentially based upon ethical, economic and social concerns about the patenting of plants (and animals) in general and of those plants produced by conventional plant breeding methods in particular.

REASONS

I. ADMISSIBILITY

(1) According to Article 112(1) (a) EPC, a board of appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal, if it considers that a decision is required in order to ensure uniform application of the law, or if a point of law of fundamental importance arises.

(2) Regarding patent proprietor T's request that the referral tomato II be rejected as inadmissible because the referred questions had already been answered by decision G 1/98 (supra), to the effect that only product claims directed to individual plant varieties fell under the exclusion of Article 53(b) EPC, the Enlarged Board

notes that this request is based up-on how patent proprietor T understood that decision. Patent proprietor T inferred from $G_{1/98}$ that all other product claims directed to individual plant parts that were not plant varieties were in principle patentable.

(3) In the case underlying <u>decision G 1/98 (supra)</u>, the Enlarged Board was concerned with questions of law in respect of the meaning and scope of application of the so-called plant variety exclusion in Article 53(b) EPC (i.e. the first exception to patentability). As a consequence, its ratio decidendi has no direct effect on the meaning and scope of application of the process exclusion (i.e. the second exception to patentability).

(4) The subject-matter of the relevant claims in the present referrals is neither limited nor even directed to a plant variety or plant varieties. Rather, all the claims explicitly concern the legal range of the exclusion from patentability of "*essentially biological processes for the production of plants*" other than plant varieties (see referral tomato II, Reasons, point 39; referral broccoli II, Reasons, point 16). Hence, since the meaning of "plant varieties" and the extent of their exclusion in Article 53(b) EPC are not covered by the scope of the referred questions, the <u>decision G 1/98</u> (supra) does not apply directly to the questions now referred to the Enlarged Board.

(5) Both referring decisions set out in detail why an answer to the referred questions was necessary for deciding the appeals which, from the referring Boards' point of view, could not be decided on the basis of the answers given by the Enlarged Board to the first set of referred questions in cases G 2/07 (supra) and G 1/08 (supra) (referral tomato II, Reasons, points 67 to. 74; (referral broccoli II, Reasons, points 21 to 2 9). The Enlarged Board is satisfied that in both cases an answer to at least some of the referred questions is necessary for the referring Board to dispose of the appeals before it on the correct legal basis. The referred questions are also not only relevant for the appeal cases at hand. Answering the questions will be relevant for similar cases as well and will there-fore serve the uniform application of the law.

(6) Consequently, the referrals fulfill the requirements of Article 112 (1) (a) EPC. (7) In respect of the withdrawal of the appeal by opponent T in case T 1242/06, which originally had led patent proprietor T to request that the proceedings before the Enlarged Board be terminated due to the prohibition of reformatio in peius (see <u>G 9/92</u> and <u>G 4/93</u>, OJ EPO 1994, 875, Order, point 1; G 1/99, OJ EPO 2001, 381, 388, Reasons, point 4.1), the Enlarged Board notes that the withdrawal has no immediate impact on the referral tomato II proceedings before the Enlarged Board. As set out in the communication dated 31 January 2013, patent proprietor T remains the sole appellant. It seeks to set aside the decision under appeal of the opposition division maintaining its patent in amended form on the basis of the then auxiliary request IIIb. With its appeal, as far as its main request and its auxiliary request I are concerned, patent proprietor T requests that that decision be set aside and that the patent be maintained in an amended, i.e. different and broader, version.

Thus, the doctrine of prohibition of reformatio in peius does not stand in the way of the current proceeding \sim .

(8) Consequently, both referrals are admissible.

II. APPLICABLE LAW

As stated in the decisions G 2/07 and G 1/08 (supra, Reasons, points 2 et seq.), in accordance with Article 1(1) of the decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 (OJ EPO 2001, Special Edition No 4, 139) and with Article 2 of the Decision of the Administrative Council of 7 December 2006 amending the Implementing Regulations to the European Patent Convention 2000 (OJ EPO 2007, Special Edition No 1, 89), Article 53 EPC in its revised version applies to European patents granted at the time of entry into force of the EPC 2000. The patents underlying both referrals having been granted before that date, the answer to both referrals are to be given applying Article 53 and the Rules pertaining thereto, in the revised version of the EPC 2000.

III. SCOPE OF THE REFERRED QUESTIONS

The questions of law referred to the Enlarged Board in both cases turn on the correct interpretation of Article 53(b) EPC, which provides as follows:

"European patents shall not be granted in respect of: (a)

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

(c) ... '

Underlying all the referred questions is the issue of the legal scope of the process exclusion in Article 53(b) EPC and its impact on the patentability of product claims and product-by-process claims. Thus, the questions referred to the Enlarged Board do not relate to the interpretation of Article 53(b) EPC in respect of the exclusion from patentability of plant or animal varieties. It is this aspect that distinguishes the present referrals from the referrals underlying the Enlarged Board's <u>decision G 1/98</u> (supra) and its decisions in the two preceding referrals <u>G 2/07 and G 1/08 (supra)</u>. Hence, the present proceedings are neither aimed at, nor allow a "rectification" or even review of either of the earlier <u>decisions G 2/07 and G 1/08</u> as requested by patent proprietors T and B.

IV. LEGAL NATURE OF THE CLAIMED INVENTION

(1) The claim versions of all pending requests of the patent proprietors in connection with both the tomato patent and the broccoli patent are directed to a product, i.e. a tomato fruit (dehydrated I raisin-type I harvested) or broccoli (edible Brassica plant I edible portion of a broccoli plant I seed of a broccoli plant I broccoli plant I broccoli inflorescence). Concerning the method for generating such products, the specification of the tomato patent discloses only a biological process and the broccoli patent defines a specific method of such kind in the respective claim itself. The claims of the tomato patent according to the patent proprietor T's main and first to fourth auxiliary requests can be categorised as product claims. The subject-matter of the broccoli patent according to all requests as well as according to the fifth and sixth auxiliary requests of the tomato patent belongs to the product-by-process claim category.

(2) A product-by-process claim - like a product claim - gives protection for the product as such, not for the process for producing it. In contrast, the scope of protection of a process claim covers the process defined in the patent claim and the product directly obtained by such process (Article 64(2) EPC).

(3) A product claim is directed to a physical entity described as a concrete physical technological embodiment of an inventive idea.

(4) A product-by-process claim defines a product in terms of the method (manipulative steps) used to manufacture that product.

(5) For a product-by-process claim to be allowable it needs to be established that (a) it is impossible to define the claimed product other than in terms of a process of manufacture and (b) the claimed product itself meets the patentability requirements of Article 52(1) EPC. Thus, the specific process needed to obtain the claimed product should make it possible to distinguish the inevitable product of the product-by-process claim over the prior-art. The use of the method parameter by which to define a particular product cannot in itself give the product novelty, nor can it constitute an inventive step over the prior-art (see T 150/82, OJ EPO 1984, 309; T 219/83, OJ EPO 1986, 211; T 248/85, OJ EPO 1986, 261, T 148/87 of 24.11.1989; T 320/87, OJ EPO 1990, 71; T 129/88, OJ EPO 1993, 598; Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, Chapter II.A.7 et seq. with further references).

(6) Thus, the subject-matter of both a product claim and a product-by-process claim is the product as such, in respect of which the legal (formal and substantive) requirements for its patentability need to be fulfilled, independently of the patentability of the process by which the product can be generated or is defined. If the product in the product-by-process claim is the same as or obvious from a prior-art product, the claimed product is unpatentable even though the prior-art product was made by a different process. Conversely, if the product in the product-by-process claim is neither the same as nor obvious from a prior-art product, it is patentable even though the process applied is the same as or obvious from a prior-art process.

V. PRINCIPLES OF INTERPRETATION

(1) For the interpretation of provisions of the EPC, the EPC itself provides relatively little guidance. There is the Protocol on the Interpretation of Article 69 EPC of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000. This deals with the extent of protection under Article 69 EPC. Otherwise, the EPC contains only regulations like the hierarchy of legal provisions (Articles 150(2) and 164(2) EPC) and the

equal authenticity of the EPC in its three official language versions (Article 177 EPC). Article 125 EPC is not concerned with the interpretation of the EPC but serves merely as a "fill-in" in case of missing procedural provisions. The EPC itself thus contains no general rules for its interpretation, and one must look outside the terms of the Convention itself for such rules.

(2) The Enlarged Board ruled in its first decisions (G 1/83, OJ EPO 1985, 60, and G 5/83, OJ EPO 1985, 64, Reasons, points 1, 3, 4 and 6) that:

"As an international treaty, the European Patent Convention has to be interpreted in accordance with the rules of interpretation developed in the so-called "law of nations" or public international law. To the traditional kind of international treaty which regulates legal relations between States must today be added the treaty which directly creates and defines rights and duties for individuals and corporate bodies. According to the generally accepted opinion, the principles of interpretation to be applied to both kinds of treaty are identical ...

3. The provisions of the Vienna Convention do not apply to the European Patent Convention ex lege, since the former Convention applies only to treaties which are concluded by States after the entry into force of the Vienna Convention with regard to such States (Article 4, Vienna Convention). At the time of conclusion of the European Patent Convention, the Vienna Convention was not in force at all.

4. Nevertheless, there are convincing precedents for applying the rules for interpretation of treaties incorporated in the Vienna Convention to a treaty to which in terms they do not apply. .. After a careful study of the whole subject, the Enlarged Board of Appeal concludes that the European Patent Office should do the same ...

6. In the interpretation of international treaties which provide the legal basis for the rights and duties of individuals and corporate bodies it is, of course, necessary to pay attention to questions of harmonisation of national and international rules of law. This aspect of interpretation, not dealt with by the provisions of the Vienna Convention, is particularly important where, as is the case with European patent law, provisions of an international treaty have been taken over into national legislation. The establishment of harmonised patent legislation in the Contracting States must necessarily be accompa-nied by harmonised interpretation. For this reason, it is incumbent upon the European Patent Office, and particularly its Boards of Appeal, to take into consideration the decisions and expressions of opinion of courts and industrial property offices in the Contracting States."

(3) Thus, it is established in the jurisprudence that the principles of interpretation provided for in Articles 31 and 32 Vienna Convention are to be applied when interpreting the EPC. Decisions and opinions given by national courts in interpreting the law may also be taken into consideration.

(4) Pursuant to Article 31(1) Vienna Convention "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." In summary, this objective method of interpretation is directed to establishing the "authentic" meaning of the relevant provision and its legal terms.

The starting point of interpretation is thus the wording, i.e. the "objective" meaning, regardless of the original "subjective" intention of the contracting parties. To this end, the provisions are to be read in their context so that they comply with the object and purpose of the European Patent Convention. The preparatory work ("travaux preparatoires") and the circumstances of the conclusion of the EPC serve only as supplementary sources of evidence to confirm the result of the interpretation or if no reasonable meaning can be determined by applying the general rule of interpretation (Article 32 Vienna Convention).

(5) These principles have been acknowledged and applied by the Enlarged Board and the boards of appeal alike (G 1/83, supra; G 5/83, supra; G 2/02 and G 3/02, OJ 2004, 483; G 2/08, OJ EPO 2010, 456; J 10/98, OJ EPO 2003, 184; T 128/82, OJ EPO 1984, 164; T 1173/97, OJ EPO 1999, 609; Case Law of the Boards of Appeal, supra, Chapter III.H.1 et seq.).

VI. INTERPRETATION OF EXCLUSIONS FROM PATENTABILITY IN GENERAL

(1) The Enlarged Board has dealt several times with the issue of whether provisions for the exclusion from patentability are to be interpreted in a restrictive manner:

(a) In <u>G 1/04 (OJ EPO 2006, 334, 349</u> et seq., Reasons, point 6) it stated, with reference to decisions of the boards of appeal that had acknowledged the existence of such an a priori principle, "*that the 'frequently cited principle', according to which exclusion clauses from patentability laid down in the EPC are to be construed in a restrictive manner, does not apply without exception.*" However, the Enlarged Board, after a thorough analysis of the provision's wording and the purpose of the exclusion clause in Article 52(4) EPC 1973 (now Article 53(c) EPC), considered that the principle of a narrow interpretation of such exclusion clauses was to apply in respect of the scope of the exclusion of diagnostic methods from patentability.

(b) The same approach was taken by the Enlarged Board in case G 2/06 (OJ EPO 2009, 306, 323 et seq., Reasons, point 16 et seq.) in respect of the interpretation of the exclusion from patentability of biotechnological inventions relating to uses of human embryos for industrial or commercial purposes under Rule 28(c) EPC (and the corresponding Article 6(2) Biotech Directive).

(c) In <u>case G 1/07 (supra</u>, 168, Reasons, point 3.1) the Enlarged Board explicitly held that:

"no general principle of narrow interpretation of exclusions from patentability which would be applicable a priori to the interpretation of any such exclusions can be derived from the Vienna Convention. Rather, the general rule in Article 31(1) of the Vienna Convention that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose must apply to the exclusion clauses.contained in the EPC in the same manner as to any other provision. If the interpretation of the provision concerned according to the principles of interpretation leads to the result that a narrow interpretation is the right approach then and only then is such restrictive meaning to be given to it."

However, it continued by saying that:

"when it comes to considering the impact of the context of a provision, the fact that a provision is an exclusion to a general rule is not without any bearing on its interpretation but this aspect is only one of the factors determining what the right interpretation of the provision concerned is. At least equally, if not more important, is, besides the ordinary meaning to be given to the wording of the provision, that the provision is interpreted in such a manner that it takes its effect fully and achieves the purpose for which it was designed. As has been said before, this must apply to an exclusion clause in the same manner as to any other requirement for patentability."

(2) Hence, whilst there is no general notion of an obligatorily restrictive construction of exceptions to patentability, for example, such as that adopted by the Court of Justice of the European Union (CJEU) when insisting on a narrow interpretation of exceptions to or derogations from fundamental EC Treaty principles embodied in the four freedoms (Judgment of 21 June 1974, C 2-74, Jean Reyners v. Belgian State, ECJ 1974, 631), such a narrow interpretation might well result from applying the general principles of interpretation to a specific provision with regard to specific legal and factual circumstances.

VII. APPLICATION OF THE RULES OF INTER-PRETATION

Thus, the term "essentially biological processes for the production of plants" in Article 53(b) EPC needs to be construed pursuant to the general rules of interpretation. The meaning of "essentially biological processes for the production" has already been defined by the Enlarged Board in <u>G 2/07 and G 1/08</u>. The present case does not involve any new issue in this respect. However, what remains to be determined is whether this conclusion is limited to method or process claims or whether it also encompasses a patent claim for a product that is directly obtained and/or defined by an "essentially biological process".

This question is to be analysed by means of a methodical interpretation of Article 53(b) EPC in respect of, primarily, its wording and, secondarily, considering also the legislator's intention and the aspects of systematic and historical interpretation.

1. Grammatical interpretation

(1) When interpreting provisions of the EPC, the Enlarged Board usually starts from the wording of the relevant provision and even if the wording of a provision reveals its meaning clearly, it is then to be examined whether the result of the literal interpretation is confirmed by the meaning of the words in their context. It could well be that the wording only superficially has a clear meaning. At any rate, a literal interpretation must not contradict the purpose of the provision (see G 1/90, OJ EPO 1991, 275, 278, Reasons, point 4; G 6/91, OJ EPO 1992, 491, 499, Reasons, point 15; G 3/98, supra, 71 et seq., Reasons, point 2.2).

(2) In various amici curiae briefs, it has been argued that the wording "essentially biological processes for the production of plants" does not in itself immediately rule out a broad reading of the exception to patentability according to Article 53(b) EPC to the effect that it extends to product claims in which the claimed product is either directly obtained or otherwise defined by an essentially biological processes.

(3) Following this understanding for the sake of the argument, more than one meaning could in principle be attributed to the wording (cf. G 1/88, OJ EPO 1989, 189, 193, Reasons, point 2.2). Therefore, the true and intended meaning of the term "essentially biological processes for the production of plants" needs to be analysed further.

2. Systematic interpretation

(1) The systematic interpretation forms a second pillar when construing a legal provision and its terms (see G 1/88, supra, 194, Reasons, point 3; G 9/92, supra, 880, Reasons, point 1; G 4/95, OJ EPO 1996, 412, 421 et seq., Reasons, points 4 and 5; G 3/98, supra, 71 et seq., Reasons, point 2.2; G 4/98, OJ EPO 2001, 131, 143, Reasons, point 4). In applying this second method of interpretation the meaning of the wording in question is to be established in the context of the relevant provision itself. In addition, the provision as such must be interpreted taking into account its position and function within a coherent group of related legal norms. (2) What is to be examined first is the context of the "essentially biological processes for term the

production of plants" within Article 53(b) EPC. (a) Article 53(b) EPC contains two exclusions from patentability, of which the first is very specifically addressed to plant varieties and animal varieties. The term "plant variety" is defined in Rule 26(4) EPC in the same way as in the Biotech Directive, namely as "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 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."

In view of the decision in <u>case G 1/98 (supra</u>, Order, point 2, and Reasons, point 3.10) and of the case law of the technical boards of appeal (see T 320/87, OJ EPO 1990, 71; T 19/90, OJ EPO 1990, 476; T 356/93, OJ EPO 1995, 545; T 315/03, OJ EPO 2006, 15; T 788/07 of 7 January 2008, not published; T 2239/08 of 10

January 2013, not published; T 1854/07 of 12 May 2010, not published), the first exclusion is restricted to very specific requirements and conditions that need to be fulfilled to justify the verdict "unpatentable". Even the scope of the exclusion is limited. In case G 1/98 (supra), the Enlarged Board concluded that where specific plant varieties are not claimed individually, the claimed subject-matter was not excluded from patentability under Article 53(b) EPC, even if it might potentially embrace plant varieties. In case T 19/90 (OJ EPO 1990, 476, Reasons, point 4.8), the board of appeal held that patents on animals as such can be granted. See also T 315/03, supra, 60, Reasons, point 11.8: "a patent should not be granted for a single animal variety (or species or race, depending on which language text of the EPC is used) but can be granted even if varieties may fall within the scope of its claims". Hence, it is rather difficult to derive from this very specific and narrow exclusion a systematic approach leading to a broad understanding of the second exclusion, extending its scope from process claims to product claims.

(b) In this context, it needs to be borne in mind that, if it were not for the process exclusion in Article 53(b) EPC, patenting of an essentially biological process for the production of plants or animals would mean that the protection conferred by a process claim extended to the product directly obtained by such process (Article 64(2) EPC), which could well encompass a plant or animal variety. In consequence, irrespective of the distinction between the subject-matter of a patent claim and the protection conferred by it, the process exclusion is inevitable to avoid a contraction. From this it further could be deduced as part of a systematic approach to Article 53(b) EPC that the second exclusion is aimed at averting an inconsistency with regard to the first group of exclusions.

(3) When examining the position and function of Article 53(b) EPC in its context, both within the scope of the application of Article 53 EPC and within Chapter I of Part II of the EPC, the following is to be considered:

(a) Article 53 EPC stipulates five main groups of inventions for which no European patent may be granted: inventions the commercial exploitation of which would be contrary to "ordre public" or morality (Article 53(a) EPC), plant or animal varieties (Article 53(b), 1st alternative, EPC), essentially biological processes for the production of plants or animals (Article 53(b), 2nd alternative, EPC), methods for treatment of the human or animal body by surgery or therapy (Article 53(c), 1st alternative, EPC), and diagnostic methods practised on the human or animal body (Article 53(c), 2nd alternative, EPC). The "system" of exclusions from patentability according to Article 53 EPC is characterised by a listing of specific inventions for which a European patent is not to be granted. Article 53 EPC is not designed as a general exclusion of inventions in the sphere of animate nature and has been interpreted by the boards of appeal rather restrictively (in respect of Article 53(a) EPC: see T

356/93, OJ EPO 1995, 545, 557, Reasons, points 5 et seq., in particular point 8; T 19/90, OJ EPO 1990, 476, 490, Reasons, point 5; T 866/01 of 11 May 2005, not published, Reasons, point 5 et seq., in particular point 5.2; concerning Article 53(b) EPC: see T 320/87, OJ EPO 1990, 71; T 19/90, OJ EPO 1990, 476; T 315/03, OJ EPO 2006, 15; regarding Article 53(c) EPC (Art. 52(4) EPC 1973): see <u>G 1/04</u>, supra; T 144/83, OJ EPO 1986, 301; T 385/86, OJ EPO 1988, 308). Thus, Article 53 EPC does not envisage a system of general exceptions to patentability that per se would allow or even necessitate a broad interpretation of any of the exclusions.

(b) Part II of the EPC lays down substantive patent law, and its Chapter I encompasses the provisions on patentability (Articles 52 to 57 EPC). In this "system", Article 52(1) EPC lays down the general principle that European patents are granted for any inventions, in all fields of technology, provided that they are new (Articles 54 and 55 EPC), involve an inventive step (Article 56 EPC) and are susceptible of industrial application (Article 57 EPC). Only Article 52(2) EPC (so-called "non-inventions"), subject to paragraph (3), and Article 53 EPC (exceptions to patentability) define exclusions from this general principle. Article 52(1)EPC expresses the fundamental principle of a general entitlement to patent protection for any invention in all technical fields (see G 5/83, supra, 66, Reasons, point 21 et seq.; G 1/98, supra, 135, Reasons, point 3.9; G 1/03, supra, 435, Reasons, point 2.2.2; G 1/04, supra, 350, Reasons, point 6; T 154/04 (OJ EPO 2008, 46, 62, Reasons, point 6). Any limitation to the general entitlement to patent protection is thus not a matter of administrative or judicial discretion, but must have a clear legal basis in the European Patent Convention. Article 52(2) EPC contains a non-exhaustive list of what should not be regarded as an invention within the meaning of Article 52(1) EPC. The enumeration of typical non-inventions in Article 52(2) EPC covers subject-matters whose common feature is a substantial lack of technical character. However, the case law clearly shows that this list of "excluded" subject-matter should not be given too broad a scope of application; the subsequent paragraph 3 is a bar to a broad interpretation of Article 52(2) EPC (T 154/04, supra, Reasons, point 6).

Therefore, considering the exception to patentability of inventions according to Article 53(b) EPC in its context within Chapter I of Part II of the EPC, one could deduce two things: first, there is no clear basis for broadly interpreting Article 53(b) EPC; second, one could rather infer from the systematic position and function of Article 53(b) EPC that exceptions to patentability are to be narrowly construed.

(4) Furthermore, Rule 27 EPC (formerly: Rule 23c EPC 1973 in the version of 1 September 1999) is to be considered in the wider context of Article 53(b) EPC.

(a) As held in G 2/07 and G 1/08 (supra, Reasons, point 2.2), the Administrative Council of the European Patent Organisation as legislator may amend the Implementing Rules in respect of matters of both

procedure and substance. In doing so, the legislator is limited only by the hierarchy of laws laid down in Article 164(2) EPC.

(b) Rule 27(b) EPC stipulates that biotechnological inventions relating to plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety. In addition, Rule 27(c) EPC allows patenting of a product other than a plant variety obtained by means of a microbiological or other technical process.

(c) Hence, Rules 27(b) and (c) EPC appear to be guided by a rather wide notion of the patentability of biotechnological inventions concerning plant-related processes and products other than plant varieties. (5) As a result, the systematic interpretation of Article 53(b) EPC does not support giving the process exclusion a broad meaning to the effect that product claims or product-by-process claims are thereby excluded from being patentable.

3. Teleological interpretation

(1) Like national and international courts, the Enlarged Board applies the method of teleological interpretation in the construction of legislative provisions in the light of their purpose, values, and the legal, social and economic goals they aim to achieve. In this, the Enlarged Board examines their objective sense and purpose (e.g. G 1/88, supra, 195, Reasons, point 5; <u>G</u> 1/03, supra, 428 et seq., Reasons, point 2.1.1). The starting point is marked by determining the general object of the relevant provision (ratio legis) because the interpretation must not contradict the provision's spirit (G 6/91, supra, 497, Reasons, point 8).

(2) In respect of the ratio legis of Article 53(b) EPC, the Enlarged Board in the two previous referrals concluded (G 2/07 and G 1/08, supra, Reasons, point 6.4.2.1): "However, since the respective legislative purposes behind the sub-items in Article 53 EPC and even those behind the alternatives of Article 53(b) EPC are quite different, the systematic context of the exclusion of essentially biological processes fro0 patentability, namely its place in Article 53(b) EPC, does not as such indicate what the purpose of the provision is." This conclusion is still valid.

(3) Thus, the object and purpose of the exclusion under Article 53(b) EPC is not sufficiently obvious to answer the question whether or not the clause is to be construed in a narrow or broad way.

4. Subsequent agreement or practice

(1) Under Article 31(3) Vienna Convention any subsequent agreement between the parties regarding the interpretation of the treaty or its application, and any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation is to be taken into account. Rule 26(5) EPC (formerly Rule 23b(5) EPC 1973) could be regarded as such subsequent agreement and practice. Rule 26(1) EPC explicitly calls for due consideration of the Biotech Directive (see G 2/06, supra, Reasons, point 16) . (2) Rule 26(5) EPC and Article 2(2) Biotech Directive both define a process for the production of plants as essentially biological if it

consists entirely of natural phenomena such as crossing or selection. As held in <u>G 2/07 and G 1/08 (supra</u>, Reasons, points 2.3 et seq. and 4 to 5), neither provision offers clear guidance with regard to the definition of "*essentially biological processes for the production of plants*" according to Article 53(b) EPC.

(3) The exception to patentability according to Article 53(b) EPC is worded identically to Article 4 (1) (b) Biotech Directive. Article 3 Biotech Directive allows patenting of "inventions which are new, which involve an inventive step and which are susceptible of industrial application ... even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used". That does not support a broad reading of the exclusion under Article 53(b) **EPC.** Notwithstanding the differences in the legal sources of the Biotech Directive and of the EPC it might even be inferred from the similarities in the wording of both Article 4 (1) (b) Biotech Directive and Article 53(b) EPC that the exclusion from patenting is to be understood restrictively, to the effect that claims directed to a product (be it a product claim or a product-by-process claim) involving a process by means of biological material are not automatically excluded from patenting in the same way that "essentially biological processes for the production of plants" are.

Article 4(2) Biotech Directive appears to confirm this idea. In the same way as Rule 27(b) EPC, it stipulates that: "inventions which concerns plants ... shall be patentable if the technical feasibility of the invention is not confined to a particular plant ... variety."

Thus the Biotech Directive, to which Rule 26(1) EPC refers as a supplementary means for interpreting the EPC in relation to biotechnological inventions, does not provide a basis for extending the process exclusion under Article 4(1) Bio-tech Directive and Article 53(b) EPC to products of such processes.

5. Historical interpretation

(1) It is a generally recognised principle in international law that when interpreting international treaties ancillary use may be made of material relating to their genesis. Under Article 32 Vienna Convention, recourse may be had to supplementary means of interpretation, particularly the preparatory work for a treaty and the circumstances in which it was concluded, in order to confirm the meaning arrived at by application of Article 31 or to determine the meaning when application of Article 31 either (a) leaves the meaning ambiguous or obscure, or (b) produces a meaning which is obviously nonsensical or unreasonable (J 8/82, OJ EPO 1984, 155, 163, Reasons, point 13; J 4/91, OJ EPO 1992, 402, 406 et seq., Reasons, point 2.4.2; T 128/82, OJ EPO 1984, 164, 169 et seq., Reasons, point 9; G 1/98, supra, 129 et seq., Rea-sons, points 3.4 et seq.; G 2/07 and G 1/08, supra, Reasons, point 4.3). (2) The Enlarged Board has dealt with the legislative history of Article 53(b) EPC on previous occasions. (a) In case G 1/98 (supra, 129 et seq., Reasons, points 3.4 et seq., in particular points 3.6), the Enlarged

Board, in referring to Article 2(b) and (c) Strasbourg Convention and Article 2(1) UPOV Convention 1961, held that the purpose of Article 53(b) EPC corresponds to the purpose of Article 2(1) UPOV Convention 1961 and Article 2(b) Strasbourg Convention, i.e. that European patents should not be granted for subject matter for which the grant of patents was excluded under the ban on dual protection in the UPOV Convention 1961. In addition, the Enlarged Board pointed to a brief remark in the travaux preparatoires to the effect that the provision in the EPC simply follows Article 2 Strasbourg Convention (Reports on the Preliminary Draft Convention, supra, Report by the British Delegation on Articles 1 to 30, page 12, point 25). Accordingly, the Enlarged Board concluded that inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the EPC provided they fulfilled the other requirements of patentability and that the travaux preparatoires contained no suggestion that Article 53(b) EPC could or even should exclude subject-matter for which no protection under a plant breeders' rights

system was available (see G 1/98, supra, Reasons, point 3.7).
(b) The Enlarged Board confirmed these findings in the two previous referrals (<u>G 2/07 and G 1/08</u>, supra, Reasons, point 6.4.2.2) and, finally, concluded that the

legislator's intention had been to exclude from patentability those plant breeding processes which were the conventional methods of plant-variety breeding at the time (Reasons, point 6.4.2.3)

(c) Due to the fact that these conclusions concern the aspects of plant varieties (<u>G 1/98</u>) and essentially biological processes (<u>G 2/07 and G 1/08</u>), they are silent on the relevant question in the present case.

(3) Early drafts show a broad concept of exclusions.

One version was directed to the exclusion of: "inventions the subject-matter of which is the breeding of a new plant variety" (travaux preparatoires, Bemerkungen zu dem ersten Arbeitsentwurf eines Abkommens uber ein europai-sches Patentrecht vom 3. J11arz 1961, Artikel 12: "Aus-genC?mmen von der Erteilung europaischer Patente sind: 1; 2. Erfindungen, deren Gegenstand die Zuchtung einer neuen Pflanzensorte oder einer neuen Tierart ist; 3").

Another version of the exclusion reads:

"European patents shall not be granted in respect of: 1; 2. Inventions relating to the production of or a process for producing a new plant variety or animal species. This provision shall not apply to processes of a technical nature. 3 " (travaux preparatoires, First Preliminary Draft Convention relating to a European Patent Law, 14 March 1961, Article 12).

The UK delegation even requested that the term "essentially biological processes" be deleted because it was not clear and there was no reason why: "any biological processes other than for the treatment of the human body should be specifically excluded by the Convention n (travaux preparatoires, minutes of the 9th meeting of Working Party I, 12-22 October 1971).'

However, the drafting committee of the Patents Working Party subsequently rephrased the wording in the form of what later became Article 53(b) EPC (see Preliminary Draft Convention relating to a European Patent Law, May 1962; travaux preparatoires, Amendments to the Preliminary Draft Convention relating to a European Patent Law, 22 January 1965). The discussion was predominantly focused on the issue of "microbiological processes or the products thereof", the intention being to bring the exclusion clause into line with Article 2 Strasbourg Convention (travaux preparatoires, minutes of the meeting of Working Party I, 8 to 11 July 1969, Article 2(b) Strasbourg Convention).

(4) The legislative history of Article 53(b) EPC in respect of the legal term in question is rather vague. The discussion in the Working Party never concerned the question of whether or not the wording "essentially bio-logical process for the production of plants" included a product that is defined or obtained by such a method for its production.

(5) Thus, in the context of the historic discussion about what kind of inventive processes, if any, should be excluded from patentability, there is no reason in the travaux preparatoires to assume that a product that is characterised by the method of its manufacture but claims protection regardless of that (or any other) method was meant to be excluded.

6. First intermediate conclusions

(1) Applying the various methodical lines of interpretation provided for in Article 31 Vienna Convention does not lead to the conclusion that the term "essentially biological processes for the production of plants" extends beyond processes to products defined or obtained by such processes. This result is confirmed when the preparatory work on the EPC is taken into account as a supplementary means of interpretation (Article 32 Vienna Convention).

(2) Thus, in view of the absence of any solid basis for a broad reading of "essentially biological processes for the production of plants" in respect of the separate claim categories of product and product-by-process claims, a first intermediate conclusion from the above elements points towards not extending the scope of application and legal effect of the exception to patentability according to Article 53(b) EPC in respect of "essentially biological processes for the production of plants".

(3) As is apparent from the above, considering its wording, context, original legislative purpose and legislative his-tory, the process exclusion of Article 53(b) EPC does not extend directly to a product claim or a product-by-process claim directed to plants or plant material such as a fruit, or to plant parts other than a plant variety.

VIII. NEED FOR SECONDARY CONSIDERATIONS

(1) Although not mentioned by the parties to the proceedings, the Enlarged Board wishes to take up an issue raised in various amici curiae briefs. That is whether the legal impact of the above understanding of

Article 53(b) EPC necessitates broadening the scope of application of the process exclusion having regard to the following questions:

(a) Is there a need for a dynamic interpretation of Article 53(b) EPC due to factors that have arisen since the Convention was signed and which give grounds for assuming that a restrictive reading of the wording of Article 53(b) EPC when applying the general principles of interpretation conflicts with the legislator's intention?

(b) Does allowing the patentability of a product claim directed to a fruit and of a product-by-process claim directed to a plant or plant material render the exception to patentability of "essentially biological processes for the production of plants" meaningless or without any sub-stance in its scope of application?

(2) Before dealing with these questions, the Enlarged Board wishes to emphasise that the issues referred to it relate to questions of law rather than to economic, social and ethical aspects mentioned in some of the amici curiae letters. Therefore, the following considerations serve the purpose of testing the legal soundness of the conclusions reached in interpreting the scope of application of the process exclusion under Article 53(b) EPC.

1. Dynamic interpretation

(1) In case G 3/98 (supra, 76 et seq., Reasons, point 2.5 et seq.), the Enlarged Board referred to a further approach when construing a legal term or provision. Such a "dynamic interpretation" might come into play where considerations have arisen since the Convention was signed which might give reason to believe that a literal interpretation of the wording of the relevant provision would conflict with the legislator's aims. It might thus lead to a result which diverges from the wording of the law.

(2) Article 53(b) EPC 1973 has remained unamended since the drafting of the EPC, although the EPC underwent a significant revision in the context of the EPC 2000 reform. Its legislative purpose is still applicable (see in this regard <u>G 2/07 and G 1/08</u>, supra, Reasons, point 6.4.2.2).

(3) However, since the drafting of Article 53(b) EPC 1973 the technical means available to support crossing and selection procedures have increased enormously and have become much more sophisticated. Whereas the breeding techniques known at the time of the conclusion of the UPOV Convention 1961 were such that they commonly resulted in new plant varieties for which protection under the UPOV Convention 1961 - but not under the EPC due to Article 53(b) EPC (exclusion from patentability of plant varieties) - could be sought, new breeding techniques nowadays may also result in new plants or plant materials other than a plant variety, for which no plant variety rights could be granted.

(4) Whereas Article 53(b) shows the legislator's clear intention to exclude from patenting essentially biological processes of the kind known at the time of the signing of the EPC, the Enlarged Board notes that the subsequent developments in the field of plant

breeding techniques did not prompt the legislator to revise the process exclusion such that it was extended to plant products obtained by essentially bio-logical processes. This decision of the legislator not to amend Article 53(b) EPC can neither be ignored when interpreting Article 53(b) EPC, nor be reversed by means of a dynamic interpretation. The Enlarged Board cannot see why the legislator's original intention to direct the exclusion from patentability in respect of plants to only two groups, i.e. "plant varieties" and "essentially biological processes for the production of plants", would no longer be justified, just because today there are new techniques available in this sector.

(5) Thus, the concept of a dynamic interpretation does not require revising the result of the interpretation established by applying traditional rules of construction.

2. Legal erosion of the exception to patentability

(1) The referring Boards (referral tomato II, Reasons, point of the reasons 47; referral broccoli II, Reasons point 19) raised the question whether allowing patenting of a product claim or a product-by-process claim for a plant or plant material other than a plant variety that is obtained by means of an essentially biological process could be qualified as circumvention of the process exclusion. Thus, it was said, the legislator's intentions could be frustrated by the choice of the claim category and by "skillful" claim drafting.

(2) It is to be noted that Article 53(b) EPC clearly applies to process claims directed to essentially biological processes for the production of plants. This scope of application remains unaffected by allowing the patenting of claims of a distinct category (i.e. product claims or product-by-process claims) even if the claimed product is a result of such a biological process.

(3) On the other hand, for the sake of argument, it could be contended that the legislator's intention to exclude from patentability method claims for an essentially biological process for the production of plants would be frustrated if an applicant or patent proprietor, faced with the fact that he could not acquire patent protection for a novel and inventive biological process, succeeded in acquiring patent protection for a product which was directly and inevitably obtained by said process. This argument might apply particularly if the product was explicitly determined by the process, making the method features a required part of the claim defining the extent of protection conferred by the patent, as in the case of a product-by-process claim. The Enlarged Board stated in G 2/06 (supra, 326, Reasons, point 22) that: "to restrict the application of Rule 28 (c) (formerly 23d(c)) EPC 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 skillful drafting of such claim."

(4) The Enlarged Board is aware that the present appeal cases are marked by a series of quite different claim versions submitted by the patent proprietors from the outset of the proceedings before the EPO. The original sets of claims contained both method and product claims. They are now limited to mere product or product-by-process claims.

(5) However, to describe these amendments and the patent proprietors' procedural behaviour as an evasion of the exception to patentability of "*essentially biological processes for the production of plants*" rendering Article 53(b) EPC meaningless, or without any substance in its scope of application, would be to assume that the legislator in-tended - or envisaged - a broadening of the term "process" as a matter of jurisprudence.

(6) Against the above conclusion that the clear wording of Article 53(b) EPC does not provide a solid basis for a broad reading of the process exclusion (see in this section point IX.6 above), such an assumption would need to bear in mind the following considerations of fact as well as law:

(a) In terms of facts: A reading of Article 53(b) EPC to the effect that a p:oduct obtained by an essentially biological process is excluded from patentability would require that the method applied would be traceable in the product. As a consequence, were the process exclusion to extend to a product claim or a product-byprocess claim one would need to determine in the claimed product itself as a matter of fact whether it was actually obtained by an essentially biological process or was obtained or is obtainable by any other process, i.e. non-biological or microbiological processes. For the purpose of the point of law referred to it, the Enlarged Board therefore concludes that Article 53(b) EPC does not imply or even permit an exception to patentability of a product claim as a result of a broad reading of the process exclusion based on specific process elements that may or may not be traceable in the claimed product, in particular when taking into account the considerable developments in the technical field of plant breeding in the past and the unpredictable nature of future developments. Broadening the scope of the process exclusion to the extent that it included also the products obtained by essentially biological processes for the production of plants would introduce an inconsistency in the system of the EPC, as plants and plant material other than plant varieties are generally eligible for patent protection.

(b) In respect of the legal issue: The referring Boards raised the question whether it was of relevance 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 (referral tomato II, Reasons, points 45 et. seq.; referral broccoli II, Reasons, points 17 et seq.). As pointed out by the referring Boards, by virtue of Article 64(2) EPC: (a) the protection conferred by a process claim extends to the products directly obtained by such process, (b) the protection conferred by a product claim comprises using as well as producing the product and (c) the product claimed in terms of a product-by-process claim extends to products which are structurally identical to the claimed product but which are produced by a different method. However, the relevant point of law referred to the Enlarged Board is whether or not the "subject-matter" of a product claim or a product-byprocess claim directed to a plant or plant material other than a plant variety is excluded from being patented under Article 53(b) EPC by virtue of the essentially biological nature of the process for making said plant or plant material. Thus, the aspect of the scope of protection conferred by such a claim has no direct impact on the point of law referred.

A distinction needs to be made between, on the one hand, the aspects of patentability and, on the other hand, the (protective) effects of European patents or patent applications. The EPC clearly provides for such a clear division, as the requirements for patentability are governed by Articles 52 to 57, 76, 83, 84 and 123 EPC whereas the extent of protection and the rights conferred by European patents or patent applications are specified in Articles 64(2) and 69 EPC in particular. In this respect, reference is made to **G** 1/98 (supra, Order, point 3, and Reasons, point 4) where the Enlarged Board decided that Article 64(2) EPC is not to be taken into consideration in examining a claim to a process for the production of a plant-variety (see also G 2/88, OJ E?O 1990, 93, Reasons, point 2.5).

This conclusion applies mutatis mutandis to the examination of product and product-by-process claims directed to plants or plant products other than plant varieties. As a consequence, whether a product claim or a product-by-process claim is patentable is to be examined irrespective of the extent of protection that is conferred by it after grant. Its allowability depends upon the fulfillment of the formal and substantive requirements of the Convention for these kinds of claim categories. In this respect, the allowability of a product-by-process claim is subject to the additional (restrictive) conditions established in the case law of the boards of appeal.

(c) The Enlarged Board is aware of the various ethical, social and economic aspects in the general debate. Such aspects are documented for example: in European Parliament resolution of 10 May 2012 on the patenting of essential biological processes (2012I2623 (RS P), in the report of the legal affairs committee of the German Parliament concerning the Federal Government's draft Law No. 17/10308 for the amendment of the German Patent Act (parliamentary publication ("Bundestags-Drucksache") 17/14222 of 26 June 2013, pages 2 and 3), in the .report of the Federal German Government to the German Parliament of 9 July 2014 on the implications of patent law in the field of biotechnology, inter alia with regard to sufficient technicality, as well as with regard to the impact in the field of plant and animal breeding (parliamentary publication ("Bundestags-Drucksache") 18/2119 of 9 July 2014, point 3.3.2), in draft resolution No. 218 of 11 December 2013 ("proposition de resolution no 218 (2013-2014) de fIIM. Jean BIZET et Richard YUNG, deposee au Senat le 11 decembre 2013", page 11, point 20), and in the explanatory note of the Swiss Federal Council of 23 November 2 005 (Swiss Federal Gazette ("Bundesblatt") 2006, No. 1, point 2.1.2.8, page 63). Those aspects also featured in numerous amici curiae briefs and were raised by opponent B2 who suggested that there should be a breeders' exemption in national law or a waiver of protection in the form of a statement in the patent specification.

However, considering such general arguments in the present referrals does not fall under the judicial decision-making powers of the Enlarged Board. It has to be borne in mind that the role of the Enlarged Board of Appeal is to interpret the EPC using generally accepted principles of interpretation of international treaties. It is not mandated to engage in legislative policy.

The Enlarged Board concurs with the District Court of The Hague in its judgment of 8 May 2013 (C/09/416501/HA ZA 12-452 and C/09/418860/HA ZA 12-577, Reasons, points 5.2 to 5.11). The Court held that in the absence of an explicit exclusion in Article 53(b) EPC, product claims to plants, other than individual plant varieties, obtainable by an essentially biological process for the production of plants, were in principle allowable, even if the essentially biological processes themselves were not. If the product itself fulfilled the criteria for patentability, the fact that the known process to obtain the product was essentially biological did not preclude a valid patent claim (Reasons, points 5.2 to 5.11)

(d) Furthermore, the Enlarged Board takes note that those legislatures that are of the view that plant products obtained by essentially biological processes should not be patentable have chosen to amend their legislation in this respect, thereby deviating from the wording of Article 53(b) EPC. Both in Germany and in the Netherlands legislation exists excluding product claims from patentability where the claimed products have been generated by an essentially biological process for the production of plants (see § 2a(1) No. 1 German Patent Act of 1936, as last amended in 2013; Article 3(1)(d) Dutch Patent Act of 1994, as last amended in 2014). No such amendments have been made in, for example, the United Kingdom (see Section 76A and Schedule A2 (1) (b) and (3) (f) UK Patents Act of 1977, as last amended in 2014), France (see Art. L. 611-19 CPI, Loi no 2004-1338 of 8 December 2004, 1.3°), Austria (see §2(2) Austrian Patent Law of 1970, as last amended in 2014) and Switzerland (see Article 2(2) Swiss Patent Law of 1954, as last amended in 2012).

(e) Therefore, the allowability of a patent claim directed to either a plant or plant material or to such a plant product defined by specific method features is governed by provisions of the EPC concerning product claims and product-by-process claims independent of the issue of the allowability of a patent claim directed to an essentially biological process for the production of plants. Thus, the choice of one or the other claim category is not a matter of some sort of "skillful claim drafting" or circumvention of legal hurdles but of the prerequisites for their patentability.

3. Second intermediate conclusions

The Enlarged Board concludes that no dynamic interpretation of Article 53(b) EPC is required to the effect that the process exclusion should extend to products obtained by essentially biological processes for the production of plants. Nor can it see any imminent legal erosion of its scope when limiting its scope to process claims as such and leaving product claims and product-by-process claim outside the scope of the process exclusion. For this reason, there is neither a need nor a legal justification to alter the understanding of Article 53(b) EPC achieved by applying the traditional means of interpretation.

IX. FINAL CONCLUSIONS

(1) The scope of application of the term "essentially biological processes for the production of plants" in Article 53(b) EPC is interpreted to the effect that product inventions where the claimed subject-matter is directed to plants or plant material such as a fruit or plant parts other than a plant variety, as such, are not excluded from being patented.

(2) Irrespective of the exclusion of plant varieties (G 1/98, supra), the exception to patentability in Article 53(b) EPC in respect of plants is limited to claims directed to processes, in particular as defined in the previous two referrals G 2/07 and G 1/08 (supra).

(3) Subject-matter claimed as a product or a productby-process is not the same as one claimed for a process, which, in the case of essentially biological processes for the production of plants, is excluded from patentability, regardless of the methods by which the claimed product is generated or - as in the case of a product-by-process claim - defined. Even if the product, i.e. the plant or plant material such as a fruit or plant parts, can only be obtained by essential-ly biological processes with no other methods either disclosed in the patent application or otherwise known, the process exclusion in Article 53(b) EPC does not extend to product claims and product-by-process claims.

(4) However, whether such product claims or productby-process claims are allowable and lead to granting of a European patent depends upon the fulfillment of the formal and substantive requirements of the Convention concerning these kinds of claim categories independent of the issue of the allowability of a patent claim directed to an essentially biological process for the production of plants. In this respect, the allowability of a product-by-process claim is subject to the additional (restrictive) conditions established in the case law of the boards of appeal. Therefore, the mere fact that an applicant or patent proprietor chooses a product claim or product-by-process claim instead of a method claim directed to an essentially biological process for the production of a plant is not a matter of some sort of "skillful claim drafting" or circumvention of legal hurdles but a legitimate choice to obtain patent protection for the claimed subject-matter, on condition that the requirements for allowability of such a claim are met.

(5) This means that the questions referred to the Enlarged Board are answered as follows:

(a) in case G 2/12, the first and third questions (see Summary of Facts and Submissions, point II.1) are answered in the negative, whereas the second questions is answered in the affirmative, using a double negation, and

(b) in case G 2/13, the first and third questions (see Summary of Facts and Submissions, point III.1) are answered in the negative, whereas the second question is answered in the affirmative, using a double negation. In the circumstances, the fourth question does not require an answer.

Order

For these reasons it is decided that:

The questions of law referred to the Enlarged Board of Appeal are answered as follows:

1. The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts.

2.

(a) The fact that the process features of a product-byprocess claim directed to plants or plant material other than a plant variety define an essentially biological process for the production of plants does not render the claim unallowable.

(b) The fact that 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 does not render a claim directed to plants or plant material other than a plant variety unallowable.

3. In the circumstances, it is of no relevance 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. 4. Not applicable.
