

ET0083.05 - 071500014

## **Interlocutory decision of Technical Board of Appeal 3.3.04 dated 22 May 2007**

### **T 83/05 - 3.3.04<sup>1</sup>**

(Language of the proceedings)

Composition of the board:

Chairman: U. Kinkeldey

Members: R. Gramaglia

R. Moufang

**Opponent I/Appellant I: Syngenta Participations AG**

**Opponent II/Appellant II: Groupe Limagrain Holding**

**Patent proprietor/Respondent: Plant Bioscience Limited**

**Headword: Broccoli/PLANT BIOSCIENCE**

**Article: 53(b), 54, 56, 83, 87, 88, 100, 112(1)(a), 123(2) EPC**

**Rule: 23b(5) EPC**

**Keyword: "Added subject-matter (no)" - "Sufficiency of disclosure (yes)" - "Entitlement to priority (yes)" - "Novelty (yes)" - "Inventive step (yes)" - "Exclusion of essentially biological processes for the production of plants - important point of law - referral of questions to the Enlarged Board of Appeal"**

*Headnote*

*The following questions are referred to the Enlarged Board of Appeal for decision:*

*1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?*

*2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?*

### **Summary of facts and submissions**

I. Appeals by opponent I (appellant I) and opponent II (appellant II) were filed against the interlocutory decision of the opposition division according to which the European patent No. 1 069 819 (application No. 99 915 886.8,

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<sup>1</sup> This is an abridged version of the decision. A copy of the full text of the language of proceedings may be obtained from the EPO Information Office in Munich on payment of a photocopying fee of EUR 0.65 per page.

ET0083.05 - 071500014

published as WO-A-99/52345 and claiming priority from US 60/081,169 of 9 April 1998) could be maintained in amended form based on claims 1 to 11 of the main request submitted by the patentee (respondent) during the opposition proceedings.

II. The board summoned the parties to oral proceedings which took place on 4 and 5 May 2006.

III. During the oral proceedings, the respondent submitted a new main request and an auxiliary request, each consisting of 9 claims. The claims of said new main request read as follows:

"1. 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 Brassica drepanensis with broccoli double haploid breeding lines;

b) selecting hybrids with levels of

4-methylsulfinylbutyl glucosinolates, or

3-methylsulfinylpropyl 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, or 3-methylsulfinylpropyl glucosinolates, or both; and

d) selecting a broccoli line with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates [sic], or both, capable of causing a strong induction of phase II enzymes,

wherein 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."

"2. A method according to claim 1, wherein the Brassica oleracea breeding lines are broccoli double haploid breeding lines comprising specific SI alleles the presence of which results in self-incompatibility in the Brassica oleracea, the method comprising crossing wild Brassica oleracea with broccoli double haploid breeding lines containing the specific SI alleles to produce plants; and selecting for said plants by screening for said specific SI alleles with molecular probes."

"3. The method according to claim 1 or claim 2, wherein only 4-methylsulfinylbutyl glucosinolate is elevated relative to that initially found in the Brassica oleracea breeding lines."

"4. The method according to claim 1 or claim 2, wherein only 3-methylsulfinylpropyl glucosinolate is elevated relative to that initially found in the Brassica oleracea breeding lines."

"5. An edible Brassica plant produced according to the method of any one of claims 1 to 4."

"6. An edible portion of a broccoli plant produced according to the method of any one of claims 1 to 4."

"7. Seed of a broccoli plant produced according to the method of any one of claims 1 to 4."

"8. A broccoli plant having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl 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

ET0083.05 - 071500014

Brassica drepanensis and the levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, are between 10 and 100 µmoles per gram of dry weight of said plant."

"9. A broccoli inflorescence having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl 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 between 10 and 100 µmoles per gram of dry weight of the inflorescence."

Claim 1 of the auxiliary request differs from claim 1 of the main request by the insertion of the step of "deriving broccoli double haploid breeding lines" as an additional step (a) of the claimed method.

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

(...)

D7 Principles of Cultivar Development, Vol. 1, Chapter 28: Backcross Method, pages 360-376 (1987);

(...)

D17 Catalogue "A Germ Plasm Collection of Crucifers", Instituto Nacional de Investigaciones Agrarias, Madrid, pages 14, 52 and 53 (1990);

(...)

D22 Palmer C.E. et al. in "In Vitro Haploid Production in Higher Plants", Kluwer Academic Publishers, Vol. 2, pages 143 -172 (1996);

(...)

V. The submissions by appellant I and/or appellant II in writing and during the oral proceedings are summarised as follows:

(...)

*Sufficiency of disclosure (Article 100(b) EPC)*

- The method of claim 1 was not reproducible since the patent did not contain sufficient information with respect to (i) the starting material, i.e. suitable wild Brassica villosa and Brassica drepanensis plants as well as suitable broccoli double haploid breeding lines, (ii) the backcrossing step, and (iii) the molecular markers to be used.

- The skilled person would not succeed in arriving at the subject-matter of claim 1, even after considerable time and effort. If, however, this view was not followed, there would be lack of sufficiency of disclosure as the skilled person would be unable to arrive at the subject-matter of claim 1 without undue burden.

ET0083.05 - 071500014

- The specific markers referred to in the patent in paragraph [0043] were not enabled since it was not sufficient that they could be obtained from Dr Osborn on request. The material had to be available for the whole duration of the patent (see decisions T 576/91 and T 815/90). A skilled person was not in a position to make other markers as the patent did not disclose the nature of the desired genetic change to be looked for.

- Furthermore, the expression "elevated levels" was open-ended and it was not sufficiently disclosed how to achieve them over the whole range of the claim.

(...)

*Exclusion of essentially biological processes for the production of plants (Article 53(b) EPC)*

- The subject-matter of claims 1 to 4 of the main request was an essentially biological process for the production of plants. The use of molecular markers in the selection step was not sufficient to escape the exclusion of Article 53(b) EPC.

- Rule 23b(5) EPC did not contain an exhaustive definition of the processes excluded under Article 53(b) EPC. The latter provision had a higher legislative rank in view of Article 164(2) EPC and excluded essentially biological processes, not only entirely biological processes. According to the case law of the boards of appeal the applicability of the exclusion had to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved (T 320/87). Granting patents for biological processes comprising no more than a step of trivial technical intervention introduced to intentionally circumvent Article 53(b) EPC would be contrary to the spirit of the Convention.

- The claimed subject-matter was excluded even under the wording of Rule 23b(5) EPC since the use of molecular markers constituted a part of the selection step which, according to the explicit definition of the rule, had to be regarded as a natural phenomenon. Furthermore, the term molecular markers was so broad as to encompass entirely natural phenomena such as phenotypic or morphological markers.

VI. The submissions made by the respondent in writing and during the oral proceedings, in so far as they are relevant to the present decision, are summarised as follows:

(...)

*Sufficiency of disclosure (Article 100(b) EPC)*

- The markers described in the patent at paragraphs [0040] and [0043] were available from Dr Osborn on request (see documents D18 and D19). Irrespective of these specific markers, a person skilled in the art would have been able to make suitable molecular markers, as all technical steps required constituted common general knowledge.

(...)

ET0083.05 - 071500014

*Exclusion of essentially biological processes for the production of plants (Article 53(b) EPC)*

- Article 53(b) EPC was an exception to the general principle of patentability as laid down in Article 52(1) EPC and had to be interpreted narrowly.

- Rule 23b(5) EPC which had to be applied to the present case provided a definition of whether a process is essentially biological or not. One non-natural step in a claimed method was enough to remove the method from the exclusion. Since the claimed methods did not consist entirely of natural phenomena, they were not embraced by Article 53(b) EPC.

- Even when interpreting the exclusion in accordance with case law preceding the introduction of Rule 23b(5) EPC, the claimed methods were patentable since (a) the use of molecular markers was a technical step requiring removal and in vitro analysis of the plant tissues, (b) the invention required the use of a non-natural starting material, i.e. a double haploid strain, and (c) the wild Brassica strains used in the claimed process had to be specifically brought into contact with broccoli breeding lines by human intervention.

VII. Appellants I and II requested that the decision under appeal be set aside and that the patent be revoked. Furthermore, appellants I and II requested that the questions of law formulated on page 10 of the submissions of appellant II dated 4 April 2006 be referred to the Enlarged Board of Appeal should the board be inclined to consider that claims 1 to 4 of the present claim requests of the respondent did not contravene Article 53(b) EPC.

The respondent requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of claims 1 to 9 of the main request, or, in the alternative, claims 1 to 9 of the auxiliary request, both filed at the oral proceedings on 5 May 2006.

VIII. At the end of the oral proceedings the chair declared the debate closed and announced that questions of law would be referred to the Enlarged Board of Appeal.

### **Reasons for the decision**

With respect to the ground of opposition of Article 100(a) in connection with Article 53(b) EPC the board considers that an important point of law arises. Since according to Article 112(1)(a) EPC questions to the Enlarged Board of Appeal should only be referred if a decision is required, the board has examined whether the other grounds of opposition prejudice the requested maintenance of the patent in suit in amended form.

*Main request*

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

(...)

*Sufficiency of disclosure (Article 100(b) EPC)*

5. At the priority date of the patent in suit, seeds of the plant species *B. villosa* and *B. drepanensis* were available to the public (see document D17), and so were techniques to obtain double haploid lines of broccoli (see document D22). In the absence of any evidence to the contrary, the board sees no reason to believe that the method of claim 1 could not be carried out using the publicly available material and techniques. Furthermore, methods of backcrossing were generally known in the art (see document D7), and, when reading the description of the patent, a skilled person would understand that the backcrossing of step (c) in claim 1 had to be done with the broccoli line. Moreover, the

ET0083.05 - 071500014

board considers that the step of selecting hybrids with glucosinolate levels elevated above that initially found in broccoli double haploid breeding lines would not cause any problem to a skilled person, given that reference is made in paragraph [0051] of the patent in suit to scientific literature dealing with a method for measuring the glucosinolate levels.

6. As concerns the molecular markers to be used in the method of claim 1, steps (b) and (c), documents D3 and D9 to D11 show that before the priority date of the patent in suit, methods to produce molecular markers that segregate with a desired trait were commonly known from the prior art and had been used in the context of Brassica species. Even though some effort is necessary to design the required specific markers, this nonetheless is a standard method which does not amount to undue burden. A skilled person would thus have been able to produce suitable markers in the light of the disclosure of the patent in suit, in particular lines 1 to 4 of paragraph [0043].

7. The board concludes that the claimed subject-matter satisfies the requirements of Article 83 EPC.

*Entitlement to priority (Articles 87 and 88 EPC)*

(...)

*Novelty (Article 54 EPC)*

(...)

*Inventive step (Article 56 EPC)*

(...)

*Exclusion of essentially biological processes for the production of plants (Article 53(b) EPC)*

*General*

36. Appellant II has raised the ground of opposition of Article 100(a) in connection with Article 53(b) EPC. It argues that the subject-matter of claim 1 of respondent's main request is an essentially biological process for the production of plants and therefore excluded from patentability under Article 53(b) EPC.

37. As set out in detail below (points 62 to 66), the outcome of the present case decisively depends on the interpretation of the process exclusion contained in Article 53(b) EPC. Since the board considers that this interpretation raises an important point of law, in particular in view of Rule 23b(5) EPC introduced in 1999 by the Administrative Council, it has decided to refer two questions to the Enlarged Board of Appeal. Under these circumstances it appears appropriate to provide a comprehensive view of the issues involved. In the following the board will review the relevant legislative history of Article 53(b) EPC (points 38 to 42) and the pertinent appeal case law (points 43 to 47) in some detail. It will then consider the possible impact of Rule 23b(5) EPC on the interpretation of Article 53(b) EPC by setting out the background of the introduction of this rule (points 48 to 50), its legislative history (points 51 to 52), its possible meaning (points 53 to 55) and certain doubts as to its applicability (points 56 to 59).

ET0083.05 - 071500014

*Legislative history of Article 53(b) EPC*

38. The wording of Article 53(b) EPC is almost identical to the wording of Article 2(b) of the Strasbourg Convention on the Unification of Certain Points of Substantive Patent Law signed in 1963. The only difference consists in that the latter provision is not a compulsory patentability exclusion but only provides the signatory states with the possibility of excluding the subject-matter mentioned therein from patentability in their national laws. As the legislative history shows, both provisions were framed in the early 1960s, the respective working groups of the European Economic Community and of the Council of Europe reciprocally influencing each other. The major steps of this development were the following.

39. Article 12 of the First Preliminary Draft Convention of the EC Working Group of 14 March 1961 (see Doc. IV/2071/61-E) read in its relevant part:

"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 a new animal species.

This provision shall not apply to processes of a technical nature.

[3. ...]."

The proposed text was explained as follows (cf. Doc. IV/2071/61-E Comments, page 6):

"Even if protection of new plant varieties and processes for producing new plants is excluded under European patent law, European patents will still have to be granted for processes which, while being applicable to plants, are of a technical nature, e.g. processes for producing new plants by irradiation of the plants themselves or of the seed with isotopes."

40. Article 2 of the Preliminary Draft Convention of the Council of Europe (cf. Doc. EXP/Brev (61) 2 rev., page 26) read:

"The words 'susceptible of industrial application' shall be understood in the widest sense.

Nevertheless, the Contracting States shall not be bound to provide for the grant of patents, in respect of new plant or animal species or of purely biological, horticultural or agricultural (agronomic) processes."

After thorough discussions in a committee meeting of 7 to 10 November 1961, this provision was substantially amended in that the words "horticultural or agricultural (agronomic)" were deleted and the remaining phrase ("purely biological processes") was replaced by the current wording "essentially biological processes for the production of plants and animals". A memorandum of the secretariat of the committee (cf. Doc. EXP/Brev 61(8), pages 4-5) contains the following explanations:

"The processes for the 'production of plants or animals' referred to in the new text include those which may produce **known** varieties as well as those which may produce **new** ones, it being understood that only new varieties can eventually qualify for protection **in themselves**. Selection or hybridisation of existing varieties may be mentioned as examples of such processes (in the vegetable kingdom). The new text specifies that the processes which may be ineligible for patents are **essentially** (and no longer **purely**) biological. It was evident that the exclusion should be extended to cover processes which were fundamentally of this type even if, as a **secondary** feature, 'technical' devices were involved (use of a particular type of instrument in a grafting process, or of a special greenhouse in growing a plant), it being understood that such technical devices may perfectly well be patented themselves, but not the biological process in which they are used."

ET0083.05 - 071500014

These explanations were repeated almost verbatim in the report of the committee of experts to the committee of ministers on the meeting held at Strasbourg from 10 to 13 July 1962 (cf. Doc CM (62) 160, page 4, point 7).

41. The wording on which the experts of the committee of the Council of Europe agreed in November 1961 became part of Article 2(b) of the Strasbourg Convention and - later - of Article 53(b) EPC. The only further modification accepted was the adding of the proviso that the provision(s) should not apply to microbiological processes and the products thereof. Other proposals for a further clarification of the exclusion (cf. Doc. EXP/Brev (62)(6), page 2) or for its deletion altogether (cf. Doc. BR/135/71, page 52) were made, but did not find a majority.

42. The above review of the Travaux Préparatoires shows that the drafters of the provision regarded "biological" as being in opposition to "technical", that they deliberately chose the adverb "essentially" to replace the narrower term "purely" and that they considered plant breeding processes based on selection and hybridisation to fall under the exclusionary provision even if secondary features of the processes were characterised by the use of technical devices.

#### *Relevant case law*

43. The exclusionary provision at issue has been considered on several occasions by the boards of appeal. In the decision T 320/87 (OJ EPO 1990, 71, points 6 and 9 of the reasons) taken by a five-member board and relating to the production of hybrid plants, it was held that the applicability of the exclusion had to be judged on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the result achieved. Although the board considered that the exclusion had to be narrowly construed, the necessity of human intervention in itself was not regarded as a sufficient criterion for the process not being "essentially biological". Human interference might only mean that the process was not a "purely biological" process, without contributing anything beyond a trivial level. The required fundamental alteration of the character of a known process for the production of plants might lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed. The case at issue was decided in favour of the appealing applicant since the claimed processes for the preparation of hybrid plants were considered to represent an essential modification of known biological and classical breeders processes, in which the efficiency and high yield associated with the product showed important technological character.

44. In the decision T 19/90 (OJ EPO 1990, 476) taken by a five-member board, it was considered that the corresponding exclusion of essentially biological animal production processes did not apply to process claims for the production of transgenic non-human mammals through chromosomal incorporation of an activated oncogene sequence into the genome of the mammal. In view of the fact that the oncogene was inserted by technical means into a vector, which was then micro-injected at an early embryonic stage, the claimed processes were held not to be directed to "essentially biological processes".

45. The decision T 356/93 (OJ EPO 1995, 545) *inter alia* concerned a process claim for producing a plant or its reproduction material. The process comprised transforming plant cells or tissue with a recombinant DNA containing a certain heterologous DNA, regenerating plants or reproduction material from the transformed plant cells and tissue and, optionally, biologically replicating the plants or the reproduction material. The board considered that the "genetic engineering" step of transforming the plant cells or tissue with a recombinant DNA was an essential technical step which had a decisive impact on the desired final result and could not occur without human intervention. It concluded that the claimed plant production process as a whole was not essentially biological.

46. In its decision T 1054/96 of 13 October 1997 (OJ EPO 1998, 511) the present board in a different composition referred several questions of law relating to the interpretation of Article 53(b) EPC to the Enlarged Board of Appeal. One of these questions was broadly framed and encompassed the issue as to how to construe the term "essentially biological processes for the production of plants". In this context the referring board identified three different approaches for arriving at the required "value judgment" (cf. points 25 to 29 of the reasons). The first of these approaches was analogous to that used under Article 52(4) EPC relating to methods of treatment by surgery and therapy and led to the result that the inclusion in a claimed process of a step of essentially biological nature would



ET0083.05 - 071500014

not be allowable. The second approach was the one adopted in decision T 320/87 (see above, point 43). The third approach was to require, in order to escape the prohibition of Article 53(b) EPC, at least one clearly identified "non-biological" process step but allow any number of additional "essentially biological steps" which would be carried into allowability by the "non-biological" process step. It was stated that this approach which was adopted by Article 2(2) of the (then) draft EU Biotech Directive would be that most favourable to applicants, but was not the approach so far adopted by the boards of appeal.

47. In its decision G 1/98 (OJ EPO 2000, 111), the Enlarged Board of Appeal answered the questions of law referred to it by decision T 1054/96. However, it refrained from substantively addressing the interpretation of the process exclusion contained in Article 53(b) EPC. Since the appealing applicant had expressed its willingness before the Enlarged Board to make further amendments to restrict the method claims to identifiable method steps in order to exclude essentially biological processes, it was considered that the relevance of the issue had not yet been clarified. The Enlarged Board regarded it as inappropriate to offer guidance without having a sound factual basis for doing so.

#### *Introduction of Rule 23b(5) EPC*

48. By decision of the Administrative Council of the EPO of 16 June 1999 which entered into effect on 1 September 1999, the Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions (in the following referred to as "Biotech Directive") was implemented. A new Chapter VI was introduced into the Implementing Regulations to the EPC, containing inter alia new Rule 23b(5) which reads:

"A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

49. The overall purpose of the Administrative Council's decision was the harmonisation of European patent law with the Biotech Directive which, according to Rule 23b(1), second sentence, EPC shall be used as a supplementary means of interpretation. The wording of Rule 23b(5) EPC is identical with that of Article 2(2) Biotech Directive.

50. In the Notice of the EPO dated 1 July 1999 concerning the amendment of the Implementing Regulations to the EPC (OJ EPO 1999, 573, point 19), the introduction of the new rule was explained as follows:

"Rule 23b(5) in keeping with Article 2(2) of the Directive specifies more precisely when a process for the production of plants or animals is 'essentially biological'. This in particular gives a more specific meaning to Article 53(b) EPC and establishes that only production processes based entirely on natural phenomena are excluded from patenting. Although the EPO boards of appeal have hitherto not given an explicit decision to that effect (see T 320/87, T 19/90, T 356/93), the interpretation developed by the boards falls within the framework of the definition given in the new rule."

#### *Legislative history of Rule 23b(5) EPC and Article 2(2) Biotech Directive*

51. The legislative history of the Biotech Directive shows that the wording of the provision which later became Article 2(2) had changed several times. As an illustration the following three draft versions are noted.

- Article 7 of the original proposal (COM(88) 496 fin./SYN 159 of 20 October 1988, OJ EC No. C 10/3 of 13 January 1989):

"A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject matter."

ET0083.05 - 071500014

- Article 6 of the Common Position (EC) No 4/94 adopted by the Council on 7 February 1994 (OJ EC No. C 101/65 of 9 April 1994):

"Essentially biological processes for the production of plants or animals shall not be considered patentable. In determining this exclusion, human intervention and its effects on the result obtained shall be taken into account. A process which, taken as a whole, does not exist in nature and is more than a traditional breeding process shall be considered patentable."

- Article 2(2) of the amended proposal of 29 August 1997 (Doc. COM(97) 446 final = OJ EC C 311/12 of 11 October 1997):

"A procedure for the breeding of plants or animals shall be defined as essentially biological if it is based on crossing and selection."

52. The final wording of Article 2(2) Biotech Directive was arrived at only at a late stage of the legislative process, namely when the EC Council adopted its Common position (EC) No. 19/98 on 26 February 1998 (OJ EC C 110/17 of 8 April 1998). The following explanation was given (cf Statement of the Council's Reasons, No. 12 and 13, OJ EC C 110/27 of 8 April 1998):

"The Council tightened up the definition of the essentially biological notion of procedure in this provision on the basis not only of amendment 48 but also of amendment 22 proposed by the European Parliament with regard to recital 18 of the original proposal.

Given the inclusion of a complete definition in Article 2(2), the Council made the corresponding recital declaratory in tone (recital 33 of the common position)."

#### *Interpretation of Rule 23b(5) EPC*

53. The wording of Article 2(2) Biotech Directive and Rule 23b(5) EPC is, in the view of the board, somewhat difficult to understand. On the one hand, only processes which consist **entirely** of natural phenomena are considered to be **essentially** biological processes for the production of plants. On the other hand, crossing and selection are given as examples of natural phenomena. This appears to be self-contradictory to some extent since the systematic crossing and selection as carried out in traditional plant breeding would not occur in nature without the intervention of man.

54. Notwithstanding these ambiguities, the board considers that, particularly when taking into account the adverb "entirely", the wording of Rule 23b(5) EPC aims at a very narrow construction of the process exclusion contained in Article 53(b) EPC. The board interprets Rule 23b(5) EPC as meaning that a process which, apart from "natural phenomena" (which appear to cover crossing and selection by way of a legal fiction), contains an additional feature of a technical nature would be outside the ambit of the process exclusion. As already pointed out in decision T 1054/96 (above, point 46), this has not been the approach adopted by the boards of appeal before the introduction of Rule 23b(5) EPC. The board thus finds it difficult to concur with the statement contained in the EPO's Notice cited above (point 50), according to which the interpretation developed by the boards falls within the framework of the definition given in the new rule.

55. Appellant II has argued that since Rule 23b(5) EPC was framed by the legislator in terms different from the definition provisions contained in its paragraphs (3), (4) and (6), it does not constitute an exhaustive definition. Accordingly, a process which does not consist entirely of natural phenomena had to be assessed under Article 53(b) EPC itself. While the board accepts that there is a difference in the wording used for Rule 23b(5) on the one hand and that used for Rule 23b(3), (4) and (6) on the other hand, it does not agree with the conclusion of appellant II. In the light of: (i) the context of paragraph (5) within Rule 23b EPC; (ii) the wording of recital (33) Biotech Directive

ET0083.05 - 071500014

which reads: "Whereas it is **necessary to define** for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological" (emphasis added); and (iii) the legislative history (above, point 52), the board considers that Rule 23b(5) EPC was meant to be a full definition.

Thus, the two approaches adopted in the appeal case law and in Rule 23b(5) EPC cannot be reconciled in the manner proposed by appellant II.

*Doubts as to the applicability of Rule 23b(5) EPC*

56. In the board's view, the introduction of Rule 23b(5) EPC does not finally settle the question as to what the correct approach is when interpreting the process exclusion of Article 53(b) EPC. Three lines of argument can be developed to put into question or to limit the applicability of this rule.

57. A first line of argument (which the board considers to be the most important one) is based on Article 164(2) EPC according to which the provisions of the Convention shall prevail in the case of conflict with provisions of the Implementing Regulations. If the approach adopted by the boards of appeal prior to the introduction of Rule 23b(5) EPC reflected the true meaning of the process exclusion of Article 53(b) EPC, it would be difficult to see how this meaning could be changed by an amendment to the Implementing Regulations. Reference is made to decision T 39/93 (OJ EPO 1997, 134, point 3.2 of the reasons) where it was held that, in view of Article 164(2) EPC, the meaning of an article of the EPC on its true interpretation as established by a ruling of the Enlarged Board of Appeal cannot be overturned by a newly drafted rule of the Implementing Regulations, the effect of which is to conflict with this interpretation. While the board notes the difference in authority between a ruling of the Enlarged Board of Appeal and decisions of the boards of appeal (including those which are taken in a five-member composition as it was the case in the decision T 320/87), it appears that, unless the previous case law erred in its interpretation of Article 53(b) EPC, the approach adopted by Rule 23b(5) EPC runs counter to the true meaning of Article 53(b) EPC and cannot be followed in view of Article 164(2) EPC.

58. Secondly, it may be argued that the competence of the Administrative Council to amend the Implementing Regulations according to Article 33(1)(b) EPC does not extend to core issues of substantive patent law and that the introduction of provisions determining the boundaries of patentable subject-matter is ultra vires. While this argument finds some support in the appeal case law - the decision of the Legal Board of Appeal in the consolidated cases J 11/91 and J 16/91 (OJ EPO 1994, 28, point 2.3.4 of the reasons) contains the far-reaching statement that the Regulations may deal only with procedural questions and not with matters of substantive law -, it has been explicitly rejected in the decision T 315/03 (OJ EPO 2006, 15, point 5.8 of the reasons) according to which the choice between Articles and Implementing Regulations is one exclusively for the legislator. Furthermore, in its decision G 2/93 (OJ EPO 1995, 275) the Enlarged Board of Appeal accepted that, with regard to microbiological inventions, a provision contained in the Regulations, i.e. Rule 28 EPC, implemented the general principle of Article 83 EPC and was, at least in part, substantive in nature.

59. A third issue which needs to be considered in the present case concerns the applicability in tempore of Rule 23b(5) EPC. The opposed patent was granted on the basis of an application whose filing date (8 April 1999) precedes the date on which the new Rules 23b to 23e EPC entered into force, i.e. 1 September 1999 (see above, point 48). Since the decision of the Administrative Council implementing the Biotech Directive does not contain any transitional provisions, it appears that in principle the new rules are to be applied when a decision has to be taken in pending proceedings, irrespectively of the filing date of the relevant patent application (see decisions T 272/95 of 23 October 2002, point 4 of the reasons, and T 315/03, points 5.1 and 5.12 of the reasons). However, the board is aware that the decision T 1374/04 of 7 April 2006 (to be published in OJ EPO<sup>2</sup>) recently referred a related question of law to the Enlarged Board of Appeal, i.e. the question as to whether new Rule 23d(c) EPC applies to an application filed before the entry into force of the rule. It would therefore not be appropriate for the present board to express a definite view on the applicability in tempore of Rule 23b EPC. However, if the introduction of Rule 23b(5) EPC changed the law by narrowing the scope of the process exclusion contained in Article 53(b) EPC and thus expanding the area of patentable subject-matter, it might be necessary to consider whether third parties should be protected in their expectation that an activity which amounted to an essentially biological process under the previous

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<sup>2</sup> In the meantime published in OJ EPO 2007, 313.

ET0083.05 - 071500014

law could not be made the subject-matter of a patent resulting from an application filed before the entering into force of Rule 23b(5) EPC.

*Correct approach for interpretation of Article 53(b) EPC still to be determined*

60. The boards of appeal have not yet decided a case whose outcome hinged on the question as to which of the two approaches set out above prevails. When the present board, in a different composition, took its final decision in the appeal case T 1054/96 on 6 December 2000, i.e. after the introduction of Rule 23b(5) EPC, it inter alia considered whether method claims which concerned the preparation of transgenic plants and which had been amended by the applicant after the Enlarged Board handed down its decision G 1/98 complied with the requirements of Article 53(b) EPC. The board's conclusions were set out in point 3 of the reasons:

"Claims 23 and 24 require that the transgenic plant be prepared by transformation and regeneration. The step of transforming the host plant requires that DNA be introduced into it, i.e. that a number of mere technical manipulations such as isolating the transforming DNA (pages 21 to 32 of the application), making the host permeable to said DNA (page 32), screening the transformants (pages 38 and 42) have to be performed. It is, thus, of the essence of the method of claims 23 and 24 now put forward that genetic engineering steps are performed, so that the claim cannot be considered to be directed to an essentially biological process for the production of plants, which would be excluded from patentability under the provisions of Article 53(b) EPC. The same conclusion would be reached by applying Rule 23b(5) EPC, in force since 1 September 1999 [...], **so that no case of a conflict between the provisions of the European Convention and those of the implementing regulations for consideration under Article 164(2) EPC arises for consideration.**" (emphasis added)

The words emphasised above in bold indicate that the board in that case was well aware of the possibility of a conflict in this context, but did not need to address and decide it.

61. In the decision T 315/03 taken by a five-member board, the objection that the claimed method for producing transgenic mice was an essentially biological process for the production of animals was addressed (point 13.3.5 of the reasons). The board cited new Rule 23b(5) EPC and concluded that it was self-evident that a process which included genetic manipulation did not consist entirely of natural phenomena and was therefore not excluded by Article 53(b) EPC. Although the board applied Rule 23b(5) EPC in order to justify the non-applicability of Article 53(b) EPC, in the light of the ex parte appeal decision T 19/90 in the same case (above, point 44) where corresponding method claims were at issue, it can safely be assumed that the claimed method would have escaped the exclusionary provision also under the "traditional" approach.

*Relevance of determination of correct approach for present case*

62. As set out below, the outcome of the present case depends on the determination of the correct approach for the interpretation of Article 53(b) EPC since, in contrast to the situation in the decisions T 1054/96 and T 315/03, the two approaches would lead to different results.

63. Claim 1 of the respondent's main request is directed to a method for the production of Brassica oleracea with elevated levels of certain glucosinolates. The method contains several steps of crossing and selection. The initial crossing ("step a") is made between certain wild Brassica oleracea species and broccoli double haploid breeding lines. From the resulting hybrids, those are selected which have an elevated level of at least one of the specific glucosinolates ("step b"). Then a step of backcrossing and selection ("step c") takes place. This means that the selected hybrids are crossed with broccoli double haploid breeding lines and again those plants that have elevated levels of at least one of the glucosinolates are selected. This is followed by the final step, i.e. the selection of a broccoli line with the desired feature ("step d"). The claim further specifies that in steps (b) and (c) molecular markers are used to select hybrids with the desired genetic combination encoding expression of elevated levels of the glucosinolates.

ET0083.05 - 071500014

Claim 1 of respondent's auxiliary request corresponds to claim 1 of the main request but adds, as the first step of the claimed method, the feature to derive broccoli double haploid breeding lines.

64. The respondent argued that there were at least three levels of human intervention which brought the claimed invention outside the exclusion from patentability of Article 53(b) EPC.

- First, the use of molecular markers in steps (b) and (c) of the claimed process was a technical step requiring removal and in vitro analysis of plant tissues.

- Secondly, the claimed invention required the use of a non-natural starting material, i.e. a double haploid strain. Haploid lines were made by extracting microspores from developing anthers which are cells that have undergone meiosis (and are therefore haploid), and would develop into pollen. The microspores were put in medium in a Petri dish containing plant hormones that induced them to grow into haploid plants. These plants were then treated with colchicine, which prevented cell division and thus "doubled up" the chromosomes to make the plants "double haploids".

- Thirdly, the wild Brassica strains mentioned in step (a) of the claimed process grew in remote geographical locations and were not likely to hybridise with broccoli breeding lines unless specifically brought into contact by human intervention.

65. The approach adopted by Rule 23b(5) EPC (above, point 54) would lead to the conclusion that at least the first feature relied upon by the respondent would be sufficient to bring the claimed process outside Article 53(b) EPC. While there has been some dispute between the parties how broadly the term "molecular markers" should be understood, in the board's view the use of such markers involves subjecting plant material to an analytical laboratory process. This means that a technical step requiring human intervention is performed before or during the selection.

66. If, however, the approach adopted by the present board in its previous decisions T 320/87 and T 356/93 were still the correct one, none of the features relied upon by the respondent would make the claimed method escape the process exclusion of Article 53(b) EPC.

- The use of molecular markers such as DNA markers is, on a general level, a well-known step in the selection of plants with desired characteristics. Methods to discover and produce molecular markers that segregate with a desired trait were commonly known from the prior art and had already been used in the context of Brassica species (above, point 6). This has been acknowledged by the respondent (above, section VI). The board does therefore not consider that this feature is able to contribute anything beyond a trivial level to the claimed invention.

- In so far as the use of double haploid lines is concerned, it is noted that the description of the patent does not contain any details of how such lines can be generally developed in broccoli, and merely refers to a prior art document in relation to a specific line (see page 8, lines 15 to 16 of the patent). The board did not regard this absence of technical information as critical with respect to Article 83 EPC since double haploid breeding lines are, as such, well-known in plant breeding and techniques to obtain them in broccoli were publicly available (see document D22 and above, point 5). The derivation of such breeding lines can therefore not be regarded as being the essence of the claimed invention or as contributing anything beyond a trivial level to it. Furthermore, claim 1 of the main request, in contrast to claim 1 of the auxiliary request, does not include the generation of a double haploid line but only its use in two steps of the claimed method.

- The argument that wild Brassica strains are unlikely to hybridise with broccoli breeding lines in nature does, in the board's view, not assist the respondent in the context of Article 53(b) EPC irrespectively of whether the approach adopted by Rule 23b(5) EPC is followed or not. Even the most traditional forms of plant breeding consisting entirely of crossing and selection are unlikely to occur in nature as such, but are characterised by some form of human intervention (above, point 53).

*Conclusion*

67. In view of the above, the board comes to the conclusion that two questions of law as set out in the Order below should be referred to the Enlarged Board of Appeal in accordance with Article 112(1)(a) EPC. When formulating the questions, the board has duly taken into account the suggestions made by appellant II (see page 10 of its written submissions of 4 April 2006). However, the questions have been framed more broadly in order to avoid restricting the Enlarged Board in its task of determining the correct interpretation of the process exclusion of Article 53(b) EPC.

**Order**

**For these reasons it is decided that:**

The following questions are referred to the Enlarged Board of Appeal for decision:

1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?
2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?