

**Decision of Technical Board of Appeal 3.3.04 dated 4 April 2008
T 1242/06 - 3.3.04**

(Language of the proceedings)

Composition of the board:

Chair: U. Kinkeldey

Members: R. Moufang

M. Wieser

Patent proprietor/Appellant I: State of Israel - Ministry of Agriculture Volcani Research Center

Opponent/Appellant II: Unilever N.V.

Headword: Tomatoes/STATE OF ISRAEL

Article: 53(b), 112(1)(a) EPC

Rule: 26(5) EPC

Directive 98/44/EC of 6 July 1998 Art. 2(2)

Rule 23b(5) EPC 1973

Keyword: "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 consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?

3. If question 2 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 were lodged by the patent proprietor (appellant I) and the opponent (appellant II) against the interlocutory decision of the opposition division according to which European patent No. 1 211 926, published as WO 01/13708, could be maintained in amended form.

The opposition division decided on the proprietor's then main request and auxiliary requests I, II and IIIb. It found that the subject-matter of claims 1 to 14 of the main request was excluded from patentability by Article 53(b) and Rule 23b(5) EPC 1973, that claim 1 of auxiliary request I did not meet the requirements of Article 123(2) and (3) EPC and that claims 1 and 2 of auxiliary request II lacked novelty contrary to the requirements of Article 54 EPC. However, claims 1 and 2 of auxiliary request IIIb were found to meet all the requirements of the EPC.

II. With its grounds of appeal, appellant I requested that the decision under appeal be set aside and the patent maintained on the basis of claims 1 to 17 of the main request, which was identical to the main request before the opposition division, or on the basis of one of auxiliary requests I to V.

Claim 1 of the main request reads:

"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 fruit to remain on the vine past the point of normal ripening; and

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

Compared with claim 1 of the main request, claim 1 of auxiliary request I additionally contains the following features at its end:

"... crossing plants derived from hybrid seeds whose progeny show reduced fruit water content with a *Lycopersicon* plant;

growing the crossed plants; and

selecting plants with tomato fruits having an increased dry weight percentage as compared to fruit from a non-crossed *Lycopersicon*."

Claims 15 to 17 of the main request correspond to claims 14 to 16 of auxiliary request I and read:

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

16. 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.

17. A tomato plant having the tomato fruit of claim 15 or 16 on the vine."

III. With its grounds of appeal, appellant II requested that the decision under appeal be set aside and the patent revoked. In addition, refund of the appeal fee was requested on the ground that the opposition division had committed a substantial procedural violation by allowing appellant I's auxiliary request IIIb, which had only been filed during the oral proceedings, into the procedure.

IV. In its interlocutory decision dated 22 May 2007 in appeal case T 83/05 (OJ EPO 2007, 644), the present board, in a different composition, decided to refer two questions of law concerning the interpretation of Article 53(b) and Rule 23b(5) EPC 1973 to the Enlarged Board of Appeal. The questions read as follows:

"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?"

V. In the present case the parties were summoned to oral proceedings to take place on 19 September 2007. In the accompanying communication, the board mentioned the above referral decision T 83/05 and informed the parties that the forthcoming oral proceedings would be limited to the issue of a possible further referral of questions of law to the Enlarged Board.

VI. In a letter dated 16 July 2007, appellant I submitted an additional auxiliary request VI. In a further letter dated 27 August 2007, it proposed referring the following question to the Enlarged Board:

"Is the feature 'consists entirely of natural phenomena' as contained in Rule 23b(5) EPC meant to exclude from patentability only breeding methods in which the trait to be selected for is essential for conferring an advantage in the survival of the plant in a natural environment?"

Moreover appellant I suggested referring the same question 2 as in case T 83/05 to the Enlarged Board with the proviso that the introductory phrase "If question 1 is answered in the negative," (see above, Section IV) be deleted.

VII. In a letter dated 29 August 2007, appellant II requested that three questions be referred to the Enlarged Board. The first of these read:

"Is Rule 23(5)b [sic] limited to biotechnological inventions only and if so what are the requirements for an invention to qualify as an [sic] biotechnological invention?"

The two further questions corresponded to questions (1) and (2) in case T 83/05, apart from the addition to question (1) of the words "..., even if the technical feature is not a biotechnological feature?" at its end.

VIII. Oral proceedings were held on 19 September 2007.

Appellant I proposed referring not only the two questions suggested in its written submissions (see above, section VI) but also the following further questions to the Enlarged Board:

"3. Is a non-microbiological (alternatively: Is an essentially biological) process for the production of plants which contains the steps of crossing and selecting of plants excluded from patentability under Article 53(b) EPC only if the direct product obtained by such a process is a specific, individual plant variety?

4. If question 1 is answered in the positive, does a feature of a technical nature include such features that are not technical as such but contribute to a technical solution in conjunction with the remainder of the features of the claims?"

Appellant II referred to the questions proposed in its written submissions (see above, section VII) and furthermore requested that, in view of product claims 15 to 17 of the proprietor's main request, a further question concerning the interpretation of the exclusion of plant varieties should be referred to the Enlarged Board.

At the end of the oral proceedings the chair announced that the debate on the only issue of the oral proceedings, namely whether, and if so, which questions would be referred to the Enlarged Board, was closed and that the procedure was to be continued in writing.

On 21 September 2007, i.e. two days after the oral proceedings, the board received a letter from appellant II which contained further submissions concerning the referral of questions to the Enlarged Board.

IX. The submissions by appellant I, as far as they are relevant to the present decision, may be summarised as follows:

- The term "essentially biological processes" in Article 53(b) EPC was not unambiguous. It had not been the intention of the legislator to exclude all processes for producing plants that involve biological steps. Patentability exclusions were to be construed narrowly since they constituted exceptions to a general rule. While plant varieties could at least be protected by plant breeders' rights, no *sui generis* protection system existed for plant breeding processes. A broad interpretation of the process exclusion in Article 53(b) EPC would enlarge the protection gap.

- Any technical step or feature having an impact on the desired result should allow the claimed process to escape the exclusion. Therefore, a process containing at least one technical feature which could not be implemented without human intervention and which had an impact on the product of the process did not fall under the term "essentially biological process".

- The terms "essentially biological" and "consists entirely of natural phenomena" in Rule 23b(5) EPC 1973 were not contradictory. Crossing and selection could either be natural or not. Non-natural crossing and selection steps were those that were carried out with a technical element based on human influence or based on a man-established criterion in contrast to a natural force.

- The interspecies crossing between *L. esculentum* and a wild tomato species required special intervention in order to reach a reliably fertile offspring and would not occur in nature since individuals belonging to separate species are generally not capable of interbreeding.

- Allowing the fruit to remain on the vine past the point of normal ripening and screening for reduced water content constituted a further essential deviation from classical breeding methods, where the tomato fruit is generally

analysed when it is ripe. This additional step was neither a breeding nor a selection step, rather it prepared the tomato fruit for being susceptible for selection.

- The selection criterion of capability of dehydration was not a natural one since tomatoes expressing this phenotype had no evolutionary advantage in any given environment over corresponding plants not expressing it.

- Claim 1 of auxiliary request I referred to the selection of plants with tomato fruits having an increased dry weight percentage. This implied an additional technical step wherein fruit samples are first weighed fresh, then dried in an oven and weighed again in their dried state.

X. The submissions made by appellant II before and during the oral proceedings, as far as they are relevant to the present decision, may be summarised as follows:

- The legislator had decided to exclude from patentability all conventional breeding techniques based on crossing and selection. This followed from the legal fiction in Rule 23b(5) EPC 1973 which qualifies them as "natural phenomena". Nevertheless, natural selection occurring without any human intervention according to the principle of Darwinian survival was very different from what happened in closed glasshouses, where plants were bred in the absence of any competition with other species and where natural selection criteria did not apply. In fact, almost anything bred under "glasshouse conditions" would not survive in nature. Thus conventional plant breeding depended on human intervention, but was nonetheless excluded from patentability.

- Contrary to the process claimed in case T 83/05, which required the use of molecular markers, the method in the present case did not require any human intervention other than crossing and selection. All the process steps cited by appellant I, namely the interspecies crossing between *L. esculentum* and a wild tomato species, allowing the fruit to remain on the vine past the point of normal ripening, screening for reduced fruit water content as well as weighing and drying, were clearly part of crossing and selection as carried out by a skilled person in a conventional breeding process.

- It could not have been the intention of Rule 23b(5) EPC 1973 to change the ratio of Article 53(b) EPC in such a way as to make normal breeding processes patentable. The only way to reconcile the intentions of the legislator was to assume that only breeding processes also containing a biotechnological step in addition to crossing and selection would escape the exclusion of Article 53(b) EPC.

- Product claims 15 to 17 of the main request were excluded under Article 53(b) EPC as relating to plant varieties. In decision G 1/98 (OJ EPO 2000, 111), the Enlarged Board had concluded that a claim wherein specific plant varieties were not individually claimed was not excluded even though it might embrace plant varieties. The plants considered by the Enlarged Board in this decision were the products of genetic engineering techniques. It was still an open issue whether the Enlarged Board's rulings should also apply to plants produced by conventional breeding techniques. It was therefore appropriate to refer a corresponding question to the Enlarged Board.

Reasons for the decision

Written submissions after closing of debate

1. The written submissions contained in appellant II's letter dated 21 September 2007 were filed two days after the board had closed the debate on the issue whether and, if so, which questions were to be referred to the Enlarged Board. Since the board does not consider it appropriate to reopen the debate on this issue, these submissions will be disregarded for the purposes of the present decision.

*Exclusion of essentially biological processes for the production of plants**General*

2. The central issue of the present case is the interpretation of the process exclusion contained in Article 53(b) EPC. The decision under appeal held that the subject-matter of claim 1 of appellant I's main request was an essentially biological process for the production of plants and therefore excluded from patentability by Article 53(b) and Rule 23b(5) EPC 1973. Appellant I contests this conclusion and takes the view that, if properly construed in the light of Rule 23b(5) EPC 1973 (= Rule 26(5) EPC), Article 53(b) EPC does not prohibit the patenting of the subject-matter of claim 1 of the main request or of auxiliary request I.

3. In case T 83/05, this board in a different composition referred two questions of law relating to the exclusion of essentially biological processes for the production of plants to the Enlarged Board of Appeal (see above, section IV). In its referral decision the board reviewed in some detail the relevant legislative history of Article 53(b) EPC (points 38 to 42 of decision T 83/05) and the pertinent appeal case law (points 43 to 47). Moreover, the board considered the possible impact of Rule 23b(5) EPC 1973 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). In points 60 to 61 of decision T 83/05 the board expressed its view that the correct approach for the interpretation of Article 53(b) EPC was still to be determined. The referral is currently pending before the Enlarged Board under reference number G 2/07.

4. It would not be appropriate for this board to decide on the scope of the exclusionary provision in the present case before the Enlarged Board has given its answer to the questions referred to it in decision T 83/05. In such a situation the board may either stay the proceedings or, if the requirements set out in Article 112 EPC are fulfilled, again refer questions of law to the Enlarged Board. The board opts for the second alternative since the present case, compared with the case underlying decision T 83/05, contains further aspects of possible relevance for the interpretation of the exclusionary provision.

Subject-matter of claim 1 of main request and first auxiliary request

5. Claim 1 of appellant I's main request relates to a method for breeding tomato plants that produce tomatoes with reduced fruit water content. The method contains steps of crossing, collecting, growing, pollinating and selecting. The initial crossing is made between a *Lycopersicon esculentum* plant and a plant of a *Lycopersicon* spp. to produce hybrid seed. Plants are grown from the first generation of hybrid seeds, the plants of the most recent hybrid generation are pollinated and the seeds produced are collected. Plants are again grown from the seeds of this most recent hybrid generation. This is followed by a final step, i.e. allowing the fruit to remain on the vine past the point of normal ripening and screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin.

6. Claim 1 of appellant I's first auxiliary request corresponds to claim 1 of the main request but adds additional crossing and selecting steps. Plants derived from hybrid seeds whose progeny show reduced fruit water content are crossed with a *Lycopersicon* plant. From the plants obtained, those are selected which bear tomato fruits having an increased dry weight percentage as compared with fruits from a non-crossed *Lycopersicon*.

Interpretation of Article 53(b) EPC in decision T 320/87

7. The exclusion of essentially biological processes for the production of plants has been considered by the boards of appeal on several occasions. In decision T 320/87 (OJ EPO 1990, 71, points 4 to 10 of the reasons), which is the most pertinent for the present case, the board 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. The necessity for human intervention alone was not regarded as a sufficient criterion for its 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.

8. If this interpretation (called the "traditional" approach in decision T 83/05) were still the correct one, the subject-matter of claim 1 of appellant I's main request and auxiliary request I would not, in the view of the board, escape the exclusion. The arguments put forward by appellant I in order to show that the claimed method requires a high level of human intervention cannot alter the conclusion that the essence of the claimed method is "classical" plant breeding technology. Neither the necessity of an interspecific cross nor the choice of an unusual selection criterion nor the existence of technical steps such as weighing and drying take the claimed method outside the realm of classical plant breeding technology which frequently uses corresponding elements of human intervention.

Possible impact of Rule 26(5) EPC

9. However, it is the position of appellant I that the traditional approach as set out in decision T 320/87 has to be modified in the light of the interpretative provision of Rule 26(5) EPC. This provision was introduced as Rule 23b(5) EPC 1973 by the decision of the Administrative Council of the EPO of 16 June 1999 implementing Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions ("Biotech Directive"). The decision entered into force on 1 September 1999, i.e. before the filing date of the patent in suit (4 July 2000). Rule 26(5) EPC is identical with Article 2(2) Biotech Directive and provides that a process for the production of plants is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

10. The wording of Rule 26(5) EPC is difficult to understand in so far as it mentions crossing and selection as examples of natural phenomena. On the one hand, the systematic crossing and selection as carried out in traditional plant breeding would not occur in nature without the intervention of man. On the other hand, it is hardly conceivable that the terms "crossing" and "selection" in Rule 26(5) EPC are intended not to refer to plant breeding at all but only to purely natural events taking place without human control. This would be irreconcilable with the expression "processes for the production of plants" (German version: "Verfahren zur Züchtung von Pflanzen", French version: "procédés ... d'obtention de végétaux") in Article 53(b) EPC which implies at least some kind of human intervention and would furthermore have the awkward consequence of restricting the scope of the exclusion to subject-matter which, owing to its complete lack of technical character, does not qualify as an invention anyway, so that there would be no need to exclude it from patentability by an explicit provision. Therefore the mere fact that a claimed process requires **some kind** of human intervention is not, even in the light of Rule 26(5) EPC, sufficient to take the process outside the patentability exclusion. The crucial issue is rather to determine **what kind** of human intervention is required.

11. Appellant I takes the view that the legislative intention of Rule 26(5) EPC is to exclude some, but not all, plant breeding processes consisting of steps of crossing and selection. The exclusion should only apply if the claimed steps reflect and correspond to phenomena which could occur in nature without human intervention. Appellant I put forward two specific arguments why the claimed method belongs to the second group of processes. First, the interspecies crossing between *L. esculentum* and a wild tomato species required special intervention in order to reach a reliably fertile offspring and would not take place in nature since generally individuals belonging to separate species were not capable of interbreeding. Second, selection for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin would not occur in nature since tomatoes expressing this phenotype had no evolutionary advantage in any given environment over corresponding plants not expressing it.

12. If the legal interpretation of Article 53(b) and Rule 26(5) EPC advocated by appellant I were to be followed, the board would consider at least the first of the two arguments set out above to be persuasive, due to the absence of any evidence in the file showing that said interspecies crossing is possible without human intervention. This would have the consequence that the subject-matter of claim 1 of appellant I's main request and auxiliary request I would escape the patentability exclusion. Determining the correct legal approach is thus decisive for the applicability of the provision in the present case. A corresponding question 1 is therefore referred to the Enlarged Board of Appeal.

13. In a supplementary line of argument, appellant I suggests that, in the light of Rule 26(5) EPC, a plant breeding process based on crossing and selection does not fall under Article 53(b) EPC if it contains, as a further step or as part of the steps of crossing and selection, an additional feature of a technical nature.

In the present case, the plant breeder had to allow the fruit to remain on the vine past the point of normal ripening and thus to deviate from normal breeding methods where the tomato fruit was generally analysed when it was ripe. This constituted an additional technical step by which the tomato fruit was prepared for being susceptible for selection. Moreover, claim 1 of the first auxiliary request referred to the selection of plants with tomato fruits having an increased dry weight percentage, which implied a further technical step wherein fruit samples are first weighed fresh, then dried in an oven and weighed again in their dried state.

14. The board does not consider the step of allowing the fruits to remain on the vine past the point of ripening to qualify as technical, since it is characterised by an abstention, albeit deliberate, from human intervention. However, the board accepts that the determination of the dry weight percentage of fruits, including the drying and weighing, is an implicit feature of claim 1 of auxiliary request I and as such constitutes a technical step. The allowability of this claim thus depends on the merits of appellant I's supplementary line of argument, i.e. on the suggestion that a plant breeding process based on crossing and selection escapes Article 53(b) EPC if it contains, as part of the steps of crossing and selection, an additional feature of a technical nature. The board therefore considers it appropriate to refer the further questions 2 and 3, which correspond to questions 1 and 2 of referral decision T 83/05, to the Enlarged Board.

15. Both parties have made additional suggestions for a possible interpretation of Article 53(b) EPC in the light of Rule 26(5) EPC. On the one hand, appellant I argued that a plant breeding process should only be excluded if its directly obtained product is a specific individual plant variety. On the other hand, appellant II considered that Rule 26(5) EPC should be limited to biotechnological inventions in distinction to traditional plant breeding. Since the board is unable to find sufficient support for either of these interpretations in the legislative provisions or in the relevant case law, it refrains from referring corresponding specific questions to the Enlarged Board. Moreover it is noted that question 3 is formulated broadly enough to allow the Enlarged Board to take up the appellants' suggestions if it considers this to be appropriate.

16. As explained above, the questions to be referred concern an important point of law since they determine the applicability of the process exclusion of Article 53(b) EPC in the light of the interpretative provision of Rule 26(5) EPC. The answer to them is decisive for the outcome of the present case. The opposition division did not examine the method claims 1 to 14 of the main request with respect to any other ground of opposition. It thus does not appear to be possible to deal with them (or to remit the case to the department of first instance) before taking a decision on the sole reason for which they were considered unallowable.

Exclusion of plant varieties

17. In view of product claims 15 to 17 of the main request, appellant II suggested referring an additional question of law concerning the exclusion of plant varieties by Article 53(b) EPC. However, in its decision G 1/98 (OJ EPO 2000, 111) the Enlarged Board has already dealt extensively with the interpretation of this exclusion. Although, as correctly pointed out by appellant II, a technological distinction may be made between plant genetic engineering and traditional plant breeding, the decision provides sufficient guidance for the examination of the product claims in the present case. In particular, the Enlarged Board made the following observations (point 5.3 of the reasons):

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

In view of these observations, the board does not consider a further decision of the Enlarged Board on the scope of the exclusion of plant varieties to be required in accordance with Article 112(1)(a) 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 consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?

3. If question 2 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?