epi

Institut der beim Europäischen Patentamt zugelassenen Vertreter

Institute of Professional Representatives before the European Patent Office

Institut des mandataires agréés près l'Office européen des brevets

The President

The Chairman,
The Enlarged Board of Appeal,
The European Patent Office,
Erhardtstrasse,
Munich,
Germany

EPO - Munich
23
07. Jan. 2008

4th January, 2008

Dear Sir,

Amicus Curiae brief in G 2/07

I attach for your consideration an Amicus Curiae brief in respect of the above-referenced reference to the Enlarged Board. If you would like any further input in writing or orally, epi would be pleased to provide such.

epi looks forward to the publication of the Enlarged Board's opinion on the referred questions.

Yours sincerely,

Chris P. Mercer
President

Chris P. Mercer
c/o epi Secretariat . P.O. Box 260112 • D-80058 München
Phone +49 (89) 242052-0 • Fax +49 (89)242052-20
Direct Phone: +44 207 242 8692 • Carpmaels & Ransford/London
Direct e-mail: cpm@carpmaels.com

AMICUS CURIAE BRIEF SUBMITTED BY EPI IN THE CASE OF G 2/07

ESSENTIALLY BIOLOGICAL PROCESSES

epi is highly interested in the questions presented to the Enlarged Board of Appeal in the case of G 2/07 and therefore presents its position in relation to the patentability of inventions pertaining to essentially biological processes for the production of plants.

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1. Introduction

The claims

1. Claim 1 in the Main Request discussed in the oral proceedings before the referring Technical Board of Appeal read as follows:

"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 elevated 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, 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."

The Questions

2. Two questions have been referred to the Enlarged Board of Appeal in case T 0083/05.[1] These questions are the following:

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 1973 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 1973 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?

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[1] T 0083/05, Broccoli/Plant Bioscience, decision of Technical Board of Appeal 3.3.04 de dato 22 May 2007, not yet published in OJ EPO.

2. Summary of the arguments

3. Exceptions to patentability are in general interpreted narrowly. In the present case, there is good cause to interpret the exclusion in Article 53(b) and Rule 23b(5) EPC 1973 narrowly. In particular, Rule 23b(5) EPC itself suggests a narrow interpretation of Article 53(b) EPC.

4. In the view of ***epi***, a process for the production of plants is only excluded from patentability on the basis of being an essentially biological process under Article 53(b) and Rule 23b(5) EPC 1973 if it consists entirely of natural phenomena[2]. As soon as a technical step is involved in the process, other than the use of a technical device to facilitate the natural phenomena, the process is no longer excluded from patentability under Article 53(b) and Rule 23b(5) EPC.

5. There is no contradiction between Article 53(b) EPC 1973 and Rule 23b(5) EPC 1973. Contrary to the suggestion of the referring Board, the Travaux Préparatoires (Travaux) do not suggest more than saying that biological processes are excluded from patentability. If there is a technical step involved in the process, other than by the use of a technical device to facilitate the natural phenomena, the process is no longer excluded from patentability. Rule 23b(5) EPC 1973 is actually referring to the same thing when it says that "... essentially biological processes are processes which consist entirely of natural phenomena such as [...]".

6. The difference in wording between "essentially biological" and "entirely" is, taking into account the above, not as contradictory as it might seem at first glance, as it seems that the legislator of Article 53(b) EPC 1973 apparently wanted to preclude that, in essence, biological processes would not become excluded from patentability by the mere use of a technical device to facilitate the natural phenomena. This is neither narrower nor broader than saying that biological processes which consist entirely of natural phenomena (= biological steps) are excluded from patentability.

7. In the view of ***epi***, after having analysed carefully the case law pertaining to Article 53(b) EPC 1973 and in particular the issue of the non-patentability of essentially biological processes for the production of plants, it must be concluded that earlier Technical Boards of Appeal had no just cause to read into Article 53(b) EPC 1973 what they have read into it.

8. Further support for the conclusion that a process which contains at least one technical step should not be excluded from patentability on the basis of Article 53(b) and Rule 23b(5) EPC 1973 is found in practice and case law in other fields of technology, such as e.g. computer implemented inventions. Practice in that field is that an invention is not excluded from patentability under Article 52 EPC 1973 if it contains a technical step, whatever the nature of that technical step and whether or not it makes an inventive contribution to the invention.

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[2] ***epi*** understands "natural phenomena" in the present case to refer to the conventional plant breeding techniques which were in common use before the development of techniques for genetic manipulation.

9. Rule 23b(5) EPC 1973 lays down the proper standard for interpreting Article 53(b) EPC 1973. This is even more so in view of developments in case law in the last 10 years in other fields of technology.

10. The standard laid down in earlier case law such as T 320/87 is, as explained above, based neither on a thorough analysis of the Travaux nor on a teleological interpretation of Article 53(b) EPC 1973.

11. In the view of ***epi***, Question 1 is to be answered in the affirmative.

12. In the view of ***epi***, the answer to Question 1 should be in the affirmative and hence there should be no reason to answer Question 2. However, ***epi*** is concerned about the consequences which would ensue for this field of technology were the Enlarged Board to decide, contrary to the view of ***epi***, that Question 1 should be answered in the negative. Therefore ***epi*** also wishes to comment on Question 2.

13. Assuming that the answer to Question 1 is given in the negative, the criterion for determining whether a process is essentially biological could then never be that it consists of only biological/natural process steps. A solution must hence be found elsewhere.

14. ***epi*** believes that a narrow interpretation should be given to Article 53(b) EPC 1973. It is therefore necessary to interpret the exclusion as narrowly as possible. Starting from that premise, ***epi*** is of the opinion that only those non-biological steps which are entirely trivial, i.e., which have no influence whatsoever on the end-product made nor in essence on the way how the end-product is produced, would not be capable of bringing such a process outside the realm of Article 53(b) and Rule 23b(5) EPC 1973. As soon as a non-biological step has an influence on the end-product made or in essence on the way how the end-product is produced, however limited this influence may be, then such invention is no longer essentially biological.

3. Analysing Question 1

3.1. Legislative history of Article 53(b) EPC 1973

15. Article 53(b) EPC 1973 says:

> *"Article 53*
> *Exceptions to patentability*
> *European patents shall not be granted in respect of:*
> *[...];*
> *(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."*

16. In order to understand properly the meaning and scope of Article 53(b) EPC 1973, it is useful to look at the legislative history of the Article.

17. For purposes of this Amicus Curiae Brief, in particular, the wording "essentially biological processes for the production of plants" is of interest.

18. The decision of the Technical Board of Appeal in case T 0083/05 was most helpful in reminding us of the legislative history:

> *"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. ...]*
> *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.*
>
> *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."*[3]
>
> *"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".*[4]
>
> *"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*

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3 T 0083/05, point 39 of the reasons.

4 T 0083/05, point 40 of the reasons.

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."[5]

3.2. What did the legislator intend to regulate?

19. What does this overview of the legislative history of Article 53(b) EPC 1973 teach us? It cannot be denied that the legislator in the process exchanged the wording "purely biological" for the wording "essentially biological". Even though this is a clear fact, finding out what was the exact rationale for this change in wording is less easy to evaluate. In the view of the referring Board in case T 0083/05:

> *"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."*[6]

20. ***epi*** cannot fully agree with the conclusions drawn by the referring Board. The change of wording is probably less clear and easy to explain than one might think at first glance. In the view of ***epi***, Article 53(b) EPC 1973, despite the fact that the wording has been amended in the legislative process, clearly shows that it was not the intention to exclude from patentability subject matter which involved human intervention.

21. ***epi*** suggests that the example given in the Travaux, clarifying the rationale for changing the wording from "purely" to "essentially", sheds a clearer light on the intentions and motives of the legislator. "Purely biological processes are excluded from patentability. This would be no different if technical devices are used in carrying out such biological processes."

22. Contrary to the interpretation given by the referring Board, the clarification given in the Travaux does not give rise to an interpretation which goes further than saying that biological processes without more are excluded from patentability.

23. Interestingly, the Travaux refer to the use of technical devices as secondary features of otherwise biological processes. The legislator has thus left us with some degree of uncertainty as to why the wording was changed from "purely biological" into "essentially biological" processes. If one reads the above-cited commentary, one inevitably gets the impression that the use of a technical device in an otherwise purely biological process cannot render the process non-biological. Such reasoning sounds logical, as the use of a technical device to perform certain activities does not change in any way the nature of the process for the production of plants. If the process is in essence biological, the use of a technical device is not

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5 T 0083/05, point 40 of the reasons.

6 T 0083/05, point 42 of the reasons

capable of rendering such process non-biological, even though the process may no longer be purely biological and is hence an "essentially biological" process.

24. If such is the rationale for changing the words "purely" into "essentially", then it could be concluded that the broader scope given to the change of wording during the legislative process by the referring Board is not based on firm ground and should consequently not be followed as a standard of interpretation of Article 53(b) EPC 1973.

25. In the view of ***epi***, it can be concluded that processes which go beyond being purely biological are not excluded from patentability under Article 53(b) EPC 1973. That is the case if there is a technical step involved in the process. However, if the only technical feature is the use of a technical device for an otherwise biological process, such process is excluded from patentability under Article 53(b) EPC 1973.

3.3. Legislative history of Rule 23b(5) EPC 1973/Article 2(2) of the Biotech Directive

26. Once again, in order to get a better understanding of the exact meaning and rationale of Rule 23b(5) EPC 1973, an overview of the legislative history of the Rule seems to be very useful. Again, the decision of the referring Board in T 83/05 is most helpful in providing ***epi*** with such an overview.

27. Rule 23b(5) EPC 1973 reads:

> *"Rule 23b*
> General and definitions
> [...]
> (5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

28. Also in this respect, the decision of the referring Board in T 0083/05 is most helpful in providing a useful overview of the legislative history of Rule 23b(5) EPC 1973. Explaining Rule 23b(5) EPC 1973 implies explaining corresponding Article 2(2) of Directive 98/44/EC (hereinafter called the Biotech Directive), as Rule 23b(5) EPC 1973 is a literal transposition of Article 2(2) Biotech Directive into the EPO legal system.

29. The Technical Board of Appeal summarized the legislative history of Article 2(2) Biotech Directive as follows:

> *"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."

"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."

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)."[7]

30. What is clear from this overview is first that it is rather difficult to evaluate the precise underlying reasons the European legislator might have had to make the wording as it reads today. What is clear, however, is that the European legislator clearly had in mind to give a narrow interpretation to the exclusionary provision of the concept "essentially biological processes for the production of plants". This stems clearly from the fact that, during the legislative process, the definition has been narrowed down consequently.

31. This was also the view of the referring Board in T 0083/05 when it held that:

"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

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[7] T 0083/05, points 51-52 of the reasons.

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."[8]

32. The EPO Guidelines also refer to the definition of essentially biological processes for the production of plants as expressed in Rule 23b(5) EPC 1973:

> *"A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. To take some examples, a method of crossing, inter-breeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth e.g. a method of pruning a tree, would not be essentially biological since although a biological process is involved the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability (see also IV, 4.2.1)."*[9]

33. Looking back at the legislative history and to the wording of Rule 23b(5) EPC 1973, it can be said that what it says is that if the process contains a step which is not purely biological, then the process is not excluded from patentability, which was also the view of the referring Board in T 0083/05.

34. In this context, the wording "crossing or selection" in Rule 23b(5) EPC 1973 should be interpreted as only those crossing and selection steps which occur in nature, i.e., without human intervention. Processes which contain steps which do not occur in nature, i.e., which require human intervention, do not fall within the scope of Rule 23b(5) EPC 1973, and hence also not under Art. 53(b) EPC 1973.

35. As will be seen further in this Amicus Curiae Brief, such a narrow interpretation is nothing out of the ordinary. In other fields of technology, such as computer implemented inventions, similar problems have arisen in respect of multi-step processes which contain both technical and non-technical steps. The established case law in these fields of technology has also decided to give a very narrow interpretation to the exclusionary provision of Article 52 EPC 1973 by holding that, as soon as a technical feature, of whatever nature, is included in the invention, it is not excluded from patentability. In determining whether an invention is excluded from patentability, there is no need to make an evaluation of the level or influence of the technical step. The case law relating to computer-implemented inventions further holds in this respect that in determining inventive step, only technical features are taken into account. In other words, in order to determine whether certain subject matter is excluded from

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[8] T 0083/05, point 54 of the reasons.

[9] EPO Guidelines C IV, 3.4.2 (June 2005)

patentability, all features are taken into account, irrespective of their inventive contribution. If there is a technical step/feature present, the invention is not excluded from patentability. In determining, however, whether such an invention has an inventive step, only technical features are taken into account.

36. A similar reasoning seems to be logical to apply in the present case.

3.4. Interpretation of Article 53(b) EPC 1973 in the light of Rule 23b(5) EPC 1973

37. The referring Board has seen a contradiction between the provision of Article 53(b) EPC 1973 and Rule 23b(5) EPC 1973. ***epi*** cannot agree with this conclusion. In the view of ***epi***, there is no conflict between the two provisions, provided a proper interpretation is given to them.

38. As has been said earlier in this Amicus Curiae Brief, a proper interpretation of Article 53(b) EPC 1973 in the light of its legislative history, is that it excludes from patentability only those processes which are biological. The legislator apparently meant to say that any process which remains in essence biological, but wherein technical devices are used, remains excluded from patentability as being essentially biological. If this line of reasoning is followed, the situation for a process which does not embrace the use of a technical device in an otherwise biological process is different from a process which includes a technical, non-biological step. This leads to the inevitable conclusion that, in the latter case, the process does not remain in essence biological and is not excluded from patentability.

39. Reading the Travaux, one gets the impression that the legislator at that time, by changing the wording "purely" into "essentially", intended to prevent the avoidance of the exclusion by adding the use of a technical device to the process. What cannot be deduced from the comments of the legislator is that it was the clear intention of the legislator to expand the scope of the exclusionary provision into the realm of non-biological process steps, i.e., leading to a process which in essence is not entirely biological, but which contains non-biological steps.

40. Looking at the comments given in the Travaux as a justification for changing the wording from "purely" into "essentially" leads to the conclusion that there is no apparent contradiction between Article 53(b) EPC 1973 and Rule 23b(5) EPC 1973. What Rule 23b(5) EPC 1973 has tried to regulate is that, if a process for the production of plants contains steps which are not entirely natural (=biological), the exclusionary provision no longer applies. The inclusion of non-biological steps in a process for the production of plants changes the nature of the process from being purely and in essence biological to a mixed process, containing biological and non-biological steps. This seems to be in conformity with what the legislator meant when it said that a process remains biological if the only feature which is added is the use of a technical device, as such use would not otherwise change the biological nature of the process. The use of a non-biological step does, however, change the nature of a process for the

production of plants, as it can at least be considered to be a mixed process, containing biological and non-biological steps.

41. The difference in wording between "essentially biological" and "entirely" is, taking into account the above, not as contradictory as it might seem at first glance. It seems that the legislator of Article 53(b) EPC 1973 apparently wished to ensure that essentially biological processes should remain excluded from patentability even if a technical device is used in an otherwise biological process. This is neither narrower nor broader than saying that biological processes which consist entirely of natural phenomena (= biological steps) are excluded from patentability.

42. In the view of ***epi***, it can be concluded that processes which go beyond being purely biological are not excluded from patentability. That is the case if there is a technical step involved in the process. It is also the view of ***epi*** that upon a proper reading of Article 53(b) EPC 1973 and Rule 23b(5) EPC 1973 in the context of their respective legislative histories, there is no contradiction between or different scope to be attributed to these provisions.

3.5. TBA case law in respect of Article 53(b) EPC 1973 and why it does not establish a proper standard

43. A subsequent issue to resolve is to see to what extent the case law of the Technical Boards of Appeal in respect of Article 53(b) EPC 1973 is reconcilable with an interpretation of the Article in light of Rule 23b(5) EPC 1973 as ***epi*** suggests in this Amicus Curiae Brief.

44. As has been established earlier in this Amicus Curiae Brief, there is in the view of ***epi*** no contradiction to be found between the text and rationale of Article 53(b) EPC 1973 and Rule 23b(5) EPC 1973.

45. This might, however, be different if one interprets Article 53(b) EPC 1973 in the manner this has been done in earlier case law. The referring Board has also held in this context that the narrow interpretation of Rule 23b(5) EPC 1973 and the consequent narrow interpretation of Article 53(b) EPC 1973 would at least stand at odds with the interpretation given by Technical Boards of Appeal in case law as we know it today.[10] According to that case law, in order to determine whether a process is deemed to be essentially biological and hence excluded from patentability, one has to take the overall process into consideration, and evaluate the level of human intervention (see e.g. T 320/87, T 0356/93).

46. The question which follows from this is whether the interpretation given by the earlier case law of the Technical Boards of Appeal can be seen as a proper interpretation of Article 53(b) EPC 1973.

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[10] T 0083/05, points 54-55 of the reasons.

47. In the view of ***epi***, after analysing carefully the case law pertaining to Article 53(b) EPC 1973, and in particular the issue of the non-patentability of essentially biological processes for the production of plants, it must be concluded that earlier Technical Boards of Appeal had no just cause to read into Article 53(b) EPC 1973 what they have read into it.

48. One of the first cases where the issue of essentially biological processes for the production of plants was analysed was the Lubrizol case T 320/87.[11] The Board in that case came to the conclusion that Article 53(b) EPC 1973 requires the making of an overall evaluation of all steps involved and of the level of human intervention, on the basis of a rather limited analysis of the Travaux and rationale of Article 53(b) EPC 1973. The Board held in this context:

> *"Like any exception to a general rule of this kind the exclusion of "essentially biological" processes for the production of plants (or animals) has to be narrowly construed. This is underscored by the fact that this exclusion does not apply to microbiological processes or the products thereof, as also stated in Article 53(b) EPC. The Board takes the view that whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC has 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. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being "essentially biological". Human interference may only mean that the process is not a "purely biological" process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of a quantitative or qualitative character."*[12]

49. That Technical Board of Appeal admitted that the Travaux do not provide clear guidance as to the meaning of the term "essentially biological":

> *"Article 53(b) EPC represents in this respect an exception to the general provision of Article 52(1) EPC according to which European patents shall be granted for any inventions, which are susceptible of industrial application, provided they are new and involve an inventive step. The exception is modelled on Article 2(b) of the Strasbourg Patent Convention of 27 November 1963. There is in the preparatory documents no clear guidance as to the interpretation of the concept of "essentially biological". It has in this respect to be born in mind that at the time when the exception was drafted, the knowledge of the potential development in the field of biotechnology was rather limited."*[13]

50. Later case law apparently adopted the reasoning applied in the T 320/87 case, without much further consideration. In T 0356/93,[14] the Technical Board of Appeal held:

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[11] T 0320/87, Lubrizol/Hybrid plants, OJ EPO, 1990, 71.

[12] T 0320/87, point 6 of the reasons.

[13] T 0320/87, point 5 of the reasons.

[14] T 0356/93, PGS/Plant cells, OJ EPO, 1995, 545

"Article 53(b) EPC further excludes "essentially biological processes for the production of plants..." from patentability. The historical documentation shows that, when drafting Article 53(b) EPC, the EPC Working Party recognised that even if protection of new plant varieties and processes for producing new plants was to be excluded under European patent law, European patents still had to be granted for processes which, while applicable to plants, were of a technical nature (see document IV/2071/61-E, page 6, first paragraph). Processes for producing new plants by irradiation of the plants themselves or the seed with isotopes were cited as an example of such processes (ibid., loc.cit.). The board observes that the example given is one in which plants or seeds undergo genetic modifications due to irradiation.

In order to provide a distinction between inventions resulting from non-technical processes for the production of plants (e.g., essentially biological processes such as selective breeding), which were to be excluded, and inventions resulting from technical processes for the production of plants, which were considered patentable, the legislator introduced in Article 53(b), first half-sentence, EPC, the exclusion from patentability of "essentially biological processes for the production of plants...". As is derivable from the example given in the quoted document of the EPC Working Party (see point 25 supra), this provision gives rise to the legal consequence that processes of a technical nature for producing plants, including processes involving genetic modification of plants, are patentable. By virtue of Article 64(2) EPC, the protection conferred by a European patent to a process extends also to the products (e.g., plants) directly obtained by such a process."[15]

51. The Technical Board of Appeal in T 1054/96[16] in fact doubted whether that interpretation was actually accurate, and therefore referred questions relating to this issue to the Enlarged Board of Appeal. The Enlarged Board of Appeal, however, in case G 1/98[17] did not deem it necessary, in view of the answers given to the other questions, and in view of amendments made by the patent applicant to the claims so as to limit such claims to identifiable method steps in order to exclude essentially biological processes, to reply to this specific question,[18] and hence the matter remained unresolved.

52. Indeed, in the view of ***epi*** there is reason to doubt the validity of the reasoning developed by the Boards of Appeal in the abovementioned case law.

53. The Technical Board of Appeal in T 1054/96, where for the first time questions were asked whether the interpretation until then given by case law regarding Article 53(b) EPC 1973 was indeed justified or not, presented various hypothetical ways of interpreting the wording "essentially biological processes".

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[15] T 0356/96. points 25-26 of the reasons.

[16] T 1054/96. Novartis AG/Transgenic plant, OJ EPO, 1998, 511.

[17] G 1/98, Transgenic plant/Novartis II, OJ EPO, 2000, 111

[18] The issue of essentially biological processes for the production of plants was addressed in Question 1, which the Enlarged Board of Appeal decided not to analyse, in view of the answers already given to questions 2 and 4. See G 1/98, point 6 of the reasons.

24. In the phrase "essentially biological process", "biological" has been interpreted sometimes as contrasting with "technical" and sometimes as contrasting with "chemical" or "physical". Given that the trend of developments is that biological processes are becoming better understood and in that sense possibly more technical, while gene technology makes use of natural mechanisms and in that sense is biological, attributing a meaning to the term "essentially biological" in terms of the present technical developments is problematic.

25. To decide whether a process can be defined as an "essentially biological process" requires a value judgment of the extent to which it should be non-biological before it loses the status of "essentially biological process", which value judgement can be arrived at by different approaches.

26. One approach is analogous to that used under Article 52(4) EPC relating to methods of treatment by surgery and therapy. As stated for example in decision T 820/92 (OJ EPO 1995, 113) "in the case of a method involving administration of two or more substances, the question for the purposes of Article 52(4) EPC is not whether the main or even the only reason for carrying out the whole of the claimed method is non-therapeutic. Rather, a method claim falls under the prohibition of Article 52(4) EPC if the administration of one of the substances is a treatment by therapy, and the administration of this substance is a feature of the claim."

27. The consequences of such an approach would be that to be considered as "non essentially biological", the claimed process for producing plants should only comprise clearly identified non-biological process steps and no "essentially biological" steps (whatever uncertainties may be attached to the term). A process involving the crossing of two existing plants such as in claim 24 would not be allowable. This approach would have the advantage that it would be clear to applicants what steps to mention in a claim.

28. A second approach would be that adopted in decision T 320/87 (OJ EPO 1990, 71) where it was held that whether or not a process is to be considered as "essentially biological" has 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 (see point 6 of the reasons). The consequences of such an approach, as discussed in T 356/93 (loc. cit., see point 28 of the reasons), would be that "a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result does not fall under the exceptions to patentability under Article 53(b) EPC first half sentence." Following such an approach leaves it to the instances of the EPO to assess whether a claim as a whole is directed to an "essentially biological process for the production of plants". Its outcome could be relatively uncertain.

29. Yet another approach would require, for a process for the production of plants to escape the prohibition of Article 53(b) EPC with regard to essentially biological processes, 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. The definition given in the proposed EU directive Article 2 No. 2 adopts this approach. The definition is "A process for the production of plants or animals is essentially biological if it consists entirely of natural

phenomena such as crossing or selection". This approach would be that most favourable to applicants. It is not the approach so far adopted by the boards of appeal."[19]

54. What emanated from these hypotheses is that at least some of the propositions lean towards a narrow interpretation of Article 53(b) EPC 1973 which comes close to the interpretation suggested by ***epi*** in this Amicus Curiae Brief.

55. In light of the analysis made earlier in this opinion, it can be concluded that in the view of ***epi***, the interpretation given by the Technical Boards of Appeal in earlier case law of Article 53(b) EPC 1973 is not entirely understandable, and created a standard which cannot be inferred from the Article. The *obiter dicta* in T 1054/96 may be seen as an indication that serious doubts about the interpretation given to that part of Article 53(b) EPC 1973 referring to "essentially biological processes arise.

56. But even making abstraction of the question whether the Technical Boards of Appeal made a proper interpretation of Article 53(b) EPC 1973 and interpreted in this connection the Travaux correctly, it can in any event be said that this case law devised a standard which complicates matters for the patent granting authorities.

57. The standard laid down in case T 320/87 and others actually requires the making of an evaluation of the level of human intervention and the influence such intervention has on the end-result. Such an evaluation is difficult to make and is indeed inevitably rather subjective. It is furthermore not very practical to make such an evaluation in the context of determining whether certain inventions are excluded from patentability. It is the mission for Patent Offices to examine patent application in an objective manner. The standard laid down in case T 320/87 aims at introducing a subjective and impractical standard, not only difficult to apply in the examination phase, but also subjective, which leads to legal uncertainty.

58. As will be explained further in this Amicus Curiae Brief, in other fields of technology, such as computer-implemented inventions, there has been a clear evolution to go to a simple, objective and practical standard to evaluate whether an invention is excluded from patentability. In computer implemented inventions (hereinafter referred to as CII), current practice is that, as soon as technical steps are included in the invention, even if such technical steps do not contribute inventively to the invention but are a mere application of prior art, such invention is not excluded from patentability. The advantage of such a practice is that it avoids making a subjective evaluation as to whether the inclusion of a technical step and the nature of it will suffice to avoid the exclusion from patentability. Instead, as soon as a technical step is included, the invention avoids the exclusion from patentability. Whether such an invention fulfils the patentability requirements of novelty, inventive step, industrial application and enabling disclosure is obviously a different matter. Indeed, evaluating whether a certain step, and the level and nature of technicality contributes to the invention or not is and should be a matter to be solved under the other patentability requirements, and more in particular in many cases under the concept of inventive step.

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[19] T 1054/96, points 24-29 of the reasons.

59. Concluding, in the view of ***epi***, the standard applied by the Technical Boards of Appeal in earlier case law in determining when a process for the production of plants can be deemed to be excluded from patentability, for being an essentially biological process, was based on an interpretation of the text and rationale of Article 53(b) EPC 1973 which can be debated. Furthermore, the standard then developed also leads to legal uncertainty as it is complicated, subjective and impractical. For these reasons, ***epi*** is of the opinion that the Enlarged Board of Appeal should not follow the line of reasoning taken in that case law in answering the questions referred to it and it is suggested that the Enlarged Board should depart from the standards applied in the above cited case law in determining whether a process for the production of plants is excluded from patentability on the basis of being essentially biological.

60. A different standard, which in the view of ***epi*** finds support in both Article 53(b) EPC 1973, in particular in the preparatory works, and definitely in Rule 23b(5) EPC 1973 deserves to be applied, with the additional but not unimportant advantage that it constitutes a far more objective and practical standard for evaluating whether certain inventions are excluded from patentability.

61. This standard prescribes that as soon as a technical step is involved in the process, the process as a whole is inevitably a non-essentially biological process, as it does not consist of processes which are entirely natural. Whether such an invention fulfils the patentability requirements is obviously a different matter, which has to be solved under the well-established standards applied in determining whether such an invention fulfils the requirements for novelty, inventive step, industrial applicability and enabling disclosure.

62. This standard does justice to the wording of Rule 23b(5) EPC 1973, does not seem to be in conflict with Article 53(b) EPC 1973 upon a proper reading of the Travaux, and is in line with developments in recent case law in other fields of technology.

3.6. Support for the *epi* standard of review in case law pertaining to other fields of technology

63. Support for the point of view defended in this Amicus Curiae Brief can be found in practice and case law in other fields of technology, in particular in developments relating to computer-implemented inventions (hereinafter referred to as CII).

64. It has been argued that no such comparison can be made, as patentability of CII is an issue resolved under Article 52 EPC 1973, while the subject matter of the present referral is a matter to be resolved under Article 53(b) EPC 1973. It has been argued that both provisions have an entirely different finality. Whereas an analysis under Article 52 EPC 1973 is made to determine whether an invention, in the sense of being a technical invention, exists, an analysis under Article 53(b) EPC 1973 is made with the aid of a legal fiction, i.e., that such invention, which is in fact technical, is deemed to be excluded from patentability by a fiction of the law.[20]

[20] This was the view of the Technical Board of Appeal in case T 1054/96, see points 52-57 of the reasons.

65. It is argued in this Amicus Curiae Brief that such an interpretation is, apart from not being very productive, also not correct. Even though it can be admitted that a legal fiction is used to exclude plant varieties from patentability, for historical reasons,[21] the same cannot be said of essentially biological processes. It can readily be assumed that the legislator wanted to exclude such processes in fact for the specific reason that such innovations cannot be called technical inventions, as they consist of biological processes, occurring in nature.

66. The preparatory works give a clearer insight in this exclusion as shown earlier in this Amicus Curiae Brief. It was believed that apart from microbiological processes for the production of plants, which are expressly held not to be excluded from patentability, other processes were to be traditional breeding processes, consisting of biological, natural phenomena. Such methods cannot be deemed to be excluded from patentability by means of a legal fiction, i.e., being in fact technical inventions, but were deemed to be excluded from patentability exactly for the very reason that such processes do not fulfil the criterion of being a patentable technical invention. Indeed, excluding essentially biological processes from patentability finds its rationale in the fact that such innovations do not constitute technical inventions,[22] very much like the fact that other subject matter is excluded from patentability on the basis of being non-technical. In this context, it can be admitted that placing the exclusion of essentially biological processes in Article 53(b) EPC 1973 is probably not the most appropriate place for such exclusion, but is from a legislative point of view perhaps understandable, as the legislator wanted to concentrate exclusions pertaining to plants into one provision.

67. Hence, contrary to what has been argued in some case law, it seems to be most appropriate to look at developments in other fields of technology, even if such analysis would entail exploring inventions which have been deemed to be excluded from patentability under Article 52 EPC 1973.

68. As said, the area of CII seems to be a perfect example of how present EPO practice and case law looks upon the question of exclusions from patentability.

69. In determining patentability of CII, Article 52(2)(c) and 52(3) EPC 1973 are in issue. The central question to answer in this context is whether an invention pertaining to CII is deemed to be excluded from patentability. The central criterion in this context is that an invention must have technical character. There was a time when Technical Boards of Appeal held that in order not to be excluded from patentability, it is not only required that the invention has technical character, but was also required that in order not to be excluded from patentability, there must be a technical contribution to the art. This approach was also called the "technical

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[21] In particular to avoid double protection for plant varieties, which were at that time already protected by plant variety right protection, and the UPOV 1961 Convention allowed this opt-out choice.

[22] A similar view has been defended in the literature by e.g., BERGMANS, B., *La protection des innovations biologiques*, Larcier, Bruxelles, 1991, 94; MOUFANG, R., Protection for plant breeding and plant varieties, *NIR*, 1992/3, 347; GUTMANN, E., The protection of biotechnological inventions within the framework of the European Patent Organisation and, more particularly, in France, *Industrial Property*, 1991,382; CRESPI, R.S., Patents and plant variety rights: is there an interface problem?, *23 IIC*, 2/1992, 172.

contribution approach".[23] The idea behind the so-called contribution approach applied by earlier jurisprudence of the boards of appeal was that the EPC only permitted patenting

> *"in those cases in which the invention involves some contribution to the art in a field not excluded from patentability. In other words, for assessing the first requirement, ie the presence of an invention within the meaning of Article 52(1) EPC, a criterion was established which relied on meeting further requirements mentioned in that article, in particular novelty and/or inventive step. Thus, some prior art was taken into account when determining whether subject-matter was excluded under Article 52(2) and (3) EPC".*[24]

70. In more recent decisions of the Technical Boards of Appeal, it has been held that there is no further room for such analysis. As the Technical Board of Appeal in case T 0258/03 said:

> *"However, in more recent decisions of the boards any comparison with the prior art was found to be inappropriate for examining the presence of an invention: Determining the technical contribution an invention achieves with respect to the prior art is therefore more appropriate for the purpose of examining novelty and inventive step than for deciding on possible exclusion under Article 52(2) and (3)*[25]*. There is no basis in the EPC for distinguishing between 'new features' of an invention and features of that invention which are known from the prior art when examining whether the invention concerned may be considered to be an invention within the meaning of Article 52(1) EPC. Thus there is no basis in the EPC for applying this so-called contribution approach for this purpose.*[26]*. This view is shared by the Board in its present composition."*[27]

71. The central criterion that the invention must be technical is fulfilled as soon as there is a technical feature in the claimed invention, even if such technical feature belongs to the prior art, and even if the contribution to the art consists in non-technical features. In determining whether an invention is technical and hence not excluded from patentability, it suffices to establish that there is at least one technical feature present in the patent application. Whether such claimed invention fulfils all other patentability requirements of novelty, inventive step, industrial application and enabling disclosure is obviously a different matter.

72. In this line of reasoning, recent case law has also held that in determining whether the invention is inventive, only technical features are taken into account. In other words, if the contribution to the state of the art lies merely in non-technical features, the invention would not be inventive vis-à-vis the prior art.

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[23] E.g., T 0038/86, IBM/Text processing, OJ EPO 1990,384, headnote II.

[24] T 0258/03, Auction method/HITACHI OJ EPO 2004, 575, at 3.2 of the reasons.

[25] T 1173/97, IBM/Computer program product, OJ EPO 1999,609, point 8.

[26] T 0931/95, Controlling pension benefits system/PBS PARTNERSHIP, OJ EPO, 2001, 441, headnote IV.

[27] T 0258/03, at 3.3 of the reasons.

73. Case T 258/03 also expressly held that the principle that there is no room for the so-called contribution approach in evaluating whether an invention is excluded from patentability is applicable irrespective of the type of claim and hence also applies to method claims:

> *"However, in order to be consistent with the finding that the so-called "contribution approach", which involves assessing different patentability requirements such as novelty or inventive step, is inappropriate for judging whether claimed subject-matter is an invention within the meaning of Article 52(1) EPC, there should be no need to further qualify the relevance of technical aspects of a method claim in order to determine the technical character of the method. In fact, it appears to the Board that an assessment of the technical character of a method based on the degree of banality of the technical features of the claim would involve remnants of the contribution approach by implying an evaluation in the light of the available prior art or common general knowledge."*[28]

74. The evolution discussed in the case law of the Technical Boards of Appeal in respect of CII seems also logical. It corresponds to the rule of logic to say that if an invention comprises both technical and non-technical features, it is in any event to some degree technical. Whether such an invention is inventive is obviously an entirely different matter, but establishing whether this is or is not the case is preferably done with the aid of the respective patentability requirements, instead of making such evaluation at the stage of determining whether such an invention is excluded from patentability.

75. Any other solution would require that an evaluation is made of the degree and nature of the technical steps, and of the contribution of those technical steps to the resulting invention.

76. The Technical Board of Appeal in case T 258/03 also recognized that the only logical reasoning in order to determine whether an invention is excluded from patentability was to determine whether there are technical steps in the invention, and not whether the contribution in the art lies in a technical feature, which is an analysis to be made in the context of the other patentability requirements of novelty, particularly inventive step etc.:

> *"Moreover, it is often difficult to separate a claim into technical and non-technical features, and an invention may have technical aspects which are hidden in a largely non-technical context (cf point 5.8 below). Such technical aspects may be easier to identify within the framework of the examination as to inventive step, which, in accordance with the jurisprudence of the boards of appeal, is concerned with the technical aspects of an invention (cf point 5.3 below). Thus, in addition to the restrictive wording of Article 52(3) EPC limiting the applicability of Article 52(2) EPC, there may be practical reasons for generally regarding mixes of technical and non-technical features as inventions in the meaning of Article 52(1) EPC."*[29]

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[28] T 0258/03, 4.3 of the reasons

[29] T 0258/03, at 3.6 of the reasons.

77. That the mere fact that there are technical features present, even though it is sufficient to consider such inventions not to be excluded from patentability, does not take away that for the evaluation of inventive step the contribution must be in a technical field has also been clarified in the case law of the Technical Boards of Appeal. In case T 641/00,[30] it was held:

> *It is legitimate to have a mix of technical and "non-technical" features (i.e. features relating to non-inventions within the meaning of Article 52(2) EPC) appearing in a claim, even if the non-technical features should form a dominating part. Thus in T 26/86 X-ray apparatus/KOCH& STERZEL, (OJ EPO 1988, 19) a mix of technical and non-technical features was considered as a matter of principle, to be patentable even if the technical was not the dominating part of the invention. As reasoned by the board, "the teaching (might, otherwise, be made) unpatentable in its entirety if the greater part is non-technical and even though the technical aspect which is found to be subordinate is in fact judged to be novel and to involve inventive step" (see paragraph 3.4 of the decision). It follows that the board, although allowing a mix of technical and non-technical features to be claimed, considered the technical part of the invention as the basis for assessing inventive step.*[31]
>
> *For the purpose of the problem-and-solution approach, the problem must be a technical problem, it must actually be solved by the solution claimed, all the features in the claim should contribute to the solution, and the problem must be one that the skilled person in the particular technical field might be asked to solve at the priority date. In this context "problem" is used merely to indicate that the skilled person is to be considered as faced with some task (German "Aufgabe"), not that its solution need necessarily involve any great difficulty. [...]If no technical problem can be derived from the application, then an invention within the meaning of Article 52 EPC does not exist (see decision T 26/81, OJ EPO 1982, 211).*[32]
>
> *Further, where a feature cannot be considered as contributing to the solution of any technical problem by providing a technical effect it has no significance for the purpose of assessing inventive step."*[33]

78. The abovementioned principles were recently confirmed in case T 0154/04.[34]

> *"The presence of technical character in an invention (as well as for the industrial applicability) is an absolute requirement that does not imply any new contribution to the prior art. Naturally, however, a patentable invention, i.e. an invention meeting all criteria of patentability, must provide a novel and inventive technical contribution to the prior art.*[35]

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30 T 0641/00, Two identities/COMVIK, OJ EPO, 2003, 352.

31 T 0641/00, at 4 of the reasons

32 T 0641/00, at 5 of the reasons.

33 T 0641/00, at 6 of the reasons

34 T 0154/04, Estimating sales activity/DUNS LICENSING ASSOCIATES, decision of Technical Board of Appeal 3.5.01 de dato 15 November 2006, not yet published in OJ EPO.

35 T 0154/04, point 9 of the reasons.

In decision T 1002/92 - Queueing system/PETTERSSON (OJ EPO 1995, 605), the appellant argued that the claimed subject-matter did not involve any contribution to the art in a field not excluded from patentability since the only claim feature not disclosed in the prior art was not a technical feature, giving rise to the following consideration (Reasons No. 1): "In the board's view, these submissions result from a misinterpretation of the relationship between Articles 52 and 56 EPC. In a case such as the present, a first question to be considered is whether the appellant is correct in his contention that the subject-matter of claim 1 does not constitute an "invention" within the meaning of Article 52(1) EPC. If, contrary to the appellant's contention, such subject- matter is not excluded from being patentable under Article 52 EPC, a further and separate question, also raised by the appellant, is whether the claimed subject-matter involves an inventive step."[36]

The examination whether there is an invention within the meaning of Article 52(1) to (3) EPC should hence be strictly separated from and not mixed up with the other three patentability requirements referred to in Article 52(1) EPC. This distinction abstracts the concept of "invention" as a general and absolute requirement of patentability from the relative criteria novelty and inventive step, which in an ordinary popular sense are understood to be the attributes of any invention, as well as from the requirement of industrial applicability. Decisive for the presence of a (potentially patentable) invention is the inherent character of the claimed subject-matter.[37]

79. Concluding, in the view of ***epi***, the approach taken in other fields of technology, such as the field of CII, is also very useful in resolving the patentability problem of processes for the production of plants which contain both biological and non-biological features. As ***epi*** will further demonstrate in this Amicus Curiae Brief, a process containing both biological and non-biological features should be considered not to be excluded from patentability by Article 53(b) EPC 1973, whatever the exact contribution of each of these biological and non-biological features is to the invention.

3.7. Applying the principles developed in other fields of technology to the present referral

80. The evolution of case law pertaining to CII fits surprisingly well with the subject matter of the present referral.

81. Summarising once again the principles applied to CII, if an invention comprises technical and non-technical features, it will in any event be considered not to be excluded from patentability, even if the contribution to the art lies entirely in non-technical features. The fact that there are technical features included in the invention implies that such an invention is not excluded from patentability.

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[36] T 0154/04, point 9 of the reasons.

[37] T 0154/04, point 10 of the reasons.

82. Whether such an invention will satisfy the patentability requirements of novelty, inventive step, industrial application and enabling disclosure is obviously an entirely different matter. In evaluating whether such is the case, the technical contribution will be of predominant importance.

83. A similar reasoning seems to be appropriate also for the type of processes which are the subject of the present referral. If a process for the production of plants comprises biological and non-biological features, it is reasonable to conclude that it is not excluded from patentability, whatever the nature of the technical feature may be in the invention. As soon as technical features/steps are included, it can no longer be said that such process is a biological process.

84. Such a position is furthermore supported by Rule 23b(5) EPC 1973, where it is said that an essentially biological process is a process which consists entirely of natural processes. In other words, as soon as one step is not purely biological, the process is no longer excluded from patentability.

85. Yet further, such a solution fits well in an evolution to put emphasis on the patentability requirements of novelty, inventive step, industrial application and enabling disclosure, instead of exhausting oneself in theoretical and abstract evaluations as from which moment on an invention is excluded from patentability. Such an exercise is apart from being abstract and difficult to perform, also always to some extent subjective. Admittedly, a minimum standard should be in place in order to evaluate whether certain inventions are excluded from patentability. However, such a minimal standard should be easy to apply, should be objective and should be practical. A standard which prescribes that a process for the production of plants will be excluded from patentability if such process consists entirely of natural processes seems to fulfil these criteria. Hence, preference is given to an objective criterion to establish whether a process is essentially biological or not. Such standard is laid down in Rule 23b(5) EPC 1973.

86. That the standard to apply with a view to evaluating whether certain inventions are excluded from patentability must be easy to apply, objective and practical also seems to have been the view of the Technical Board of Appeal in case T 258/03 when it confirmed the standard that in order not to be excluded from patentability under Article 52 EPC 1973, it is sufficient that technical features are included, irrespective of the contribution which these technical features deliver to the state of the art:

> *"Moreover, it is often difficult to separate a claim into technical and non-technical features, and an invention may have technical aspects which are hidden in a largely non-technical context. Such technical aspects may be easier to identify within the framework of the examination as to inventive step, which, in accordance with the jurisprudence of the boards of appeal, is concerned with the technical aspects of an invention. Thus, in addition to the restrictive wording of Article 52(3) EPC limiting the applicability of Article 52(2) EPC, there may be practical reasons for generally*

regarding mixes of technical and non-technical features as inventions in the meaning of Article 52(1) EPC.'[38]

3.8. Rule 23b(5) EPC 1973 prescribes a proper standard for interpreting Article 53(b) EPC 1973

87. Rule 23b(5) EPC 1973 lays down the proper standard in interpreting Article 53(b) EPC 1973. This is even more so in view of developments in case law in the last 10 years in other fields of technology. ***epi*** consequently sees no reason why the Enlarged Board of Appeal should further analyse any of the three hypotheses suggested by the referring Board to set Rule 23b(5) EPC 1973 aside.[39] In the view of ***epi***, Rule 23b(5) EPC 1973 lays down a correct standard for interpreting Article 53(b) EPC 1973. The hypotheses formulated by the referring Board aim at setting Rule 23b(5) EPC 1973 aside, thereby assuming that it would be in conflict with Article 53(b) EPC 1973, which, as has been earlier and will be further set out in this Amicus Curiae Brief, is not the case.

88. It should be clear that the exclusion of essentially biological processes from patentability should be narrowly construed, especially in view of the fact that the statute expressly allows microbiological and technical processes to be patented.

89. It is also logical to conclude that the wording "essentially biological process" refers to a process which is in essence and in nature biological. A process which contains non-biological steps cannot be deemed to be in nature biological, hence such a process should not be excluded from patentability. This is also what Rule 23b(5) EPC 1973 tries to explain, even if its wording is somewhat clumsy. The message deriving from Rule 23b(5) EPC 1973 is clear, however. It clearly says that an essentially biological process is a process which consists entirely of natural processes such as crossing or selection.

90. It is clear that the wording "crossing or selection" is limited to those crossing and selection processes which are purely natural, thus excluding those processes which require human intervention.

91. It is furthermore clear that the wording "consists entirely of natural processes" reflects a desire to give a narrow interpretation, and indeed limits the exclusion to these situations where the process is in essence or in nature biological. As soon as there is a non-biological step involved, the process no longer consists entirely of natural processes, and hence it is no longer essentially biological.

92. In this standard, there is no room for evaluating the level of human intervention and the effect on the end-result. Such a standard, as it has been applied by the Technical Boards of Appeal, is not efficient, is unclear and leads to legal uncertainty, as it leaves it up to the Patent

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[38] T 0258/03, at 3.6 of the reasons.

[39] T 0083/05, points 56-59 of the reasons.

Examiner and at the end to the Technical Boards of Appeal to make such evaluation in order to establish whether the subject matter is excluded from patentability. As it has been witnessed in other fields of technology, it is desirable that Patent Offices should as little as possible be required to make such difficult, and by definition rather subjective, evaluations.

93. To the contrary, the standard laid down in Rule 23b(5) EPC 1973 leads to a clear-cut decision-making process. As soon as there is a non-biological step involved, the process is no longer excluded from patentability as an essentially biological process. Whether a rather minor non-biological step will make the invention fulfil the patentability requirements of novelty, inventive step, industrial application and enabling disclosure is obviously an entirely different matter, which needs to be resolved with the appropriate and well-established tests and principles laid down in the EPC and further refined in practice and by the case law of the Technical Boards of Appeal.

94. It is self-evident that giving such a very narrow interpretation to Art. 53(b) EPC 1973 can only help in creating legal certainty. Making the subjective evaluation of the level of human intervention and the effects on the end-result is not desirable as EPO practice has no standard objective test to make such evaluation, and hence such an exercise should preferably be avoided.

3.9. Conclusion and Answer to Question 1

95. As soon as one non-biological step is included in the claimed process, such process is not excluded from patentability as being essentially biological.

4. Analysing Question 2

4.1. The Approach to Question 2

96. 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 1973 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?

97. ***epi*** considers that the answer to question 1 should be in the affirmative and that Question 2 need not be considered. However, ***epi*** is concerned about the consequences which would ensue for this field of technology were the Enlarged Board to decide, contrary to the view of ***epi***, that Question 1 should be answered in the negative. The following comments are made on the assumption that the Enlarged Board answers Question 1 in the negative, contrary to the view of ***epi***.

98. Determining the criteria to be used to determine which plant production processes are excluded from patentability and those which are not requires making an analysis of the scope of a biological process. As microbiological processes are expressly not excluded from patentability under Article 53(b) EPC 1973, and as technical processes are in fact equally not excluded from patentability as being non-biological, the question arises as to what might be the exact scope of the exclusion of Article 53(b) EPC 1973.

99. Answering such a question leads inevitably to an evaluation of the nature of the process and of the process steps included in such process. If the criterion should be that only those processes are excluded from patentability which are in their entirety biological, i.e., which contain no non-biological step, then one falls back to the reasoning laid down earlier in this Amicus Curiae Brief under Question 1.

100. Assuming that the answer to Question 1 is to given in the negative, the criterion for determining whether a process is essentially biological could then never be that it consists of only biological/natural process steps. A solution must hence be found elsewhere.

101. Under the underlying hypothesis formulated in Question 2, it must thus be assumed that the process consists of both biological and non-biological steps. The question then arises when such process comprising mixed steps falls within the scope of the definition of essentially biological as laid down in Article 53(b) EPC 1973.

102. ***epi*** believes that a narrow interpretation should be given to Article 53(b) EPC 1973. It is therefore necessary to interpret the exclusion as narrowly as possible. Starting from that premise, ***epi*** is of the opinion that only these non-biological steps which are entirely trivial, i.e., which have no influence whatsoever on the end-product made nor in essence on the way how the end-product is produced, would not be capable of bringing such a process outside the realm of Article 53(b) and Rule 23b(5) EPC 1973. As soon as a non-biological step has an influence on the end-product made or in essence on the way how the end-product is produced, however limited this influence may be, then such invention is no longer essentially biological. When referring to influence as used in this paragraph, meant is a non-biological step which is part of the process or is necessary for the production of the plant. If a non-biological step is not part of the claimed process (for example a step for producing the marker where any marker can be used in the claimed process) or is not necessary for the production, then this step cannot contribute to the technical nature of the process and the exception of Art. 53(b) EPC 1973 remains applicable.

103. Such reasoning is logical. Assuming that a test is applied which deviates from the standard defended in the previous chapter of this Brief, if a technical step is entirely trivial without any effect on the end-result, it is difficult to see how this could turn the process into a non-essentially biological process, as the process would remain biological in essence.

104. However, as soon as the non-biological step has any influence on the end-product made or in essence on the way how the end-product is produced, of whatever nature, there is no reason to assume that such process would still be excluded from patentability, as it would no longer be an essentially biological process, as the process is no longer in essence biological.

105. Such a solution would also be in conformity with the provision of Rule 23b(5) EPC 1973, as according to this provision only those processes are excluded from patentability which consist entirely of natural phenomena, such as crossing or selection. A process which contains a non-biological step which has an influence on the end-product made or in essence on the way how the end-product is produced cannot be deemed to be a process which consists entirely of natural phenomena, and hence would on that basis not be excluded from patentability.

106. A process which contains a non-biological step which is entirely trivial, i.e., without any influence whatsoever on the end-product made nor in essence on the way how the end-product is produced, could still be considered to be a process which consists entirely of natural phenomena, as the process in essence would remain biological, and the steps which matter in the process would still remain biological.

107. A technical step which has no influence on the end-product made or in essence on the way how the end-product is produced renders the process as being essentially biological. At the same time, a process containing a human intervention step which has no influence on the end-product made or in essence on the way how the end-product is produced, can still be deemed to be a process which consists entirely of natural phenomena, as such step does not make any contribution to the end-result, and hence can be severed from the process as such. The step does not change the nature and essence of the process, which remains biological.

108. Such an interpretation of the exclusionary provision of "essentially biological processes for the production of plants" as laid down in Article 53(b) and Rule 23b(5) EPC 1973, which does not seem to be illogical, can reconcile the apparent contradiction between Article 53(b) and Rule 23b(5) EPC 1973 which the referring Board in T 0083/05 has referred to in its decision.[40]

109. In this context, the wording "crossing or selection" in Rule 23b(5) EPC 1973 should be interpreted as only those crossing and selection steps which occur in nature, i.e., without human intervention. Processes which contain steps which do not occur in nature, i.e., which require human intervention, do not fall within the scope of Rule 23b(5) EPC 1973, and hence also not under Art. 53(b) EPC 1973.

4.2. Conclusion and answer to Question 2

110. The criterion to be applied for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC 1973 from non-excluded ones should be that, if the non-biological step has some influence on the end-product made or in essence on the way how the end-product is produced, i.e., if an identical end-result would not have been achieved without the non-biological step, then such process is not deemed to be essentially biological.

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[40] See T 0083/05, points 54-55 of the reasons.

5. Answers to the Questions

111. **Question 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 1973 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?

Answer to Question 1:

As long as one non-biological step is included in the claimed process, such process is not excluded from patentability as being essentially biological.

112. **Question 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 1973 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?

Answer to Question 2:

The criterion to be applied for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC 1973 from non-excluded ones should be that, if the non-biological step has some influence on the end-product made or in essence on the way how the end-product is produced, i.e., if an identical end-result would not have been achieved without the non-biological step, then such process is not deemed to be essentially biological, and hence not excluded from patentability.

Mercer, Christopher Paul

President - epi