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Dear Sirs

Amicus Curiae Brief by CropLife International filed in connection with Case G2/07 before the Enlarged Board of Appeal

We write in response to the Invitation of the Enlarged Board of Appeal (OJ EPO 2007, 468) and pursuant to Article 11b of the Rules of Procedure of the Enlarged Board of Appeal, and file herewith an Amicus Curiae Brief on behalf of CropLife International. Annex 1 as referred to in the enclosed Amicus Curiae Brief is also filed herewith.

A Form 1037 for acknowledgement of receipt is enclosed with the confirmation copy of this letter.

Yours faithfully
Frank B. Dehn & Co.

Hanna Dzieglewska

Encs./nbb

IN THE ENLARGED BOARD OF APPEAL
OF THE EUROPEAN PATENT OFFICE

CASE: G2/07

AMICUS CURIAE BRIEF
BY CROPLIFE INTERNATIONAL

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1. These submissions are made in response to the invitation of the Enlarged Board of Appeal (OJ EPO 2007, 468) and pursuant to Article 11b of the Rules of Procedure of the Enlarged Board of Appeal (OJ EPO 2003, 59).

2. CropLife International is a global federation representing the plant science industry and a network of regional and national associations in 91 countries. The company members include BASF, Bayer CropScience, Dow Agrosciences, Dupont, FMC, Monsanto, Sumitomo and Syngenta. These companies are committed to sustainable agriculture through innovative research and technology in the areas of crop protection, non-agricultural pest control, and seed and plant research and development.

3. The present Amicus Curiae Brief presents observations in connection with case G2/07, referred to the Enlarged Board of Appeal by Decision T83/05. Monsanto (as an exclusive licensee of the patent in suit) and Syngenta (as an opponent) each have a material interest in the case (T83/05) which has given rise to the questions which have been referred to the Enlarged Board of Appeal. The questions referred to the Enlarged Board of Appeal are 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?

4. Referred to herein is a published article by Michael A. Kock entitled "Essentially biological processes: the interpretation of the exception under Article 53(b) of the European Patent Convention" (Journal of Intellectual Property Law & Practice, 2007, volume 2, pgs 286-297). A copy of this article is attached hereto as Annex 1 and is referred to herein with permission from the author.

5. It is clear from the questions referred to the Enlarged Board of Appeal in Decision T83/05 that the interpretation of the exception from patentability of "essentially biological processes for the production of plants" in Article 53(b) EPC requires clarification.

6. In particular, clarification is required concerning how this provision is to be applied to processes for the production of plants which contain the steps of crossing and selection, where the selection step involves or includes a technical step. The technical steps in the particular case in question include marker assisted selection (MAS). As set out in more detail below (and contrary to the position of Appellant II set out in T83/05), it is submitted that such a technical step can be sufficient to take the claimed process outside the Article 53(b) EPC exclusion.

Exceptions are to be construed narrowly

7. Article 52(1) EPC sets out the general provision that:

> *"European patents shall be granted for any inventions which are susceptible of industrial application, provided they are new and involve an inventive step."*

8. Article 53(b) EPC sets out an exception to the general principle set out in Article 52(1) EPC and states:

> *"European patents shall not be granted in respect of:*

(a) ....;

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

9. It is however an accepted legal principle of the EPO that exceptions to patentability should be narrowly construed. This principle has been well established in EPO Case Law at both Technical Board of Appeal and Enlarged Board of Appeal level (see, for example, T320/87, Reasons, point 6 "the exclusion of "essentially biological" processes for the production of plants (or animals) has to be narrowly construed"; see also T315/03, Reasons, point 7.4 "the Board agrees that exclusions are generally interpreted narrowly"; and the recent decision G1/04, Reasons, point 6 "the Enlarged Board of Appeal considers that the principle of a narrow interpretation of such exclusion clauses is to apply in respect of the scope of the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods").

10. Thus, it has been clearly established that exclusions to patentability in general (and indeed specifically the "essentially biological process" exclusion of Article 53(b) EPC - see the above quote from T320/87) should be interpreted narrowly.

The Protection Gap

11. Article 53(b) EPC makes it clear that processes for the production of plants are patentable except when such methods are essentially biological. The purpose of the exclusion in Article 53(b) EPC, when it was drafted, was to ensure that double protection provided by plant variety protection (PVP) and patents was avoided. This can be seen from the analysis set out in G1/98 (see in particular Reasons, points 3.4 to 3.7, which contain a review of the legislative history behind the drafting of the relevant parts of the Strasbourg Patent Convention (from which the wording of Article 53(b) is derived) and the EPC itself). Indeed, point 3.7 of G1/98 indicates that "Accordingly, inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the EPC provided that they fulfilled the other requirements of patentability".

12. In the interests of the public, diagnostic methods were excepted from patentability in Article 52(4) EPC in order to provide physicians with a general freedom to operate (see G5/83, Reasons, point 22, which makes it clear that gaps in protection were deliberately accepted in order to free from restraint certain medical and veterinary activities). However, there is nothing in the legislative history or travaux preparatoires of the Strasbourg Patent Convention or the EPC to suggest that the exclusions outlined in Article 53(b) EPC were aimed at providing a similar general freedom to operate for plant breeders. Thus, there is no support for the interpretation that Article 53(b) EPC could or even should exclude subject matter for which no protection under a plant breeders rights' (PVP) system was available. (This is confirmed in G1/98, Reasons, point 3.7, where the distinction between the purpose behind Article 53(b) EPC and Article 52(4) EPC is acknowledged).

13. Processes for the production of plants are of course not protectable by the PVP (plant variety protection) system and thus are prime examples of inventions which are intended to be patentable under the EPC.

14. It should also be noted that, if deprived from patent protection by a broad interpretation of the exception outlined in Article 53(b) EPC, then no alternative mechanism of protection will exist for such inventions, other than perhaps trade secrets. It is submitted that this outcome does not reflect the purpose behind the drafting of the process exclusion of Article 53(b), nor does it fit with the principles set out in Article 52(1) EPC. In addition, such a complete denial of IP protection may be in conflict with the constitution of some of the EPC member states (see Annex 1, page 288, column 2, lines 17 to 19 and footnote 24).

15. Furthermore, it is submitted that the deprivation of patent protection for processes for producing plants based on technical selection steps (such as MAS) would have a significant economic impact. In this regard, MAS technology has had a large and beneficial impact on the breeding industry and enables new and improved varieties of plants to be produced more quickly. In particular, MAS is a vital technology for breeding plants with traits which are difficult (or even practically impossible) to breed for using conventional methods, such as traits which have no visible phenotype and/or traits which are determined by multiple genes.

16. If patent protection is denied for such technical, MAS-based, breeding processes, then this would reduce the likelihood of the breeding companies investing the time and the money necessary to develop such beneficial breeding processes, as they would instead favour biotechnology processes that result in patentable subject matter. While breeding companies may continue to engage in some MAS-based breeding processes, it is likely that they would maintain their new found knowledge of plant genetics solely as trade secrets. This is clearly not a desirable outcome for the public. The vast benefits and impact which MAS has had on the breeding industry are discussed in an FAO (Food and Agricultural Organization of the UN) Report, Rome 2007, which can be accessed at the following internet address: \ http://www.fao.org/docrep/010/a1120e/a1120e00.HTM . The report notes that MAS-based breeding processes have benefits for crop development in both developed and developing countries.

Technical processes are patentable

17. Furthermore, the explicit wording of Article 53(b) EPC to limit the process exclusion to "essentially biological" processes and the specific indication that microbiological processes are patentable (i.e. that the exclusion "*does not apply to microbiological processes or the products thereof*"), shows that the intention was for other breeding processes to be patentable. Indeed, the legislative history (EPC working party document IV/2071/61-E, page 6, first paragraph, cited in T356/93, Reasons, point 25) explicitly indicates that European patents still ***had to be granted*** for processes which, while applicable to plants, were of a technical nature.

18. Interestingly, this point was further endorsed in T356/93 (Reasons, point 38), where it was indicated that processes for producing plants, which are shown to be of a technical nature (e.g. involving genetic engineering techniques) are patentable under the EPC without limitation and that, had the historical legislator been aware of such processes, it would have considered them to be further examples of ***technical*** processes, applicable in particular to plants, for which European patents had to be granted.

19. It is further submitted that Rule 23c(c) EPC (which has its roots in the Directive 98/44/EC on the legal protection of biotechnological inventions, referred to hereinafter as the "EU Biotech Directive") now explicitly endorses this principle and states:

> *"Biotechnological inventions shall also be patentable if they concern:*
>
> *(c) a microbiological or* ***other technical process,*** *or a product obtained by means of such a process other than a plant or animal variety."* (emphasis added)

20. This rule thus makes it clear that "technical" processes are to be regarded as patentable, i.e. that technical processes should be excluded from the Article 53(b) EPC exception. As set out above, it is submitted that certain selection methods used in plant breeding, such as MAS, are clearly technical and, as such, processes involving such steps should be found patentable by virtue of Rule 23c(c) EPC, which is also supported by the legislative history and Case Law discussed in points 17 and 18.

21. As indicated above, Rule 23c(c) EPC has its origins in the EU Biotech Directive. This is important as, according to Rule 23b(1) EPC, the EU Biotech Directive has to be used as a supplementary means of interpretation of the EPC.

22. Significantly, in the EU Biotech Directive, the equivalent provision to Rule 23c(c) EPC (i.e. Article 4(3) of the Directive) qualifies further the equivalent "essentially biological process" provision to Article 53(b) EPC (i.e. Article 4(1)(b) of the Directive) and excludes from the "essentially biological process" exception "all inventions which concern a microbiological or ***other technical process***" as follows:

> *1. The following shall not be patentable:*
> *(a) ...*
> *(b) essentially biological processes for the production of plants or animals.*
> *2. ...*
> *3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.* (Article 4 EU Biotech Directive).

In contrast to the EU Biotech Directive, Rule 23c(c) EPC has not been incorporated in the EPC as an explicit exception to the Article 53(b) exception, but is separate and construes a positive definition for patentable inventions.

23. However, as the EU Biotech Directive must be used as a supplementary means of interpretation, and as it is clearly important that the legal outcome of what is patentable under the terms of the EU Biotech Directive (and thereby the national laws of Member States) and the EPC are the same, then it is submitted that processes for the production of plants which concern a technical process (i.e. involve a technical step) should be found patentable, and only those processes which are non-technical should be excluded.

24. Rule 23b(5) EPC (which also has its origin in the EU Biotech Directive) supports this position and states:

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

Thus, this Rule indicates that if the crossing and selection steps used in the process for the production of plants are not natural phenomena such as (natural) crossing or (natural) selection, then the processes are NOT excluded under Article 53(b) EPC. As such, methods involving technical selection methods, such as MAS, can be regarded as outside the exclusion.

Possible approaches for the interpretation of Article 53(b) EPC

25. Three possible approaches for the interpretation of Article 53(b) EPC have been identified in EPO Case Law (see T1054/96, decision 13 October 1997, Reasons, points 25 to 29). T1054/96 referred several questions to the Enlarged Board of Appeal which were considered in G1/98. In the circumstances pertaining in G1/98 the Enlarged Board of Appeal did not find it necessary to decide which interpretation, if any, was correct. However, these three approaches have also been referred to by the Technical Board of Appeal in the referring decision T83/05 (see point 46, Reasons).

26. In this regard, the first approach is analogous to that used under Article 52(4) EPC relating to methods of treatment by surgery and therapy and would lead to the result that the inclusion in a claimed process of a single step of an "essentially biological" nature would mean that the process fell within the Article 53(b) EPC exclusion. The second approach is the one adopted in decision T320/87, i.e. to adopt the test that the applicability of the exclusion should 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 T320/87, Reasons, point 6). The third approach is to require at least one clearly identified "non biological" process step (but allow any number of additional "essentially biological steps") in order for a process to escape the prohibition of Article 53(b) EPC. The Board in T1054/96 stated that this approach was the one adopted by Article 2(2) of the (then) draft EU Biotech Directive, which now forms part of the EPC as Rule 23b(5).

Appropriate interpretation of the process exception of Article 53(b) EPC

27. It is submitted that the first approach for interpretation of Article 53(b) EPC set out above is inappropriate. Firstly, there is no analogy between Article 52(4) EPC and Article 53(b) EPC in terms of providing a general freedom to operate principle (see point 12 above). Secondly, as set out in points 11 and 17 above, it is clear that the legislation was drafted such that breeding processes are patentable so long as they fulfill the requirements of patentability and are not also eligible for protection under the plant breeders' rights system. Thus, an interpretation in which the inclusion of a single "essentially biological" step would exclude the process from patentability cannot be appropriate.

28. The third approach set out above (i.e. a literal interpretation of Rule 23b(5)) is the most preferable approach for interpreting Article 53(b) EPC because it provides the benefit of a clear cut and certain approach for applicants and third parties (and indeed the EPO). Points 17 to 24 above provide further reasons why this approach should be adopted. Whilst the referring Board of Appeal in T83/05 has noted an inconsistency of this approach with certain EPO Case Law, it should be noted that this approach is not inconsistent with all EPO Case Law (see the discussion of T356/93 in point 18 above). The implementation of Rule 23(b)(5) was made in full consideration of Article 53(b) EPC and its related Case

Law, and should provide the starting point for any further interpretation of Article 53(b). Furthermore, the third approach is supported by aspects of the legislative history (see point 17 above), and is in accordance with a straightforward literal interpretation of the EU Biotech Directive and Rules 23c(c) and 23b(5) EPC where the exclusion in Article 53(b) EPC is restricted to entirely natural phenomena (see also points 19 to 24 above).

29. In this approach Question 1 as referred to the Enlarged Board of Appeal would be answered in the affirmative and there would be no need to answer Question 2.

30. However, in the event that the Enlarged Board of Appeal cannot agree with this interpretation, then it is submitted that the second approach to interpretation of Article 53(b) EPC, i.e. to apply the test as set out in T320/87 of judging the applicability of the exclusion on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved, should be adopted.

31. In this regard, as well as being in agreement with previous case law of the Boards of Appeal, it is submitted that this approach can also be seen to be consistent with Rule 23b(5) EPC by applying an interpretation to that Rule which is consistent with the case law and the intent of Rule 23b(5) EPC. In this regard, the term "essentially" as used in Article 53(b) EPC ("essentially biological process") can be seen to have both a quantitative and a qualitative element; a quantitative element which requires that there be at least one non-biological (i.e. technical) step and a qualitative element which requires that such a step needs to have an effect. Thus, a technical step which has no impact on either the process or the product thereof, (i.e. has no impact on the result achieved) can be regarded as severable and therefore not considered part of the process (see also Annex 1, page 295, column 1). In consequence, a biological process with irrelevant technical steps, would still consist entirely of natural phenomena and would still be excluded. Thus, on this interpretation, there is no conflict between Article 53(b) and Rule 23b(5) EPC.

32. It is submitted that, in accordance with this approach, any technical step which has an impact on the process or the product of the process should render the process outside the exception. This is in line with Rule 23b(5) EPC, which is a clear indication that the exception is to be construed very narrowly (see also

Annex 1, page 296, column 1, 1st full paragraph). The possibility that the "impact" might have an effect at the level of the process (e.g. the performance of the process in terms of it being faster, more efficient, more cost effective, etc.) or the product (e.g. by way of a genetic modification of a plant) is supported by T320/87 and T356/93.

33. It is submitted however that when determining whether or not the human intervention has an "impact" on the result achieved, it is not appropriate to interpret this as a requirement for the impact to be an inventive contribution (see also Annex 1, page 295, column 2, line 24 to page 296, column 1, line 2) and indeed the Case Law to date supports this position. Thus, this question has to be assessed from a neutral perspective, without taking into account issues of novelty or inventive step. Indeed, of course, Articles 54 and 56 EPC should safeguard against the patenting of processes which have trivial variations over known methods (and thus as a whole do not have the requisite novelty and inventive step), and it is submitted that these grounds are the appropriate ones under which such assessments should be made, once it has been established that the claimed subject matter is not excluded under Article 53(b) EPC by virtue of the presence of a technical step which has an impact on the result achieved. For these reasons, subjective qualifiers of the level or type of impact required for the purposes of Article 53(b), such as requiring a "substantially significant" impact or the like, should be avoided. If an impact test is adopted, the legal standard for the determination of the scope of the Article 53(b) exclusion should be as clear cut and as certain as possible.

34. Turning now to the case in question before the referring Board in Decision T83/05, it is submitted that the Board has misapplied the "impact" test. In this regard, the referring Board appears of the view that the use of molecular markers in steps (b) and (c) of the claimed process (i.e. basically the use of MAS), although considered a technical step, was a "well-known step" in the selection of plants with desired characteristics. The Board also indicates that "Methods to discover and produce molecular markers that segregate with a desired trait were ***commonly known*** from the prior art and had already been used in the context of *Brassica* species" (emphasis added).

35. As discussed above however, it is submitted that when considering whether the subject matter of a claim is excluded under Article 53(b) EPC, the relevant test is to assess the "impact" of the technical step(s) on the result achieved and that it is inappropriate to consider whether the technical step(s) or the impact on the result achieved is inventive. Thus, the fact that the use of molecular markers in selection methods might have been "well known steps" or "commonly known" is irrelevant to the question of whether the subject matter of the claim is excluded under the process exception of Article 53(b) EPC.

36. It is furthermore submitted that when applying the "impact" test, it is too simplistic to look only at the general nature of the technique behind the technical step (in this case MAS). In the case underlying the referral, it is clear that the choice of the selection criterion (increased levels of certain glucosinolates) has an ***impact*** on both the process and the result, as without measuring the levels of the glucosinolates in question the goal of the process (i.e. the production of anti-carcinogenic plants with elevated levels of those certain glucosinolates) cannot be efficiently achieved through classical breeding.

37. Again, whether or not the particular selection criteria used in the case underlying the referral are inventive might be disputed, but this is not relevant for evaluating whether the method is excluded (see also Annex 1, page 297, column 2, paragraph 1). In this regard, an analogy can be made with methods of genetic engineering to introduce a recombinant DNA molecule/transgene into a plant. The techniques for this are known, but their use in relation to a specific gene has been acknowledged to make the required "impact" (see T356/93, Reasons, point 40). In the case underlying the referral, the Patent in suit analogously uses MAS to achieve a plant having significant new properties and hence the required "impact" is made.

38. If the above discussed second approach is adopted then Question 2 as referred to the Enlarged Board of Appeal falls to be answered. In this regard, we would submit that the answer to Question 2 would be that the test set out in T320/87 provides a means for assessing whether a process is excluded or non excluded. That is, a process involving a technical step which has an impact on the process or the product of the process should render the process outside the exception (see points 30 to 33 above).