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SUBJECT: Patentability under the EPC of plants and animals produced by essentially biological processes following the EU Commission Notice of 3 November 2016 on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

SUBMITTED BY: President of the European Patent Office

ADDRESSEES: Committee on Patent Law (for opinion)

SUMMARY

In combined decisions G 2/12 and G 2/13 of 25 March 2015 the EPO's Enlarged Board of Appeal found that the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit.

In its Notice of 3 November 2016 on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, the EU Commission takes the view that the EU legislator's intention was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.

In the meeting of the Committee on Patent Law in November 2016 the Office was asked to analyse the effect of the EU Commission Notice on the EPO's legal framework and practice, and to present options for the way forward, including a proposal for amending the Implementing Regulations to the EPC.

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I. STRATEGIC/OPERATIONAL

1. Strategic.

II. RECOMMENDATION

2. The Committee on Patent Law is requested to give its opinion on the options set out under points V. and VI.

III. MAJORITY NEEDED

3. N/A.

IV. CONTEXT

4. Under Article 53(b) EPC European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals. The wording of the provision and the wording of Article 4(1) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereafter "EU Biotechnology Directive") correspond.

5. Pursuant to Rule 27 EPC, biotechnological inventions shall also be patentable if they concern (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature, as well as (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety. This provision corresponds to Articles 3(2) and 4(2) of the EU Biotechnology Directive. Under Rule 26(1) EPC the EU Biotechnology Directive shall be used as a supplementary means of interpretation when applying and interpreting the relevant provisions of the EPC. Rules 26-29 EPC were inserted into the EPC in 1999 in order to implement the requirements of the EU Biotechnology Directive in European patent law.[1]

[1] See Administrative Council document CA/7/99 of 4 May 1999 and the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 573.

6. In its combined decisions G 2/07 and G 1/08 of 9 December 2010[2] the EPO's Enlarged Board of Appeal held that a non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC and does not 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, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

7. In its further combined decisions G 2/12 and G 2/13 of 25 March 2015[3] the Enlarged Board of Appeal found that the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit. The fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application and encompassed by the protection conferred by the product claim does not render a claim directed to plants or plant material other than a plant variety unallowable.

[2] OJ EPO 2012, 130 and 206.
[3] OJ EPO 2016, A27 and A28.

8. In the same way as Article 53(b) EPC has been interpreted by the Enlarged Board of Appeal, the practice of EPO examining and opposition divisions has been to allow product claims to plants or plant material such as fruit, provided that the application or patent and the invention to which it relates fulfils the formal and substantive requirements of the EPC. This practice has been reflected in the Guidelines for Examination in the EPO (hereafter "Guidelines").[4] Between 1995 and the stay of proceedings in November 2016[5] the EPO granted about 80 European patents claiming conventional plants.[6]

9. Keeping pace with technological developments in this field, the EPO has refined and re-enforced its examination practice. The patentability requirements of novelty (Article 54 EPC) and inventive step (Article 56 EPC) are rigorously assessed. Particular weight is additionally given to the examination of reproducibility of the claimed invention without undue burden by the skilled person. In that assessment account is taken of the public availability of the plant line from which the desired trait is obtainable (Article 83 EPC). The requirement of clarity of the claims (Article 84 EPC) is equally applied in a strict manner. In addition to the ISO 9001 quality management of the EPO's entire patent granting process, special quality controls in the biotechnology field ensure an enhanced monitoring of sensitive applications through each procedural phase, with an additional check by an experienced examiner in the grant phase. Further clarification about the EPO's examination practice in the biotechnology field is intended to be included in the Guidelines during the next revision cycle.

[4] Sections G-II, 5.4.2 and F-IV, 4.12. The interpretation of Article 53(b) EPC adopted in decisions G 2/12 – G 2/13 was first incorporated into the Guidelines version of 1 November 2015 and subsequently carried over into the Guidelines version of 1 November 2016.

[5] See the notice from the European Patent Office dated 24 November 2016 concerning the staying of proceedings due to the Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ EPO 2016, A104, as well as marginal number 15 below.

[6] See also document CA/PL 3/16, marginal number 40.

10. In December 2015 the European Parliament adopted a resolution[7] asking the EU Commission to clarify the patentability of conventional plants under the EU Biotechnology Directive, in particular under its Article 4 concerning plant-related inventions, and to communicate its clarification regarding the patentability of products obtained from essentially biological processes to the EPO so that it could be used as a supplementary means of interpretation. In parallel, the issue was brought to the attention of EU Council meetings and the Netherlands Presidency organised, in co-operation with the EU Commission, a symposium on patents and plant breeders' rights in Brussels on 18 May 2016.

11. On 11 February 2016 the EPO signed an Administrative Arrangement with the EU Community Plant Variety Office (CPVO) to enhance bilateral co-operation, in particular with the aim to strengthen the interinstitutional relationship through the exchange of information and in order to increase transparency. Two bilateral workshops were held in Angers in September 2016 and in Munich in March 2017 to increase technical awareness and legal expertise among experts from both organisations and to share knowledge and working practices, in particular regarding the use of databases and other working tools. A joint EPO-CPVO public conference is scheduled to take place in Brussels at the end of 2017.

12. In parallel, the patentability of plant-related inventions and the implications of decisions G 2/12 – G 2/13 were discussed in the meetings of the Committee on Patent Law of 15 September 2015 and 12 May 2016.[8] At the latter meeting the EU Commission informed the EPO that it intended to issue the interpretive notice requested by the European Parliament before the end of 2016.

[7] P8_TA-PROV(2015)0473: European Parliament Resolution of 17 December 2015 on patents and plant breeders' rights, 2015/2981(RSP).
[8] See documents CA/PL 12/15, CA/PL 3/16 and CA/PL 4/16.

13. On 3 November 2016, the EU Commission adopted Notice C/2016/6997 on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereafter "EU Commission Notice"), which was subsequently published in the EU Official Journal.[9] Based on an analysis of the *travaux préparatoires* relating to the adoption of the EU Biotechnology Directive, particularly concerning Article 4, as well as on an interpretation of other provisions of the EU Biotechnology Directive, the EU Commission takes the view that the EU legislator's intention when adopting the EU Biotechnology Directive was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.[10]

14. In a meeting of 20 February 2017 the Council of the EU/Competitiveness Council adopted conclusions welcoming the EU Commission Notice, recalling that the EU legislator's intention when adopting the EU Biotechnology Directive had been to exclude from patentability products obtained through essentially biological processes, and urging member states to advocate that the practice of the EPO be aligned with the EU Commission Notice.[11]

[9] Official Journal of the EU C 411/3 of 8 November 2016.
[10] The other issues addressed in the EU Commission Notice, namely compulsory cross-licensing and deposit of biological material are not relevant for the present analysis.
[11] Council conclusions on the Commission Notice on certain Articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Official Journal of the EU C 65 of 1 March 2017, p. 2–3.

15. In the meeting of the Committee on Patent Law of 21 and 22 November 2016 the EU Commission presented its Notice.[12] The Office invited delegations to provide some orientation on the consequences of the EU Commission's conclusions for the EPO's legal framework and examination practice. A number of delegations taking the floor expressed their agreement with the interpretation advanced in the EU Commission Notice. Some of these delegations stated to be in favour of an amendment of the EPC Implementing Regulations. Other delegations as well as the epi expressed the view that, due to the non-binding nature of the EU Commission Notice, the EPO should take a cautious approach and not change its Implementing Regulations or its practice before a decision of the EU Court of Justice (CJEU) on the matter. It was nevertheless recognised that disharmony between the EPC and the national practices should be avoided. In reply the Office proposed to prepare for the next meeting a paper setting out options and including a draft proposal for an amendment of the EPC Implementing Regulations. In the meantime, the Office would stay affected proceedings. The Committee on Patent Law expressed support for the proposed way forward and invited the Office to prepare the suggested analysis.[13]

16. On 24 November 2016, the President of the EPO decided that, in view of the discussions with the EPO contracting states about the potential impact of the EU Commission Notice, all proceedings before EPO examining and opposition divisions in which the decision depends entirely on the patentability of a plant or animal obtained by an essentially biological process would be stayed *ex officio* while the discussions with the representatives of the member states are underway. The Notice was published on the EPO website on 12 December 2016 and subsequently in the EPO's Official Journal.[14]

[12] See document CA/PL 18/16.
[13] See Minutes of the 47th meeting of the Committee on Patent Law (Munich, 21/22 November 2016), document CA/PL 17/16, marginal numbers 4 to 45.
[14] Notice from the European Patent Office dated 24 November 2016 concerning the staying of proceedings due to the Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ EPO 2016, A104.

V. OPTIONS AND ARGUMENTS

A. INTRODUCTION

17. The European Patent Organisation as an independent international organisation with its own legal order is itself not legally bound by the EU Biotechnology Directive. Acts of EU institutions taken under or in relation to the EU Biotechnology Directive are not directly applicable and have no direct effect in the legal order of the EPC.[15] At the same time, according to Rule 26(1) EPC and the case law of the EPO Boards of Appeal the EU Biotechnology Directive is to be taken into account in the interpretation and application of the relevant EPC provisions. Any effect of the EU Commission Notice on the EPC and the Office's practice thus depends on an act by the European Patent Organisation.

18. Possible options for such action are:

- to continue the examination practice based on the interpretation of Article 53(b) EPC established by decisions G 2/12 – G 2/13 (option 1)
- an amendment of the Convention (option 2)
- an amendment of the Implementing Regulations to the EPC (option 3) or
- a change of practice by the first instance based on modified administrative instructions (EPO notice, Guidelines) issued under Article 10(2)(a) EPC (option 4).

19. Decisions G 2/12 – G 2/13 do not *per se* rule out any of these options. Although decisions of the Enlarged Board of Appeal on the interpretation of the EPC *de facto* form the basis for the Office's practice, they are from a legal point of view only binding on the board of appeal in respect of the appeal which gave rise to the referral.[16] Decisions of the Enlarged Board of Appeal thus do not *per se* preclude a development in the law or its interpretation and in the practice based thereon.

[15] See decisions G 2/06, OJ EPO 2009, 306, point 7 of the Reasons for the Decision, T 1441/13, not published in the OJ EPO, point 4.1 of the Reasons for the Decision, as well as T 2221/10, not published in the OJ EPO, point 38 of the Reasons for the Decision; see also the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 573, marginal number 3.

[16] Article 112(3) EPC.

20. As a matter of course, any of the above-mentioned options would be subject to review for compliance with the EPC by the boards of appeal. One decisive issue in this regard is the potential impact of the EU Commission Notice on the interpretation of the EPC. A decision on the way forward thus needs to be taken in full consideration of the rules and principles under which the boards of appeal may scrutinise a development in the law or its interpretation and in the examination practice which occurs subsequent to a decision of the Enlarged Board of Appeal (below a)). Likewise, it must duly take into account how the EU Commission Notice and the findings set forth therein may be taken into account in the EPC framework (below b)).

a) Procedure and standard of review for the analysed options

21. The President of the EPO cannot refer to the Enlarged Board of Appeal the question of the potential impact of the EU Commission Notice and the findings set forth therein on the EPC and the EPO's practice. Under Article 112(1)(b) EPC the EPO President's right of referral is limited to cases where two boards of appeal have given different decisions on a point of law.[17]

22. Any action taken by the EPO with regard to the patentability of conventional plants can be scrutinised by the boards of appeal via proceedings in a particular case. Decisions of examining and opposition divisions with regard to the patentability of plants or animals obtained by means of an essentially biological breeding process taken under any of the options 1 to 4 could be appealed either by an opponent (in case of rejection of an opposition on the ground of Article 53(b) EPC under option 1) or by an applicant/proprietor (in case of refusal of an application/ revocation of a patent under options 2 to 4). The boards of appeal could then assess the compliance of any of the options 1 to 4 with the EPC. In doing so the competent board would, from a legal point of view, not be directly bound by decisions G 2/12 – G 2/13 since under Article 112(3) EPC they are only binding on the board of appeal in respect of the appeal which gave rise to the referral.[18] Rather, as explained below, the board may refer the matter to the Enlarged Board of Appeal.

[17] See G 3/08, OJ EPO 2011, 10.
[18] Article 112(3) EPC.

23. In reviewing an amendment of the Implementing Regulations to the EPC (option 3), the boards of appeal may have regard to the hierarchy of norms principle set forth in Article 164(2) EPC. Under this article the provisions of the Convention will prevail in case of conflict with the Implementing Regulations.[19] On this basis, the boards of appeal have jurisdiction to refuse enforcement of a rule of the EPC Implementing Regulations if it is considered to conflict with an EPC article.[20] In other words, an amendment of the EPC Implementing Regulations is only effective if it does not conflict with the meaning of an article of the EPC on its true interpretation as established by a ruling of the Enlarged Board of Appeal.[21]

24. A board of appeal concerned with a decision of an examining or opposition division in relation to conventional plants based on a new EPC rule might possibly find the rule not to conflict with Article 53(b) EPC and hence to be valid, or might possibly come to the contrary conclusion. A board of appeal may also consider that the validity of a new EPC rule concerning the patentability of conventional plants and animals would depend on a re-interpretation of Article 53(b) EPC. If this were the case, the board would have the power to refer the question to the Enlarged Board of Appeal. This follows from Article 21 Rules of Procedure of the Boards of Appeal according to which the matter shall be referred to the Enlarged Board of Appeal if a board considers it necessary to deviate from an interpretation of the Convention contained in an earlier decision of the Enlarged Board of Appeal.[22]

[19] Article 164(2) EPC reads: "*In case of conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail*."
[20] See, for example, T 315/03, OJ EPO 2006, 15, point 5.8 of the Reasons for the Decision.
[21] See T 39/93, OJ EPO 1997, 134, point 3.2 of the Reasons for the Decision.
[22] The exact wording of Article 21 Rules of Procedure of the Boards of Appeal is: "*Should a Board consider it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier opinion or decision of the Enlarged Board of Appeal, the question shall be referred to the Enlarged Board of Appeal*."

25. The Enlarged Board of Appeal, for its part, would have the power to review the interpretation of the EPC given in one of its earlier decisions. In decision G 9/93 concerning the admissibility of an opposition filed by the proprietor, the Enlarged Board of Appeal found that the modification of the interpretation of the EPC given in one of its earlier decisions may be necessary "*where there are very clear reasons for not following the earlier interpretation*".[23] In decision G 2/08 the Enlarged Board of Appeal modified the interpretation of the EPC given in its earlier decision G 5/83 with regard to Swiss-type claims in view of new Article 54(4) and (5) EPC 2000.[24] In case of a referral, the validity of an amendment of the EPC Implementing Regulations (option 3) may thus depend on whether or not the Enlarged Board of Appeal would modify the interpretation of Article 53(b) EPC as established in decisions G 2/12 – G 2/13 on account of the EU Commission Notice. If available, the Enlarged Board of Appeal may in this context take into account a decision of the CJEU on the matter as persuasive.[25]

26. An amendment of the Convention (option 2) is not subject to an examination for compliance with Article 164(2) EPC. The boards of appeal may only refuse enforcement of an EPC article if it has been defectively enacted, i.e. if the amendment of the article lacks a legal basis.[26]

27. A decision with regard to the patentability of conventional plants and animals taken on the basis of administrative instructions (options 1 and 4) would be subject to review for compliance with the EPC, in particular with Article 53(b) EPC. Again, a board of appeal may decide under Article 21 of its Rules of Procedure to refer the matter to the Enlarged Board of Appeal if it considers that the validity of the practice depends on a new decision of the Enlarged Board of Appeal on the interpretation of Article 53(b) EPC.

[23] OJ EPO 1994, 891, point 6 of the Reasons for the Decision.
[24] OJ EPO 2010, 456, point 7.1.4 of the Reasons for the Decision.
[25] See decisions T 2221/10 and T 1441/13.
[26] T 315/03, point 5.8 of the Reasons for the Decision.

28. The boards of appeal, including the Enlarged Board of Appeal, also have jurisdiction to assess the applicability of a new provision or practice to pending European patent applications and European patents in the light of the principle of the protection of legitimate expectations (good faith). Application of this well-established general principle to procedures before the EPO implies that measures taken by the EPO should not violate the reasonable expectations of parties to such proceedings.[27] Under certain circumstances, e.g. in case of purely procedural issues, users may have a legitimate expectation that a new interpretation of the EPC and the new practice based thereon is not applied to pending cases or only applied after a transitional period.[28] There is no general rule, though, that new (case) law may never be applied retrospectively.[29] In principle, any interpretation of the EPC by the Enlarged Board of Appeal implies that the law has always been in conformity with that interpretation.[30]

[27] See Case Law of the Boards of Appeal of the EPO, 8th ed. 2016, page 513 et seq.

[28] See in this regard, for example, G 2/08, OJ EPO 2010, 456, point 7.1.4 of the Reasons for the Decision, concerning Swiss-type claims and ordering that the interpretation of the EPC given by the Enlarged Board of Appeal in this decision shall only apply to new applications filed on or after a date of three months after publication of the decision in the OJ; see also G 9/93, OJ EPO 1994, 891, point 6.1 of the Reasons for the Decision, overruling decision G 1/84 with regard to the admissibility of an opposition filed by the proprietor and ordering that the ruling should not be applied to notices of opposition filed before publication of the decision.

[29] See G 2/07 and G 1/08, OJ EPO 2012, 130 and 206, point 2.4 of the Reasons for the Decision, as well as T 716/91, not published in the OJ EPO, point 2.2 of the Reasons for the Decision.

[30] G 9/93, OJ EPO 1994, 891, point 6.1 of the Reasons for the Decision.

b) EU Commission Notice on the Biotechnology Directive and EPC legal framework

29. Although, as stated above, the European Patent Organisation as an independent international organisation with its own legal order is itself not legally bound by the EU Biotechnology Directive[31], there is a strong formal link between the latter and the EPC. Namely, by incorporating the provisions of the EU Biotechnology Directive into the EPC, the EPC legislator expressed the clear will that the relevant EPC provisions and the practice based thereon be in full accord with the EU Biotechnology Directive. This also follows from Rule 26(1) EPC according to which the EU Biotechnology Directive shall be used as supplementary means of interpretation when applying and interpreting the relevant EPC provisions. It has moreover been expressly confirmed by the Enlarged Board of Appeal in decisions G 2/12 – G 2/13[32] and earlier decision G 2/06.[33]

30. When incorporating the EU Biotechnology Directive into the EPC and at other occasions the EPC legislator furthermore underlined the importance of uniformity in harmonised European patent law.[34] The significance of this principle is also recognised in the established case law of the boards of appeal.[35]

31. In line with the aforementioned principles, decisions of the CJEU on the interpretation of the EU Biotechnology Directive are taken into account as persuasive by the EPO.[36] Under the EU Treaties the CJEU alone is accorded interpretative supremacy for EU law and the EU Commission Notice is without prejudice to the interpretation that could be given to the issues addressed by the CJEU.[37] At present, a decision of the CJEU dealing with the patentability of products obtained through essentially biological processes under the EU Biotechnology Directive is not imminent. Five years (at least) would appear realistic as a time frame for a possible decision on the matter by the CJEU.

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[31] See decisions G 2/06, OJ EPO 2009, 306, point 7 of the Reasons for the Decision, T 1441/13, not published in the OJ EPO, point 4.1 of the Reasons for the Decision, as well as T 2221/10, not published in the OJ EPO, point 38 of the Reasons for the Decision; see also the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 573, marginal number 3.

[32] See point VII.4(1) of the Reasons for the Decision.

[33] G 2/06, OJ EPO 2009, 306, points 5 and 16 of the Reasons for the Decision.

[34] See the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 573, marginal number 3.

[35] Established case law since decision G 5/83, OJ EPO 1985, 64.

[36] See decisions T 2221/10 and T 1441/13, as well as Guidelines G-II, 5.3 (iii).

[37] See the EU Commission Notice, Introduction, sixth par.; see also Article 267 of the Treaty on the Functioning of the EU/TFEU.

32. The EU Commission Notice was issued to assist in the application of the EU Biotechnology Directive.[38] Although not legally binding, EU Commission Notices have an established function within the EU legal order. They are issued to reduce the risk of divergent legal interpretation, to promote the harmonised application and implementation of EU law by EU institutions and member states and to make addressees of certain rules fully aware of their rights and obligations. They are clearly distinct from mere political statements which cannot be taken into account in the interpretation of the EPC (under Rule 26(1) EPC).[39] Until a decision on the matter, if applicable, is handed down by the CJEU, the EU Commission Notice thus carries considerable weight and persuasive character. Besides, the Council of the EU and the European Parliament – i.e. the two other EU organs involved in the adoption of the EU Biotechnology Directive – have endorsed the view set out in the EU Commission Notice with regard to the exclusion from patentability of products obtained through essentially biological processes.

B. ANALYSIS OF OPTIONS 1 TO 4

33. With due regard to the jurisdiction of the boards of appeal and the legal status of the EU Commission Notice on the Biotechnology Directive as set out above, the potential options mentioned above are analysed in the following:

a) Option 1: Continuation of practice based on decisions G 2/12 – G 2/13

34. One possible option would be that the Office continues the practice based on the interpretation of Article 53(b) EPC given by the Enlarged Board of Appeal in decisions G 2/12 – G 2/13 to consider product claims to plants (and animals) or plant material such as fruit obtained by means of essentially biological processes allowable, provided that all formal and substantive requirements of the EPC are fulfilled.

[38] See the EU Commission Notice, Introduction, sixth par.
[39] See in this regard G 2/12, OJ EPO 2016, A27, point VIII.2(6)(c) of the Reasons for the Decision.

35. It constitutes established practice that the interpretation of the EPC by the Enlarged Board of Appeal forms the basis for the examination of patent applications and oppositions to granted patents.[40] As explained above, while from a legal point of view decisions of the Enlarged Board of Appeal under Article 112(1)(a) EPC on a point of law of fundamental importance are only binding on the board of appeal in respect of the appeal which gave rise to the referral[41], they have a *de facto* binding effect both for first-instance departments and boards of appeal. This is due to the fact that a board shall, if it considers it necessary to deviate from an interpretation of the Convention contained in an earlier decision of the Enlarged Board of Appeal, refer the question to the latter.[42]

36. The Enlarged Board of Appeal is the highest judiciary organ of the Organisation assigned with interpretative supremacy in order to ensure the uniform application of the EPC.[43] While decisions of the CJEU on the interpretation of the EU Biotechnology Directive are taken into account as persuasive by the EPO[44], the EU Commission Notice is not binding. It does not prejudge any future position of the EU Commission on the matter, and is without prejudice to a decision of the CJEU.[45] It could thus be argued that the Office should not change its practice in consideration of an EU Commission Notice unless and until the boards of appeal re-interpret Article 53(b) EPC taking into account the EU Commission Notice, or the CJEU confirms the interpretation of the EU Biotechnology Directive set out in the EU Commission Notice.

[40] See G 3/08, point 7.2.2 of the Reasons for the Opinion.
[41] Article 112(3) EPC.
[42] Article 21 Rules of Procedure of the Boards of Appeal.
[43] See Article 112(1) EPC.
[44] See decisions T 2221/10 and T 1441/13, as well as Guidelines G-II, 5.3(iii).
[45] See EU Commission Notice, Introduction, sixth par.

37. Under this option a European patent claiming a plant or fruit obtained by means of an essentially biological breeding process would be granted, provided that all formal and substantive requirements are fulfilled. In the case of an opposition filed against the European patent on the ground that such an invention should be considered excluded from patentability under Article 53(b) EPC[46], the opposition would be rejected and the decision could be appealed by the opponent. The competent board of appeal could under Article 21 of its Rules of Procedure refer the matter to the Enlarged Board of Appeal if the board considers that Article 53(b) EPC should be re-interpreted after the issue of the EU Commission Notice. The Enlarged Board of Appeal could either confirm or modify the interpretation of Article 53(b) EPC established by decisions G 2/12 – G 2/13 which, in the latter case, would only then trigger a change of practice by examining and opposition divisions.

38. If available by that time, a decision by the CJEU on the interpretation of Article 4 EU Biotechnology Directive could be taken into account as persuasive by the Enlarged Board of Appeal.[47] It is impossible to know, though, whether a CJEU decision on the matter will be available by the time a potential referral reaches the Enlarged Board of Appeal. About five years would appear realistic as a time frame for a potential decision on the matter by the Enlarged Board of Appeal and/or by the CJEU.

[46] See Article 100(a) EPC.
[47] See decisions T 2221/10 and T 1441/13, as well as Guidelines G-II, 5.3(iii).

39. Pending a decision on the matter by the CJEU, option 1 could significantly and for a considerable time compromise the harmonised treatment of affected applications and patents by the EPO, on the one hand, and contracting states' institutions, including the future Unified Patent Court (UPC), on the other. To continue allowing product claims to conventional plants would be inconsistent with the interpretation of the EU Biotechnology Directive set out in the EU Commission Notice and endorsed by the Council of the EU and the European Parliament. In post-grant proceedings a national court, not being legally bound by decisions G 2/12 and G 2/13 of the Enlarged Board of Appeal[48], could in the interpretation of Article 53(b) EPC give stronger consideration to the EU Biotechnology Directive as interpreted by the EU Commission when scrutinising the validity of a conventional plant patent granted by the EPO for its territory.[49] According to the information provided by delegations in document CA/PL 4/16, a number of contracting states already follow a practice which is in line with the interpretation set forth in the EU Commission Notice. If in the future the validity of a conventional plant patent granted by the EPO were challenged before the UPC, the Court would be obliged to respect the primacy of EU law over the EPC, and could possibly follow the interpretation of the EU Biotechnology Directive set forth in the EU Commission Notice.[50]

b) Option 2: Amendment of Article 53(b) EPC

40. As another option, the Administrative Council could decide to amend Article 53(b) EPC to the effect that – in accordance with the interpretation of the EU Biotechnology Directive set out in the EU Commission Notice – plants and animals produced by essentially biological breeding processes would be excluded from patentability.

[48] See in this regard the answers provided by delegations in document CA/PL 4/16 with regard to the legal effect of decisions of the Enlarged Board of Appeal in national jurisdictions.
[49] See Article 138(1)(a) EPC.
[50] See Articles 20 and 24 UPC Agreement.

41. Under Article 33(1)(b) EPC the Administrative Council has the competence to amend Part II of the Convention (Article 52 et seq. EPC) to bring it into line with European Community legislation relating to patents. This competence was introduced as part of the EPC 2000 reform to allow "*any consensus already achieved at EU ... level to be directly echoed in the EPC*" and thus to avoid "*having to hold revision conferences for the sole purpose of adapting the EPC to texts already adopted by all or a majority of contracting states*".[51] So far the Administrative Council has not yet made use of its competence under Article 33(1)(b) EPC.

42. An amendment of Article 53(b) EPC would mean that the exclusion of plants and animals obtained by essentially biological processes is regulated on the same normative level as the exclusion of essentially biological breeding processes, i.e. in an article of the Convention itself.[52] Such an amendment would not be subjected to an assessment for compliance with the hierarchy of norms principle and could thus not be refused enforcement by the boards of appeal on the ground of Article 164(2) EPC.[53]

43. Article 33(1)(b) EPC gives the Administrative Council the competence to bring the article into line with EU legislation. The wording of Article 53(b) EPC, though, is already identical to the corresponding Article 4(1)(b) of the EU Biotechnology Directive. The EU Commission Notice does not constitute EU legislation but rather, as explained above, a non-binding instrument intended to assist in the application of the EU Biotechnology Directive. An amendment of Article 53(b) EPC would thus require that the competence under Article 33(1)(b) EPC can also be used to bring an EPC article into line *with the interpretation* of a provision of the EU Biotechnology Directive set out in an EU Commission Notice, while at the same time and thereby going beyond the wording of the EU Biotechnology Directive. The boards of appeal have jurisdiction to scrutinise the legal basis of a legislative change and thus refuse enforcement also of an EPC article if it has been defectively enacted.[54]

[51] See Special edition No. 4, OJ EPO 2007, page 32.
[52] See in this regard the considerations made under point 1.1 of the EU Commission Notice.
[53] See in this regard decision T 315/03, point 5.8 of the Reasons for the Decision.
[54] T 315/03, point 5.8 of the Reasons for the Decision.

44. Apart from these considerations regarding the Administrative Council's competence to align Article 53(b) EPC with the EU Commission Notice, it needs to be taken into account that under Article 35(3) EPC amendments based on Article 33(1)(b) EPC require unanimity of all 38 contracting states. Under the same provision a decision taken on the basis of Article 33(1)(b) EPC shall not take effect if a contracting state declares, within twelve months of the date of the decision, that it does not wish to be bound by that decision. This means that an amendment of Article 53(b) EPC based on Article 33(1)(b) EPC, if adopted by unanimity, could only enter into force and be applied one year after the Administrative Council's decision, i.e. not before late-2018, and would thus prolong the state of uncertainty as to the EPO's examination practice and extend the stay of affected cases.

c) Option 3: Amendment of the EPC implementing regulations

45. As a further option, the Administrative Council could decide to amend the Implementing Regulations to the EPC under Article 33(1)(c) EPC to the effect that – in accordance with the interpretation of the EU Biotechnology Directive set out in the EU Commission Notice – plants and animals produced by essentially biological breeding processes would be excluded from patentability. Possible formulations and their likely effects are discussed in section VI, together with a draft rule proposal.

46. An amendment of the EPC Implementing Regulations would only be effective if it was not in conflict with the Convention, in particular Article 53(b) EPC. According to Article 164(2) EPC, in the case of conflict between the provisions of the Convention (the EPC articles) and those of the Implementing Regulations (the EPC rules), the provisions of the Convention will prevail. The boards of appeal are not bound by an amendment of the EPC Implementing Regulations clarifying the scope of an EPC article if they perceive the rule to be in conflict with an article, and can declare the rule invalid and non-enforceable under Article 164(2) EPC. This also applies in case of conflict of an EPC rule with the interpretation of an EPC article as established by a ruling of the Enlarged Board of Appeal.[55]

[55] See, for example, T 315/03, op. cit., point 5.7 of the Reasons for the Decision, as well as T 39/93, point 3.2 of the Reasons for the Decision: "*In other words, the meaning of an Article of the EPC (here, Article 114), on its true interpretation as established by a ruling of the Enlarged Board of Appeal cannot, in the Board's view, be overturned by a newly drafted Rule of the Implementing Regulations, the effect of which is to conflict with this interpretation.*"

47. While any limitation to the general entitlement to patent protection set forth in Article 52(1) EPC must have a clear legal basis in the EPC articles[56], it is permissible under the EPC, in particular under Article 164(2) EPC, that the scope of a patentability exclusion set forth in an EPC article is further defined in the EPC Implementing Regulations. Precisely the incorporation of the EU Biotechnology Directive is an example for EPC rules which clarify the meaning and scope of pre-existing EPC articles, in particular by providing rules for the more detailed application and interpretation of Article 53 EPC.[57]

48. In the case law concerning the rules inserted into the EPC from the EU Biotechnology Directive the boards of appeal found the EPC rules at stake to comply with Article 164(2) EPC since they only gave a more detailed interpretation of the meaning of Article 53 EPC and did not change the scope of the exclusion.[58] The relevant decisions of the boards of appeal concerned both Article 53(a) EPC and Article 53(b) EPC. Still, the considerations made in these decisions may not be directly applicable to the situation in which in the EPC rules the process exclusion of Article 53(b) EPC is extended to plants and animals obtained by essentially biological processes.

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[56] See, for example, G 2/12, OJ EPO 2016, A27, point VII.2(3)(b) of the Reasons for the Decision.

[57] See the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 573, marginal numbers 8-13.

[58] G 2/06, point 13: "*It has not been argued that Rule 28 (formerly 23d) EPC took away the possibility to patent anything which had previously been regarded as patentable under Article 53(a) EPC...*".

G 2/07 and G 1/08, point 2.5: "*It was generally accepted by those involved in the proceedings before the Enlarged Board that any protection of 'legitimate expectations' could only fall to be considered if the Enlarged Board's conclusion was that the introduction of Rule 23b(5) EPC 1973 changed the scope of the process exclusion contained in Article 53(b) EPC 1973, but not if the Enlarged Board solely deemed it necessary to make corrections to the approach in the jurisprudence hitherto, as established by decision T 320/87 (supra), which would not, however, be the result of the introduction of Rule 23b(5) EPC 1973.*"

T 315/03, point 5.1: "*The Board notes that it is clear from that sentence that the only function of the new Rules is to supply provisions for the application and interpretation of pre-existing provisions of the EPC. This reinforces views of the Board expressed both above (that the new Rules did not mark an entire change of régime as regards animal patents - see paragraph 4.5) and below (that the new Rules did not create retrospective bars to patentability - see paragraphs 5.9 and 5.10).*"

T 272/95, point 4: "*The Board concludes from the absence of transitional provisions that the Administrative Council must have been of the opinion that Rules 23(b) to 23(e) EPC only gave a more detailed interpretation of the meaning of Article 53 EPC as intended from its inception, and hence were also applicable to cases already pending before 1 September 1999 such as the present case.*"

49. In combined decisions G 2/12 – G 2/13 the Enlarged Board of Appeal held – based on the wording, context, legislative purpose and history – that Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit. In the reasons for the decision it is stated that Article 53(b) EPC does not extend to product claims and product-by-process claims directed to plants or plant material such as a fruit or plant parts other than a plant variety, that such inventions are not excluded from patentability under Article 53(b) EPC but rather patentable under the EPC if all formal and substantive requirements are fulfilled.[59] The Enlarged Board of Appeal also stated that the intention of the legislator of Article 53(b) EPC 1973 was to direct the exclusion from patentability in respect of plants to only two groups, i.e. "plant varieties" and "essentially biological processes for the production of plants", and that the decision of the legislator not to amend Article 53(b) EPC at a later stage could not be ignored.[60] Last but not least the Enlarged Board of Appeal did not find a basis in the EU Biotechnology Directive for extending the process exclusion under Article 4(1) EU Biotechnology Directive and Article 53(b) EPC to products of such processes.[61]

50. Notwithstanding this finding with regard to the EU Biotechnology Directive, the reasoning of the Enlarged Board of Appeal shows that in its decision it attaches great importance to the EU Biotechnology Directive, in accordance with the legislator's instruction expressed in Rule 26(1) EPC that it be taken into account in the interpretation of the relevant EPC provisions.[62] The Enlarged Board of Appeal moreover acknowledges that the incorporation of the EU Biotechnology Directive into the EPC amounts to a "subsequent agreement" by the EPC legislator.[63] The Enlarged Board of Appeal also refers to the development of the legislator's intention subsequent to the signing of the EPC 1973.[64]

[59] See in particular points VII.2(5), VII.6(2), IX(1), (3) and (4) of the Reasons for the Decision.
[60] See point VIII.1(4) of the Reasons for the Decision.
[61] See point VII.4 of the Reasons for the Decision.
[62] See point VII.4 of the Reasons for the Decision.
[63] See point VII.4(1) of the Reasons for the Decision.
[64] See point VIII.1 of the Reasons for the Decision.

51. This reasoning of the Enlarged Board of Appeal may give grounds for assuming that the EU Commission Notice constitutes an element which would have been taken into account by the Enlarged Board of Appeal under Rule 26(1) EPC in the interpretation of Article 53(b) EPC and likewise would be considered in the case of a new referral concerned with the interpretation of Article 53(b) EPC.

52. Interpreting Article 53(b) EPC in the light of the EU Commission Notice, notably its section 1.2, and in accordance with the principles of interpretation provided for in Articles 31 and 32 Vienna Convention[65], may give grounds for arguing that an EPC rule which explicitly excludes from patentability plants or animals obtained by means of an essentially biological process is not in conflict with Article 53(b) EPC.

53. More specifically, based on section 1.2 of the EU Commission Notice and the statements of the Council of the EU and the European Parliament, it may be accepted that the EU legislator intended the process exclusion to cover also products obtained by essentially biological processes. On this basis there are grounds to conclude that shortly thereafter when incorporating the EU Biotechnology Directive into the EPC and carrying the amendments forward as part of the EPC 2000 reform the EPC contracting states, including those not members of the EU, reached the subsequent agreement within the meaning of Article 31(3)(a) Vienna Convention that Article 53(b) EPC be interpreted in the same way.[66]

[65] See established case law of the EPO boards of appeal, including G 2/12 – G 2/13, point V of the Reasons for the Decision.

[66] See in this regard G 2/06, OJ EPO 2009, 306, points 5 and 16 of the Reasons for the Decision; G 2/12 – G 2/13, OJ EPO 2016, A27 and A28, point VII.4(1) of the Reasons for the Decision; documents MR/24/00, page 3, CA/155/98 and CA/7/99, as well as the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 575.

54. In the case of an appeal against a decision refusing a European patent application based on a new EPC rule explicitly excluding from patentability conventionally bred plants and animals, the competent board of appeal might have to assess whether the rule is valid and enforceable under Article 164(2) EPC. In this context it may decide to refer the matter to the Enlarged Board of Appeal if it intends to deviate from the interpretation of Article 53(b) EPC established in G 2/12 – G 2/13.[67] The Enlarged Board of Appeal would then be called upon to decide on the interpretation of Article 53(b) EPC taking into account the EU Commission Notice and with regard to the new EPC rule. A decision of the CJEU on the interpretation of the EU Biotechnology Directive could be taken into account as persuasive if available by that time.

d) Option 4: Change of practice based on modified administrative instructions taking into account the EU Commission Notice

55. As a non-legislative measure, modified administrative instructions (EPO notice, Guidelines) could be issued which take into account the EU Commission Notice in defining the practice of the EPO's first-instance departments under Article 53(b) EPC. On this basis examining and opposition divisions could be instructed to consider product and product-by-process claims to plants or animals exclusively obtained by means of an essentially biological process not allowable and excluded from patentability under Article 53(b) EPC.

56. As explained above, the reasoning of the Enlarged Board of Appeal in decisions G 2/12 – G 2/13 may give grounds for assuming that the EU Commission Notice constitutes an element which, if available at the time of deliberation and decision-making, would have been taken into account by the Enlarged Board of Appeal under Rule 26(1) EPC in the interpretation of Article 53(b) EPC, and would likewise be looked at in the case of a new referral concerned with the interpretation of Article 53(b) EPC. Under these circumstances it could be considered that the first instance should not continue basing its practice on decisions G 2/12 – G 2/13 which do not and could not take into account the EU Commission Notice in the interpretation of Article 53(b) EPC. As the President of the EPO cannot refer the issue to the Enlarged Board of Appeal[68], the first instance would itself need to re-interpret Article 53(b) EPC in the light of the EU Commission Notice until the matter is eventually clarified by the boards of appeal.

[67] Under Article 21 Rules of Procedure of the Boards of Appeal, a board may, if it considers it necessary to deviate from an interpretation of the Convention contained in an earlier decision of the EBA, refer the question to the EBA.

[68] Under Article 112(1)(b) EPC the President may only refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given different decisions on that point; see also decision G 3/08, op. cit.

57. Such a re-interpretation by the first instance does not directly disregard the interpretative supremacy of the Enlarged Board of Appeal, neither in general nor specifically with regard to these decisions. Rather, it is in line with the teaching of these decisions to take full account of the EU Biotechnology Directive and thus also of any new element arising after publication of the decisions. The Office has in the past interpreted an EPC provision which had been subject of a decision by the Enlarged Board of Appeal in the light of new technical or legal developments or in order to apply it to a different case. For example, decision G 2/06 of the Enlarged Board of Appeal on the interpretation of Article 53(a) and Rule 28(c) EPC had to be re-interpreted in the light of new technical developments and decisions of the CJEU.[69] In a similar manner, decisions G 2/07 – G 1/08 on the interpretation of the process exclusion in Article 53(b) EPC are continuously applied to different types of breeding processes.[70]

58. The EPO's examining and opposition divisions could be instructed at short notice to apply this interpretation of Article 53(b) EPC explained in marginal number 53 above[71] in the examination of affected applications or patents without the need to wait for entry into force of a new EPC rule and extend the current stay of proceedings until that time. In the case of an appeal against a refusal or revocation decision by an examining or opposition division, the interpretation of Article 53(b) EPC by the division would be subject to review by the competent board of appeal. Should the board decide to refer the matter to the Enlarged Board of Appeal under Article 21 of the Rules of Procedure of the Boards of Appeal, the Enlarged Board of Appeal could express itself on the effect, if any, of the EU Commission Notice for the interpretation of Article 53(b) EPC and the approach of the division in this regard. A decision of the CJEU on the interpretation of the EU Biotechnology Directive could be taken into account as persuasive if available by that time.

[69] See in this regard CA/PL 6/11 as well as decisions T 2221/10, T 1441/13 and T 2365/13.
[70] See in this regard decision T 1729/06, point 9 et seq. of the Reasons for the Decision.
[71] Namely that interpreting Article 53(b) EPC in the light of the EU Commission Notice, notably its section 1.2, and in accordance with the principles of interpretation provided for in Articles 31 and 32 Vienna Convention, would give grounds for considering that plants or animals obtained by means of an essentially biological process for the production plants or animals are excluded from patentability under Article 53(b) EPC. More specifically, based on section 1.2 of the EU Commission Notice and the statements of the Council of the EU and the European Parliament, it may be accepted that the EU legislator intended the process exclusion to cover also products obtained by essentially biological processes. On this basis there are grounds to conclude that shortly thereafter when incorporating the EU Biotechnology Directive into the EPC and carrying the amendments forward as part of the EPC 2000 reform the EPC contracting states, including those not members of the EU, reached the subsequent agreement within the meaning of Article 31(3)(a) Vienna Convention that Article 53(b) EPC be interpreted in the same way.

C. SUMMARY

59. In accordance with the clear will of the EPC legislator and the established case law of the boards of appeal, particular importance should be attached to the need to safeguard uniformity in harmonised European patent law. As far as possible, a solution should be sought which provides clarity about the practice of the EPO. While from the perspective of legal certainty it may be considered preferable to take any action only after a decision of the CJEU, it is impossible to know if and when such a decision could become available.

60. To consider product claims to conventional plants (and animals) allowable under Article 53(b) EPC on the basis of decisions G 2/12 – G 2/13 (option 1), which could not take into account the EU Commission Notice in the interpretation of Article 53(b) EPC, would bring the Office's practice into conflict with the interpretation of the EU Biotechnology Directive set out in the EU Commission Notice and endorsed by the Council of the EU and the European Parliament.

61. An amendment of Article 53(b) EPC (option 2), if it can be based on Article 33(1)(b) EPC, would avoid issues under Article 164(2) EPC but would require unanimity of the contracting states and a longer time frame before becoming applicable.

62. An amendment of the EPC Implementing Regulations (option 3) would provide a clear legal basis for the Office's practice; its compliance with Article 164(2) EPC could be based on a modified interpretation of Article 53(b) EPC which takes into account the EU Commission Notice. An amendment of the EPC Implementing Regulations is the option raised in the previous meeting by a number of delegations and addressed in more detail in section VI.

63. The release of modified administrative instructions (EPO notice, Guidelines) which take into account the EU Commission Notice in defining the practice of examining and opposition divisions under Article 53(b) EPC (option 4) could be implemented at short notice and become the subject of review by the boards of appeal.

64. Under any option, ultimate legal certainty for the EPO's legal framework and practice will be established by a decision of the Enlarged Board of Appeal which, if available, takes into account a decision of the CJEU.

VI. PROPOSAL FOR AMENDMENT OF THE EPC IMPLEMENTING REGULATIONS

65. The purpose of a possible amendment of the EPC Implementing Regulations would be to align the EPC and the EPO's practice under Article 53(b) EPC with the interpretation of the EU Biotechnology Directive set out in the EU Commission Notice. The draft proposal presented hereunder (C) takes into account existing formulations/terminology (A) and is based on a definition of the technical subject-matter to be excluded (B).

A. EXISTING FORMULATIONS/TERMINOLOGY

66. In its Notice the EU Commission refers to "***products derived from*** *essentially biological processes*"[72], "***products emanating from*** *essentially biological processes*"[73], "***plants or plant material (fruits, seeds, etc.) or animals/animal material obtained through/by*** *essentially biological processes*"[74] and "*animals that are* ***directly obtained from*** *essentially biological processes*"[75]. The EU Commission also states that "[t]*he trigger point for ensuring the patentability of either a plant or an animal is the technical process, such as for instance the insertion of a gene into a genome*."[76]

67. Four contracting states – France, Germany, Italy and the Netherlands – are known to have introduced into their national patent acts an explicit exclusion for conventionally bred plants and animals.[77] The relevant provisions read as follows:

- Article L 611-19 I. 3°bis of the French Code de la Propriété Intellectuelle:

  "Ne sont pas brevetables : ... ***Les produits exclusivement obtenus par des procédés essentiellement biologiques définis au 3°, y compris les éléments qui constituent ces produits et les informations génétiques qu'ils contiennent****."*[78]

[72] See Introduction, fifth par.
[73] See Introduction, sixth par.
[74] See, for example, section 1.1, first par. and section 1.3, last par.
[75] See section 1.3, last par.
[76] See section 1.3, tenth par.
[77] See in this regard the information provided by delegations reproduced in document CA/PL 4/16 and its addenda.
[78] "The following shall not be patentable: ... The products exclusively obtained by essentially biological processes as defined in paragraph 3, as well as the elements making up these products and the genetic information they contain."

- Article 2a (1) No. 1 of the German Patent Act:

  "Patente werden nicht erteilt für ... im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren ***und die ausschließlich durch solche Verfahren gewonnenen Pflanzen und Tiere****;"*[79].

  The explanatory notes state that the exclusion covers seed and sperm but not products derived from conventionally bred plants and animals such as plant oils. It is further stated that the term "exclusively" ("*ausschließlich*") intends to clarify that genetically modified plants and animals are not covered by the exclusion even if in addition to the genetic modification an essentially biological process of crossing and selection has been applied in producing the plant or animal.[80]

- Article 81*quater* (e) of the Italian Industrial Property Code reads (in English translation):

  "The following may be patented provided that they meet the requirements of novelty and inventive activity and are susceptible to industrial application:
  e) an invention regarding plants or animals ..., if their application is not limited ... to the obtainment of a specific plant variety or animal species, and they are not exclusively obtained by essentially biological processes, ...".[81]

- Article 3(1)(d) of the Dutch Patent Act provides (in English translation):

  "No patents shall be issued for ... essentially biological processes consisting entirely of natural phenomena such as hybridisations or selections in order to produce plants or animals ***and the products obtained thereby****".*[82]

[79] "Patents shall not be granted in respect of ... essentially biological processes for the production of plants or animals or the plants or animals resulting exclusively from such processes."
[80] See parliamentary publication ("*Bundestags-Drucksache*") 17/14222 of 26 June 2013, page 3.
[81] "*(1)(e) Sono brevettabili purché abbiano i requisiti di novità e attività inventiva e siano suscettibili di applicazione industriale: un'invenzione riguardante piante o animali ... se la loro applicazione non è limitata ... all'ottenimento di una determinata varietà vegetale o specie animale e non siano impiegati, per il loro ottenimento, soltanto procedimenti essenzialmente biologici ..."*
[82] "Niet vatbaar voor octrooi zijn: werkwijzen van wezenlijk biologische aard, geheel bestaand uit natuurlijke verschijnselen zoals kruisingen of selecties, voor de voortbrenging van planten of dieren alsmede de hierdoor verkregen voortbrengselen."

68. There are many other examples, including in the case law (e.g. decisions G 2/12 – G 2/13), of the different terminology used to identify what is or should be excluded from patentability as the result of an essentially biological process for the production of plants and animals: whether it is "*plants and animals*" or "*products*", "*produced by*", "*emanating from*" or "*obtained through/by/from*", whether the additional qualifier "*directly*" or "*exclusively*" is used, and whether explicit reference is made to plant/animal "*parts*" and breeding material such as "*seed and sperm*".

69. Although not with regard to conventional plants and animals, the EPC already foresees provisions dealing with the products of certain processes:

- Article 53(b) *ad fine* EPC and Rule 27(c) EPC, which exempt microbiological processes and products from the exclusion from patentability for essentially biological processes, refer to "***the products thereof***"[83] and "***a product obtained by means of such a process***"[84].

- Article 64(2) EPC concerning the extent of protection of process claims refers to "***the products directly obtained by such process***".[85]

- Rule 28(d) EPC concerning the exclusion of processes for modifying the genetic identify of animals refers to "***animals resulting from such processes***".[86]

[83] Article 53(b) EPC: "*...; this provision shall not apply to microbiological processes or the products thereof;*"
[84] Rule 27(c) EPC: "*Biotechnological inventions shall also be patentable if they concern: a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety*."
[85] Article 64(2) EPC: "*If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process*."
[86] Rule 28(d) EPC: "*Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes*."

B. SUBJECT-MATTER CONCERNED

70. The plurality of existing formulations suggests that a possible EPC rule should be drafted to clearly define and delimit in technical terms the subject-matter to be excluded in consideration of the interpretation of the EU Biotechnology Directive set forth in the EU Commission Notice.[87]

a) Non-technical processes vs. technical processes

71. According to the EU Commission Notice the EU legislator intended to exclude the products (plants/animals and plant/animal parts) obtained by non-technical breeding processes, i.e. plant and animal production processes which are not of a technical nature (natural processes).[88]

72. The EU Commission Notice further takes the view that the trigger point for ensuring the patentability of either a plant or an animal is the technical process, such as for instance the insertion of a gene into a genome. Essentially biological processes are not of a technical nature and therefore, they cannot be covered by a patent.[89]

73. In accordance with decisions G 2/07 – G 1/08 of the EPO's Enlarged Board of Appeal, a process for the production of plants or animals is considered as being essentially biological and thus non-technical if it is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals. This applies even if the process comprises human intervention, including the provision of technical means, serving to enable or assist the performance of the process steps or if other technical steps relating to the preparation of the plant or animal or its further treatment are present in the claim before or after the crossing and selection steps. For example, a method of crossing, inter-breeding, or selectively breeding plants involving merely selecting for breeding and bringing together the parental plants (or their gametes) having certain characteristics is considered essentially biological. This method remains essentially biological even if it contains an additional feature of a technical nature, for example, the use of genetic molecular markers to select either parent or progeny.[90]

[87] See EU Commission Notice, section 1.
[88] See EU Commission Notice, section 1.3.
[89] See EU Commission Notice, section 1.3, tenth par.
[90] See Guidelines G-II, 5.4.2.

74. However, if such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC but qualifies as a potentially patentable technical teaching.

75. In inventions falling under this exception, the genetic characteristics of the resulting plant or animal have been changed by a technical process which exceeds crossing and selection.

76. The essential point is that the technical effect, i.e. the characteristics of the plant in the example above, is exclusively brought about by the essential biological process. The use of molecular markers for the selection of the desired plant does not change the characteristics of the plant. The definition in decisions G 2/07 – G 1/08 of what is required to render a process technical confirms this concept. This is in line with the consideration made in the EU Commission Notice that "[t]*he trigger point for ensuring the patentability of either a plant or an animal is the technical process*".[91]

77. This means that, according to the EU Commission Notice, what was intended to be excluded by the EU legislator under the EU Biotechnology Directive and what should be covered by a potential EPC rule are plants and animals obtained by crossing and selection **only**, i.e. by conventional breeding techniques where no direct intervention in the genome of the plants or animals takes place as the relevant parental plants or animals are merely crossed and the desired offspring is selected for.

[91] See EU Commission Notice, section 1.3, tenth par.

b) Transgenic plants or animals, including transgenic descendants

78. As explicitly held in the EU Commission Notice, transgenic plants or animals are not considered to be the products of essentially biological processes. The insertion of a transgene into a genome constitutes a technical process. They are thus patentable under the EU Biotechnology Directive if not consisting of a particular plant or animal variety.[92]

79. Transgenic plants or animals are made by transforming a plant or parts thereof, or a fertilized animal embryo or stem cell in the case of animals, with a nucleic acid construct of interest. The plant which was either directly transformed or which is regenerated from the transformed parts is usually designated T0. By analogy the animal developing from the transformed embryo is designated F0.

80. Transgenic plants or animals are thus the result of a technical process. This is in line with the practice of the EPO based on the interpretation of Article 53(b) EPC established in decision G 1/98, according to which transgenic plants are considered to be the product of a technical process and in principle patentable if not confined to a particular plant variety. The same applies *mutatis mutandis* to transgenic animals.

81. Descendants from a transgenic plant are not obtained by transformation but by crossing a transgenic plant with further plants (transgenic or not). Still, all descendants of a transgenic plant which carry the transgene are equally transgenic, due to the genetic modification present in these further generations being the result of the genetic modification done to plant T0. Since the technical effect (e.g. resistance to a pathogen) is the result of a technical process, i.e. the technical result produced by the features of the invention (namely the insertion of a gene into the genome), a transgenic plant cannot be considered a product obtained by means of an essentially biological process even if, as in the case of descendants from a transgenic plant, it is obtained by crossing. The same applies, again, *mutatis mutandis* to generations of transgenic animals. This corresponds to the EPO's current practice.

[92] See EU Commission Notice, section 1.3.

c) Mutagenesis

82. Similar considerations apply to plants or animals obtained by mutagenesis. In the case of mutagenesis, a first generation of plants (designated M0) is created by subjecting a plant or a plant cell to a mutation process. Mutagenesis as such is considered to be a technical process which results in a modification of the genome of the plant or animal. This applies to "traditional" methods like irradiation or chemical mutagenesis, but even more so to molecular methods like Zinc Finger Nucleases and CRISPR which require man-made molecules for targeted mutagenesis. As for transgenics, the further generations (M1, M2, etc.) are made by crossing a mutated plant or animal with any other desired plant or animal.

83. Some forms of mutagenesis occur in nature (usually called spontaneous mutagenesis). However, whether a specific mutation indeed would occur as the result of spontaneous mutagenesis is entirely speculative. Application of an exception to patentability cannot depend on hypothetical considerations and on whether specific process elements are traceable in the claimed product, in particular when taking into account the considerable developments in the technical field of plant breeding in the past and the unpredictable nature of future developments. This would introduce an inconsistency into the system of the EPC with far-reaching consequences, in particular in the field of chemical compound inventions. The mere possibility that a claimed mutated plant might also result from a natural (i.e. non-technical) process thus does not permit to extend the envisaged exclusion to mutant plants which the patent application describes as being obtained and produced through the application of mutagenesis techniques resulting in the modification of the genome and the achievement of a technical effect. This would concern, for example, a case in which a plant is made resistant to a pathogen by the process of artificial mutation while maintaining the characteristics of the commercial cultivar and without introducing foreign genetic material.

d) Plant and animal propagation material (seed, embryo, seed coated with chemicals)

84. Plant or animal propagation material is defined as material which can be used to produce whole plants or animals, such as plant seeds or in the case of animals fertilised ova and embryos. In addition, a whole plant can be regenerated from plant parts containing live cells, i.e. leaves or any other live plant organs. Such products are regarded as not different from seeds. Propagation material is to be treated in the same manner as the plants or animals themselves. This means that they would fall under the exclusion, too, if the technical effect is exclusively brought about by an essential biological process. This corresponds to current EPO practice with regard to the exclusion of plant varieties: An applicant cannot circumvent the prohibition of patenting a plant variety by claiming the seeds or other propagation material instead of the plant.

85. Thus, seeds for which the technical contribution lies in a trait of the resulting plant which was exclusively brought about by an essential biological process would be excluded from patentability in the same way as the plant itself. Transgenic seeds, on the other hand, would be patentable, even though the seeds as such can only be obtained by fertilising a flower and hence by an essentially biological process. This is in line with the principle that the product should be patentable if the technical effect (here: the transgene and the technical effect caused thereby) is not brought about by an essential biological process.

86. There are also inventions on seeds for which the technical contribution does not lie in a feature of the resulting plants, but in an additional technical feature imparted on the seed itself. Seeds coated with various chemicals lead to better germination, pathogen resistance, etc. These transient features are not heritable and cannot be detected in the adult plant. As underlined in the EU Commission Notice, the trigger point for patentability of a plant is the technical process used to produce the characterising feature. In accordance with Articles 52 and 53(b) EPC and in line with the interpretation of the EU Biotechnology Directive set forth in the EU Commission Notice, seeds covered with a certain chemical, etc., are not to be regarded as excluded from patentability under European patent law.

87. The same applies to compositions comprising non-human animal embryos, wherein the composition protects or cryopreserves the embryo. Said subject-matter is not to be regarded as excluded from patentability under Article 53(b) EPC.

e) Plant or animal parts (other than propagation material) and derived products

88. As regards plant parts as well as plant-derived products, there is an essential difference between plant parts from which an entire plant can be regenerated, and other plant-derived parts/products. The patentability of plant and animal parts qualifying as propagation material should be assessed in the same way as entire plants and animals (see above d)). The EU Commission Notice explicitly refers to plant/animal parts.

89. The situation is entirely different for any plant products that are not propagation material, such as meal, sugars or fatty acids. Such subject-matter has to be considered on the basis of its chemical properties only. If a sugar molecule fulfils the general patentability requirements, it will not be relevant whether it was produced in a living plant, which is the product of an essentially biological process, or in a laboratory. The same applies *mutatis mutandis* to animal-derived products which are not propagation material such as, for example, fur or leather or cellular extracts obtained from non-human fertilised embryos.

90. In this context it is noted that such plant or animal products often do not enjoy the same inventive step as the live organism they are derived from, e.g. a plant carrying a resistance might be patentable but in its meal said resistance is not a technical feature.

91. There is no suggestion in the EU Commission Notice that the EU legislator intended to exclude from patentability under the EU Biotechnology Directive also such plant- or animal-derived products.

C. DRAFT PROPOSAL FOR AMENDMENT OF RULES 27(B) AND 28 EPC

92. The amendment of the EPC Implementing Regulations is intended to supply provisions for the more detailed application and interpretation of Article 53(b) EPC, namely for the exclusion of *"essentially biological processes for the production of plants or animals"*. For this reason a possible new EPC Rule should explicitly refer to **Article 53(b) EPC** and replicate the term "**essentially biological process**".

93. It should furthermore employ the terms "**plants or animals**", as in Article 53(b) EPC. This would clarify that plants and animals as well as propagation materials thereof are covered by the exclusion from patentability, but not any plant- or animal-derived products like fur or meal, or even other products like fungi or yeasts (see above).

94. For the purpose of clarifying that a plant or animal originating from a technical process or characterised by a technical intervention in the genome is not covered by the exclusion from patentability even if in addition a non-technical method (crossing and selection) is applied in its production (as in the case of descendants from a transgenic plant or animal), the wording "**exclusively** obtained by" could be used.

95. **Rule 28 EPC** concerning "exceptions to patentability" relates to Article 53 EPC and clarifies the meaning and scope of Article 53(a) EPC. It thus lends itself to the insertion in an additional paragraph 2 of a possible new provision relating to Article 53(b) EPC.[93]

96. **Rule 27(b) EPC** also needs to be taken into account as it reflects the principle that plants and plant material other than plant varieties are generally eligible for patent protection.[94] It would thus appear appropriate to make clear that any new rule inserted into the EPC Implementing Regulations constitutes a *lex specialis* in relation to Rule 27(b) EPC and that therefore the principle set forth in Rule 27(b) EPC is "**without prejudice**" to the exclusion of conventionally bred plants and animals clarified in the new rule.

[93] See G 2/06, OJ EPO 2009, 306, point 13 of the Reasons for the Decision; G 2/07- G 1/08, OJ EPO 2012, 130 and 206, point 2.5 of the Reasons for the Decision; T 315/03, OJ EPO 2006, 15, point 5.1 of the Reasons for the Decision; T 272/95, point 4 of the Reasons for the Decision, as well as the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 573, marginal numbers 8-13.

[94] See G 2/12 – G 2/13, OJ EPO 2016 A27 and A28, point VIII.2(6)(a) of the Reasons for the Decision.

97. In view of the importance of the matter, the amended rules could enter into force on the first day of the month immediately following the Administrative Council's decision to amend the Implementing Regulations to the EPC. As explained above, the statutory exclusion of plants and animals exclusively obtained by an essentially biological breeding process could be applied to pending applications and European patents as well as to newly filed applications.

98. Taking into account these considerations, amended Rule 27(b) and new Rule 28(2) EPC could read as follows:

Present wording	Proposed wording
Rule 27 **Patentable biotechnological inventions**	**Rule 27** **Patentable biotechnological inventions**
Biotechnological inventions shall also be patentable if they concern:	Biotechnological inventions shall also be patentable if they concern:
(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;	(a) *Unchanged*
(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;	(b) **without prejudice to Rule 28, paragraph 2,** plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.	(c) *Unchanged*
Rule 28 **Exceptions to patentability**	**Rule 28** **Exceptions to patentability**
Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:	**(1)** Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
(a) processes for cloning human beings;	(a) processes for cloning human beings;

Present wording	Proposed wording
(b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.	(b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes. **(2) Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.**

D. ALTERNATIVE APPROACH FOR AN AMENDMENT OF THE IMPLEMENTING REGULATIONS

99. As an alternative to the draft proposal presented above, the possibility could be explored to define the excluded plants and animals not by reference to the applied breeding process but rather by reference to the resulting genetic composition. For example, if a claimed plant or fruit solely comprises naturally occurring material or a combination thereof which can be brought about by essentially biological processes only, it could be considered excluded from patentability taking into account the EU Commission Notice. It is unclear, though, how the skilled person could ascertain this feature in the final product without having to resort to the process used.

100. It could further be considered to define plants and animals as patentable only if (in addition to the requirement set forth in Rule 27(b) EPC that the technical feasibility of the invention is not confined to a particular plant or animal variety) the technical effect or technical character of the invention is not exclusively brought about by an essentially biological breeding process.

101. As a further consideration, the possibility of defining in the EPC rules more precisely the distinction between an essentially biological or natural process as opposed to a technical process as set forth also in the EU Commission Notice could be analysed, in particular in view of the fact that the Enlarged Board of Appeal considered in decision G 2/07 that the definition in Rule 26(5) EPC does not give any useful guidance on how to interpret the term "essentially biological process for the production of plants" in Article 53(b) EPC.

102. It appears, however, that any attempt to clearly define the product or the process, as mentioned above, would introduce unclear terms and thereby legal uncertainty into the EPC and may raise issues with regard to the definition of essentially biological process developed in decision G 2/07.

VII. FINANCIAL IMPLICATIONS

103. N/A.

VIII. LEGAL BASIS

104. Article 10(2)(c) EPC; Article 33(1) EPC.

IX. DOCUMENTS CITED

105. CA/155/98; CA/7/99; CA/PL 6/11; CA/PL 12/15; CA/PL 3/16; CA/PL 4/16; CA/PL PV47; MR/24/00.

X. RECOMMENDATION FOR PUBLICATION

106. Yes.