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SUBJECT: Exclusion from patentability under Article 53(b) EPC of plants and animals produced by essentially biological processes – amendment of Rules 27(b) and 28 EPC

SUBMITTED BY: President of the European Patent Office

ADDRESSEES:

1. Administrative Council (for decision)
2. Committee on Patent Law (for information)

SUMMARY

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 order to align the EPO's law and practice with the interpretation of the Directive and to safeguard uniformity in harmonised European patent law, it is proposed to clarify the interpretation of Article 53(b) EPC by way of amendments to Rules 27(b) and 28 EPC.

In its 48th meeting in April 2017 the Committee on Patent Law, having considered various options (CA/PL 4/17), gave a favourable opinion on the proposed Rule changes.

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PART I

I. STRATEGIC/OPERATIONAL

1. Operational.

II. RECOMMENDATION

2. The Administrative Council is requested to approve the draft decision in Part II of this document.

III. MAJORITY NEEDED

3. Three quarters.

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 2010² 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 2015³ 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 2016⁵ 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. 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.
10. In December 2015 the European Parliament adopted a resolution⁷ 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.

⁴ Parts 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 edition of 1 November 2015 and subsequently carried over into the Guidelines edition 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.

⁷ P8_TA-PROV(2015)0473: European Parliament Resolution of 17 December 2015 on patents and plant breeders' rights, 2015/2981(RSP).

11. 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.
12. 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
13. 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
14. In the meeting of the Committee on Patent Law of 21 and 22 November 2016 the EU Commission presented its Notice.¹² Delegations invited the Office 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.¹³

⁸ See documents CA/PL 12/15, CA/PL 3/16 and CA/PL 4/16.

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.

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.

15. 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
16. In its 48th meeting on 27 and 28 April 2017 the Committee on Patent Law discussed various options for the way forward on the basis of the analysis prepared by the Office (CA/PL 4/17). The Committee expressed clear support for the option of amending the EPC Implementing Regulations. For the precise wording of the amendment, alternative proposals from the Swiss delegation, which was later withdrawn, as well as from Business Europe (CA/PL 8/17) and epi (CA/PL 9/17) were taken into account in addition to the draft text included in the Office's analysis (point 98 of CA/PL 4/17). The discussions resulted in a clear support for the wording set out in the Office's analysis. The Committee invited the Office to maintain the technical details of points 70-91 of CA/PL 4/17 in the Council document as explanatory notes.¹⁵ Likewise, the Committee proposed to reflect in the document on the ideas underlying the Swiss proposal, in particular the considerations relating to a disclaimer, without the substance having been discussed in the Committee. On this basis the Office was invited to submit a proposal for amendment of the Implementing Regulations to the EPC for decision by the Administrative Council in June.

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.

¹⁵ See section V. B. of the present document.

V. ARGUMENTS

A. REASONS FOR THE AMENDMENT

17. Although the European Patent Organisation as an independent international organisation with its own legal order is itself not legally bound by the EU Biotechnology Directive¹⁶, 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 2/13¹⁷ and earlier decision G 2/06.¹⁸
18. 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.¹⁹ The significance of this principle is also recognised in the established case law of the boards of appeal.²⁰
19. 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.²¹

¹⁶ See 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.

¹⁷ See point VII.4(1) of the Reasons for the Decision.

¹⁸ G 2/06, OJ EPO 2009, 306, points 5 and 16 of the Reasons for the Decision.

¹⁹ 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.

²⁰ Established case law since decision G 5/83, OJ EPO 1985, 64.

²¹ See T 2221/10 and T 1441/13, as well as Guidelines G-II, 5.3 (iii).

20. The EU Commission Notice was issued to assist in the application of the EU Biotechnology Directive.²² It does not prejudice any future position of the EU Commission on the matter, and is without prejudice to a decision of the CJEU.²³ 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).²⁴ 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.
21. 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. In particular, four contracting states (DE, FR, NL, IT) have in their national Patent Acts an explicit exclusion for plants and animals obtained by conventional breeding processes:

Article L 611-19 I. 3°bis of the French Code de la Propriété Intellectuelle reads (in English translation):

*"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."*²⁵

²² See EU Commission Notice, Introduction, sixth par.

²³ See EU Commission Notice, Introduction, sixth par.

²⁴ See in this regard G 2/12, OJ EPO 2016, A27, point VIII.2(6)(c) of the Reasons for the Decision.

²⁵ *"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."*

Article 2a (1) No. 1 of the German Patent Act reads (in English translation):

*"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."*²⁶

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.²⁷

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, ..."*²⁸

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 crossing or selection in order to produce plants or animals and the products obtained thereby"*²⁹

²⁶ "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;".

²⁷ See parliamentary publication ("*Bundestags-Drucksache*") 17/14222 of 26 June 2013, page 3.

²⁸ "(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 ..."

²⁹ "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."

22. Four more contracting states (AT, CH, PL, PT) are currently discussing or implementing a corresponding amendment of their national law. This means not only that a national authority in these countries would not allow product claims to conventional plants and animals. Also in post-grant proceedings relating to a European patent a national court could give stronger consideration to the EU Biotechnology Directive as interpreted by the EU Commission when scrutinising the validity of the patent for its territory.³⁰
23. Against this background the European Patent Organisation should align its law and practice with the interpretation of the EU Biotechnology Directive in order to safeguard legal certainty as well as the uniformity in harmonised European patent law and the harmonised treatment of affected applications and patents by the Office, on the one hand, and by contracting states' institutions, including the future UPC, on the other.
24. The alignment of the EPC with the interpretation of the EU Biotechnology Directive can be achieved via an amendment of the EPC Rules. 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 Convention³¹, it is permissible under the EPC that the scope of a patentability exclusion set forth in an EPC article is further defined in the EPC Implementing Regulations. Under Article 164(1) EPC the Implementing Regulations are an integral part of the Convention and hence are equally binding on the EPO's Boards of Appeal (Article 23(3) EPC) and on national courts. Hence, for practical application of the Convention, only the interpretation of its provisions laid down in the Implementing Regulations is binding. A different interpretation of the Convention would be possible only if it is specifically demonstrated that a particular rule of interpretation is inconsistent with the Convention itself (see marginal number 25.). 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.³²

³⁰ See Article 138(1) EPC.

³¹ See, for example, G 2/12, OJ EPO 2016, A27, point VII.2(3)(b) of the Reasons for the Decision.

³² 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.

25. The Boards of Appeal, in particular the Enlarged Board of Appeal, have jurisdiction to review the compliance of EPC Rules with the Articles of the Convention.³³ As in decisions G 2/12 - G 2/13 and in accordance with Rule 26(1) EPC, the EU Biotechnology Directive is taken into account in the interpretation of the relevant EPC provisions. In this context, a possible decision of the CJEU, which under the EU Treaties is responsible for the legally binding interpretation of the EU Biotechnology Directive, can be taken into account as persuasive by the Boards of Appeal and the Enlarged Board of Appeal.

B. SUBJECT-MATTER CONCERNED

26. The purpose of the proposed amendment of the EPC Implementing Regulations is 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.

a) Non-technical processes vs. technical processes

27. 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).³⁴
28. 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.³⁵

³³ See Article 164(2) EPC, as well as for example T 315/03, OJ EPO 2006, 15, point 5.8 of the Reasons for the Decision and T 39/93, OJ EPO 1997, 134, point 3.2 of the Reasons for the Decision.

³⁴ See EU Commission Notice, section 1.3.

³⁵ See EU Commission Notice, section 1.3, tenth par.

29. 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.³⁶
30. 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.
31. 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.

³⁶ See Guidelines G-II, 5.4.2.

32. The essential question thus is whether the technical effect, i.e. the characteristics of the plant in the example of paragraph 29. above, is exclusively brought about by the essential biological process, or whether it is the consequence of a technical process. The use of molecular markers for the selection of the desired plant does not change the characteristics of the plant. On the other hand, technical processes such as transformation or mutagenesis modify the genetic 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".³⁷
33. 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 is covered by the proposed EPC Rule are plants and animals exclusively obtained by crossing and selection, 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. This is the case even if technical means are provided serving to enable or assist the performance of the essentially biological process steps. In contrast, plants or animals produced by technical processes which modify the genetic characteristics of the plant or animal remain patentable in accordance with the EU Biotechnology Directive.

b) Plants and animals obtained by marker assisted breeding

34. A process 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.³⁸ Therefore plants or animals obtained by crossing and selection where molecular markers are used as an aid to select the progenitors or the descendants are excluded from patentability.
35. A process for selection of plants or animals using molecular markers, which does not include the production of the plants or animals, is not excluded from patentability.

³⁷ See EU Commission Notice, section 1.3, tenth par.

³⁸ G 2/07 - G 1/08, OJ EPO 2012, 130 and 206, headnote 2.

c) Transgenic plants or animals, including transgenic descendants

36. 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.³⁹
37. 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.
38. Transgenic plants or animals are thus the result of a technical process. The EPO practice follows this line 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.
39. 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.

³⁹ See EU Commission Notice, section 1.3.

d) Plants and animals obtained by technically induced mutagenesis

40. 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, CRISPR, TALEN, ODM (oligonucleotide directed mutagenesis), etc.⁴⁰ 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.
41. 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.
42. Thus plants or animals obtained by induced mutagenesis, including descendants, are not to be regarded as excluded from patentability under Article 53(b) EPC if the technical feasibility of the invention is not confined to a specific variety.

⁴⁰ These methods, which introduce a change in the genome, are among the so called "New Breeding Techniques".

e) Plant and animal parts which are propagation material (seed, embryo, seed coated with chemicals)

43. Plant or animal parts which are propagation material are 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.
44. 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.
45. 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.
46. 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.

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

47. 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 e)). The EU Commission Notice explicitly refers to plant/animal parts.
48. For any plant products that are not propagation material, such as flour, sugars or fatty acids, the 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.
49. 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.
50. 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.
51. Plant or animal cells or cell populations which are the subject of in vitro culture remain patentable as they are treated like microorganisms. Modern biotechnology has developed from traditional microbiology and cells are comparable to unicellular organisms.⁴¹ In vitro plant and animal cells are regarded as patentable microbiological inventions.⁴²

⁴¹ See G 1/98, OJ EPO 2000, 111, point 5.2. of the Reasons for the Decision.

⁴² See Articles 2(b) and 4(3) EU Biotechnology Directive; Article 53(b) and Rules 26(6), 27(c) EPC; Guidelines G-II, 5.5.1.

C. USE OF "DISCLAIMERS"

52. The claims, interpreted in light of the description and drawings, determine the extent of protection of a European patent (Article 69 EPC). The EPC only contains very few provisions dealing with the extent of protection conferred by a European patent⁴³, this matter mainly being left to the applicable national law after grant of a patent⁴⁴ and to the competent court in post-grant proceedings, especially in infringement proceedings. Agreements between the parties (e.g. in licensing contracts) or undertakings by patentees (e.g. on the basis of industry code of conducts) not to enforce their rights under certain circumstances may also have a bearing on the rights conferred by a patent.
53. A general distinction is made between, on the one hand, the aspects of patentability and, on the other hand, the (protective) effects of European patents or patent applications.⁴⁵ The EPC clearly provides for such a clear division, as the requirements for patentability are governed by Articles 52 to 57, 76, 83, 84 and 123 EPC whereas the extent of protection and the rights conferred by European patents or patent applications are specified in Articles 64(2) and 69 EPC in particular.
54. The EU Commission Notice does not deal with the provisions of Chapter II of the EU Biotechnology Directive and with issues relating to the extent of protection of plant or animal-related patents in general.
55. The proposal for amendment of the EPC Implementing Regulations submitted by the Swiss delegation during the 48th meeting of the Committee on Patent Law sets forth the following approach: If the protection conferred by a claim extends to plants or animals exclusively obtained by an essentially biological process, a disclaimer should be added to the claim to exclude the non-patentable plants or animals. This should apply also if such a disclaimer was not disclosed in the application as filed.⁴⁶

⁴³ Articles 64(2) and 69 EPC.

⁴⁴ Articles 2(2) and 64(1) EPC.

⁴⁵ G 1/98, OJ EPO 2000, 111, point 4 of the Reasons for the Decision; G 2/12, OJ EPO 2016, A27, VIII.2.(6)(b) of the Reasons for the Decision; Guidelines F-IV, 4.12.

⁴⁶ Possible wordings advanced by the Swiss delegation for such a disclaimer were "*A plant characterized by [...], provided that said characteristic is not the result of a sexual crossing of whole genomes []*," or "*Plant with a mutation in gene x, except for a plant exclusively obtained by means of an essentially biological process.*"

56. The claims of a European patent (application) shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description (Article 84 EPC). The EPC does not set forth specific requirements regarding the definition of the subject-matter to be protected. The claims may also include "negative" technical features, generally referred to as "disclaimer".⁴⁷ Examples are the exclusion of specific embodiments or areas from a general feature. According to the case law of the EPO boards of appeal, disclaimers are allowable for the purpose of restoring novelty over a disclosure under Article 54(3) EPC or over an accidental anticipation under Article 54(2) EPC, and to remove subject-matter which under Articles 52 to 57 EPC is excluded from patentability for non-technical reasons (for example, the insertion of "non-human" in order to satisfy the requirements of Article 53(a) EPC).⁴⁸
57. Disclaimers must in particular comply with the clarity requirement (Article 84 EPC). If disclaimers are added during examination or after grant of a patent, they must not lead to an extension of subject-matter under Article 123(2) EPC (which is examined according to the so-called "gold standard") or enlarge the scope of protection (Article 123(3) EPC).⁴⁹ Whether the gold standard also applies if the subject-matter to be excluded is not disclosed in the application as originally filed (so-called undisclosed disclaimers)⁵⁰ is currently subject of a referral pending before the Enlarged Board of Appeal.⁵¹ The use and allowability of disclaimers is extensively explained in the Guidelines for Examination, particularly in section H-V, 4.1 concerning undisclosed disclaimers.

⁴⁷ G 1/03, OJ EPO 2004, 413, point 2 of the Reasons for the Decision.

⁴⁸ See Guidelines H-V, 4.1 (iii).

⁴⁹ G 2/10, OJ EPO 2012, 376, headnote 1a; Guidelines H-V, 4.2.

⁵⁰ Guidelines H-V, 4.1.

⁵¹ Referral G 1/16, OJ EPO 2016, A105. The questions referred seek to clarify whether the "gold standard" applies in addition to the requirements established in decision G 1/03 that an undisclosed disclaimer is only allowable in the situations mentioned in point 56 above, must not remove more than is necessary, must not be or become relevant for the assessment of inventive step or sufficiency of disclosure, and finally must comply with the clarity requirement.

58. Where a plant or animal not exclusively obtained by means of an essentially biological process is claimed, a disclaimer excluding from protection plants/animals possessing the same characteristics and obtained independently from the invention by an essentially biological process has to fulfill the requirements of, in particular, Article 84 EPC (clarity) and Article 123(2) EPC (allowability of amendments).⁵²

D. PROPOSED AMENDMENT OF RULES 27(B) AND 28 EPC

59. 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*" with a view of aligning it with the interpretation of the EU Biotechnology Directive set forth in the EU Commission Notice.

60. In its Notice the EU Commission refers to "*products derived from essentially biological processes*"⁵³, "*products emanating from essentially biological processes*"⁵⁴, "*plants or plant material (fruits, seeds, etc.) or animals/animal material obtained through/by essentially biological processes*"⁵⁵ and "*animals that are directly obtained from essentially biological processes*"⁵⁶. 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."

⁵² A related question, namely whether in the context of product claims to plants it would be possible to waive the protection for generation of the claimed product by means of a process excluded from patentability under Article 53(b) EPC was referred to the Enlarged Board of Appeal in case G 2/13 (see T 83/05 of 8 July 2013, not published in the OJ EPO, points 27 and 28 of the Reasons for the Decision, and referred question 4). In view of the findings of the Enlarged Board of Appeal on the other questions referred, the question relating to the allowability of the "disclaimer" was not answered or addressed in decision G 2/13 (see G 2/13, OJ EPO 2016, A28, point IX. (5) (b) of the Reasons for the Decision).

⁵³ See Introduction, fifth par.

⁵⁴ See Introduction, sixth par.

⁵⁵ See, for example, section 1.1, first par. and section 1.3, last par.

⁵⁶ See section 1.3, last par.

61. 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*".
62. 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*"⁵⁷ and "*a product obtained by means of such a process*"⁵⁸.
 - Article 64(2) EPC concerning the extent of protection of process claims refers to "*the products directly obtained by such process*".⁵⁹
 - Rule 28(d) EPC concerning the exclusion of processes for modifying the genetic identity of animals refers to "*animals resulting from such processes*".⁶⁰

⁵⁷ Article 53(b) EPC: "...; *this provision shall not apply to microbiological processes or the products thereof*;"

⁵⁸ 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.*"

⁵⁹ 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.*"

⁶⁰ 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.*"

63. 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 clarifying provision relating to Article 53(b) EPC.⁶¹
64. The proposed new paragraph 2 of Rule 28 EPC explicitly refers to Article 53(b) EPC and replicates the term "essentially biological process". It furthermore employs the terms "plants or animals", as in Article 53(b) EPC. This clarifies 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. The use of the term plant/animal parts would imply that these derived products would also be excluded from patentability which is not suggested in the EU Commission Notice or the EU Biotechnology Directive.⁶² The understanding that derived products are indeed not excluded is in line with the definition of "biological material" set forth in Rule 26(3) EPC and in Article 2(1)(a) EU Biotechnology Directive as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system".
65. 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 or of descendants from mutants), the wording "exclusively obtained by" is used.⁶³ This does not affect or change the definition of "essentially biological process for the production of plants or animals" set forth in Article 53(b) EPC (and Article 4(1)(b) EU Biotechnology Directive). Rather, it underlines that - in accordance with Rule 27(b) EPC, the EU Biotechnology Directive and the EU Commission Notice - plants or animals emanating from technical processes remain patentable if the technical feasibility of the invention is not confined to a particular variety.

⁶¹ 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.

⁶² See above marginal numbers 47-51.

⁶³ From the four national patent laws of member states which foresee an explicit exclusion for conventional plants and animals, three (DE, FR, IT) use the term "exclusively" obtained; see above marginal number 21.

66. Rule 27(b) EPC also needs to be taken into account as it reflects the principle that plants/animals and plant/animal material other than varieties are generally eligible for patent protection.⁶⁴ It is thus pertinent to make clear that new paragraph 2 of Rule 28 EPC constitutes a *lex specialis* in relation to Rule 27(b) EPC and that therefore the principle set forth in Rule 27(b) EPC does not override the exclusion of conventionally bred plants and animals.
67. Taking into account these considerations, the amended Rules 27 and 28 EPC shall read as follows:

Present wording	Proposed wording
Rule 27	Rule 27
Patentable biotechnological inventions	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) <i>Unchanged</i>
(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) <i>Unchanged</i>

⁶⁴ See G 2/12 – G 2/13, OJ EPO 2016 A27 and A28, point VIII.2(6)(a) of the Reasons for the Decision.

Present wording	Proposed wording
<p style="text-align: center;">Rule 28 Exceptions to patentability</p> <p>Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:</p> <p>(a) processes for cloning human beings;</p> <p>(b) processes for modifying the germ line genetic identity of human beings;</p> <p>(c) uses of human embryos for industrial or commercial purposes;</p> <p>(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.</p>	<p style="text-align: center;">Rule 28 Exceptions to patentability</p> <p>(1) Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:</p> <p>(a) <i>Unchanged</i></p> <p>(b) <i>Unchanged</i></p> <p>(c) <i>Unchanged</i></p> <p>(d) <i>Unchanged</i></p> <p>(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.</p>

E. IMPLEMENTATION

68. The envisaged date of entry into force of amended Rules 27(b) EPC and 28(2) EPC is 1 July 2017. The provisions give a more detailed interpretation of Article 53(b) EPC in line with Rule 26(1) EPC and the EU Biotechnology Directive and are thus applicable to European and international applications filed on or after the date of entry into force as well as to pending European patent applications and European patents. This corresponds to the approach taken in the framework of incorporating the EU Biotechnology Directive into the EPC in 1999.⁶⁵
69. Due to the clarifying nature of the amendments, the application to pending European patent applications and European patents is considered to be in accordance with the principle of the protection of legitimate expectations (good faith).⁶⁶ A clarifying interpretation of the EPC implies that the law has always been in conformity with that interpretation and may hence be applied to pending cases.⁶⁷
70. The application of the provisions in the practice of examining and opposition divisions will be set out in administrative instructions issued under Article 10(2)(a) EPC. To the extent possible, instructions will still be included in the 2017 Guidelines revision, with further clarifications in the 2018 edition.

VI. FINANCIAL IMPLICATIONS

71. N/A.

VII. LEGAL BASIS

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

VIII. DOCUMENTS CITED

73. CA/7/99; CA/PL 12/15; CA/PL 3/16; CA/PL 4/16; CA/PL 17/16; CA/PL 18/16; CA/PL 4/17; CA/PL 8/17; CA/PL 9/17.

IX. RECOMMENDATION FOR PUBLICATION

74. Yes.

⁶⁵ See T 272/95, not published in the OJ EPO, point 4 of the Reasons for the Decision.

⁶⁶ See Case Law of the Boards of Appeal of the EPO, 8th ed. 2016, page 513 et seq.

⁶⁷ See in this regard G 2/07 and G 1/08, OJ EPO 2012, 130 and 206, point 2.4 of the Reasons for the Decision; T 716/91, not published in the OJ EPO, point 2.2 of the Reasons for the Decision; as well as G 9/93, OJ EPO 1994, 891, point 6.1 of the Reasons for the Decision.

PART II

Draft

DECISION OF THE ADMINISTRATIVE COUNCIL
of [date of decision]
amending Rules 27 and 28 of the Implementing
Regulations to the European Patent Convention

THE ADMINISTRATIVE COUNCIL OF THE EUROPEAN PATENT ORGANISATION,

Having regard to the European Patent Convention (hereinafter referred to as "EPC") and
in particular Article 33(1)(c) thereof,

On a proposal from the President of the European Patent Office,

Having regard to the opinion of the Committee on Patent Law,

HAS DECIDED AS FOLLOWS:

Article 1

Paragraph (b) of Rule 27 of the Implementing Regulations to the EPC shall be amended
as follows:

"(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;"

Article 2

Rule 28 of the Implementing Regulations to the EPC shall be amended as follows:

1. The current text shall become paragraph 1 (a) to (d).

2. The following new paragraph 2 shall be added:

"(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."

Article 3

This decision shall enter into force on 1 July 2017. Rules 27 and 28 EPC as amended by Articles 1 and 2 of this decision shall apply to European patent applications filed on or after this date, as well as to European patent applications and European patents pending at that time.

Done at The Hague, [date of decision]

For the Administrative Council
The Chairman

Jesper KONGSTAD