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From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	12441/19
Subject:	Submission of the European Union to the Enlarged Board of Appeal of the European Patent Office on the patentability of plants obtained by essentially biological processes ('Pepper case')

Delegations will find attached, for information, the written statement (*amicus curiae* submission) of the European Union to the Enlarged Board of Appeal of the European Patent Office (EPO) in Case G 3/19 (the 'Pepper case'), pursuant to Article 10(1) of the Rules of Procedure of the Enlarged Board of Appeal.

The annexes to this statement – which reproduce existing Parliament, Council, Commission and EPO documents – as well as the cover letters to the statement, are not attached to this Note. The written statement, including its cover letters and annexes, is available on the website of the EPO, at the following link: https://www.epo.org/law-practice/case-law-appeals/eba/pending/g3-19.html

At its meeting of 25 September 2019, the Committee of Permanent Representatives was informed of the upcoming Union submission.

EUROPEAN COMMISSION

Brussels, 1 October 2019
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Court procedural document
EBAamicuscuriae@epo.org
for the attention of Mr Wiek Crasborn

TO THE ENLARGED BOARD OF APPEAL,
EUROPEAN PATENT OFFICE

Written statement pursuant to Article 10(1) of the Rules of Procedure of the Enlarged Board of Appeal

submitted by

THE EUROPEAN UNION,
REPRESENTED BY THE EUROPEAN COMMISSION

represented by Eric Gippini Fournier, Legal Adviser, and Flor Castilla Contreras, Member of its Legal Service, acting as agents, with an address for service in Brussels at the Legal Service, Greffe contentieux, BERL 1/169, 200, rue de la Loi, 1049 Brussels,

in relation to

Case G 3/19

Referral pursuant to Art. 112(1)(b) EPC
by the President of the European Patent Office -
"Article 164(2) EPC / Pepper"

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1. INTRODUCTION

1. In Case G 3/19 the European Commission submits, on behalf of the European Union, the following statement within the meaning of Article 10 of the Rules of Procedure of the Enlarged Board of Appeal (hereinafter "**EBoA**"), with a view to supporting the referral made by the president of the European Patent Office ("**EPO**") on 4 April 2019 ("**the Referral**"). Only the Commission is empowered to represent the European Union in the present case by virtue of the powers vested upon it by Articles 17(1) TUE[1] and 335 TFUE.[2]

2. PROCEDURE AND BACKGROUND

2. Under Article 112(1)(b) EPC,[3] in order to ensure uniform application of the law, or if a point of law of fundamental importance arises, the President of the EPO may refer a point of law to the EBoA where two Boards of Appeal have given different decisions on that question.

3. On 5 April 2019, pursuant to Article 112(1)(b) EPC, the President of the EPO submitted questions to the EBoA concerning the patentability of plants obtained by essentially biological processes. In the Referral, the President of the EPO requests the EBoA to clarify the applicable legal framework.

4. The referral arises after the decision of a Technical Board of Appeal of December 2018 in case T 1063/18 (hereinafter "case **T 1063/18**" or the "*Pepper*" case). This decision would allow a patent over a plant obtained by essentially biological processes. This is contrary to Rule 28(2) EPC,[4] which states "*European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological*

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1 Article 17(1) TUE states that the Commission "shall ensure the Union's external representation".

2 Article 335 TFEU is the expression of a general principle that the European Union has legal capacity and is to be represented, to that end, by the Commission (see judgments in cases Council v Commission ("ITLOS"), C-73/14, EU:C:2015:663, paragraphs 58-59, and Reynolds Tobacco and Others v Commission, C-131/03 P, EU:C:2006:541, paragraph 94).

3 Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

4 Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973, as adopted by decision of the Administrative Council of the European Patent Organisation of 7 December 2006 and as last amended by decision of the Administrative Council of the European Patent Organisation of 28 June 2018. In the present statement, provisions of the Implementing Regulations are cited as in the example "Rule 28(2) EPC".

process". It is also contrary to Article 4.1(b) of the EU Biotechnology Directive ("the **Biotech Directive**").[5]

5. The Board of Appeal in case T 1063/18 declined to follow Rule 28(2) EPC. The Board of Appeal took the view that Article 53(b) EPC, and in particular the patentability of plants resulting from essentially biological processes, had been reviewed by the EBoA in decisions G 2/12 and G 2/13 (*Tomato II/Broccoli II*), where the EBoA held that Article 53(b) EPC does not exclude plants from patentability, even if they are obtained through an essentially biological process.

6. The Board found that Rule 28(2) EPC was in conflict with "Article 53(b) EPC as interpreted by the EBoA". Having regard to Article 164(2) EPC, Article 53(b) EPC "as interpreted by the EBoA", prevailed, as the Board found it impossible to interpret Rule 28(2) EPC in such a way that no contradiction exists. The Board also declined to follow the interpretation of the Biotech Directive set out by the European Commission in its 2016 Notice.[6] The Board held that the interpretation of the Biotech Directive put forward in the Notice "cannot be seen as a relevant development because it has not been confirmed in a legally binding way" and concluded that it has "no legal authority".[7] As only the Court of Justice of the European Union (hereinafter "**CJEU**") is competent to issue a binding interpretation of the Biotech Directive, the Board believed that following the Commission's Notice would risk conflicting with a future decision of the CJEU.[8]

7. Under Article 10 of its Rules of Procedure, the EBoA invited the public to file written statements on the President's referral, setting 1 October 2019 as the deadline for the submission of such statements (Official Journal EPO 2019, A52).

3. ADMISSIBILITY OF THE REFERRAL

8. The Commission supports the arguments set out in the Referral in relation to admissibility, and submits in addition the following comments.

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5 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p. 13.

6 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, C/2016/6997, OJ C 411, 8.11.2016, p. 3.

7 Decision of the Board of Appeal in case T 1063/18, point 29.

8 Decision of the Board of Appeal in case T 1063/18, point 43 ("*adopting the interpretation of the Notice in the absence of a decision of the CJEU on the matter, creates a risk of misaligning the provisions of the EPC with the Biotech Directive, should the CJEU later concur with the analysis of the EBA*").

9. A single Board of Appeal, namely Technical Board of Appeal 3.3.04, is competent for all appeals as regards biotechnology. For this simple reason, the literal wording of Article 112(1)(b) EPC requiring different decisions 'of *two* Boards of Appeal' may be virtually impossible to satisfy in that field. Thus a purely literal interpretation would prevent referral of points of law to the EBoA under Article 112(1)(b) EPC in that field .[9]

10. The objective of that safeguard – to prevent EPO President's referrals on abstract points of law – is not disputed. Nevertheless, referrals must remain possible in situations such as the one at issue, where a concrete (legal) question has arisen, which affects a significant number of pending cases, and is causing considerable concern and legal uncertainty for economic operators in the sector concerned.

11. It is submitted that when a rule (such as the rule allowing referrals to the EBoA only on concrete points of law of practical import) is complemented by a condition or safeguard (such as that requiring diverging decisions of two Boards of Appeal), that condition or safeguard should not be implemented in a restrictive way which would conflict with the genuine intent of the rule. A teleological interpretation is to be favoured here, one that is as broad as necessary to ensure that the provision is capable of serving its purpose to the fullest possible extent.

12. This reasoning was followed by the EBoA in its Opinion G 4/98, where a referral from the EPO President was considered admissible although it was based on conflicting decisions of a single Board of Appeal, with the following argument:

> *'If his power of referral were to be defined by a restrictive reading of the term "*two Boards of Appeal*" based on organisational structure, then no referrals would be possible with respect to the Legal Board of Appeal, which is one organisational unit only. This would unduly restrict the effect of Article 112 EPC, since it is quite clear that conflicting decisions might also occur in cases within the competence of that board,* […]'

13. Alternatively, the negotiation history of Article 112(1)(b) shows that its current wording causes a legal gap which should be bridged by a purposive interpretation of this provision. The preliminary draft contained the following options:

> *b) the President of the European Patent Office may:*
>
> *[- at any time ask the Enlarged Board of Appeal for an opinion on any question, except where such question arises in proceedings on a case]*

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[9] At least 19 appeals against decisions based on Rule 28(2) EPC are currently pending; all of them, to the best of our knowledge, have been attributed to the same Board of Appeal (Technical Board of Appeal 3.3.04).

- refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given different decisions on that question.

14. The first indent (targeting legal questions not arising in actual proceedings, i.e. abstract legal questions) was not retained in the final text. It may be deduced that Article 112(1)(b) EPC was intended to allow the President of the EPO to refer to the EBoA only such points of law which were of fundamental importance and were not abstract, i.e. had arisen in actual proceedings. However, the second indent, taken literally, only covered situations where two Boards of Appeal have given different decisions. Thus, situations where legal questions affecting many concrete cases arise because of a single decision of a Board of Appeal, would not be covered by the literal wording of Art. 112(1)(b) EPC.

15. In other words: the first indent in the preliminary draft was meant to cover only abstract points of law, *i.e.* points that had not arisen in actual proceedings; the second indent was meant to cover concrete points of law, *i.e.* points of law which had arisen in actual proceedings, but was subject to the condition of two conflicting decisions. The fact that the Diplomatic Conference deleted the first indent may mean that the Conference was reluctant to give the President the "quasi-legislative" power to refer abstract points of law that had not even arisen in proceedings. Nevertheless, this concern does not apply when concrete points of law, arising from the decision of one Board of Appeal, are liable to generate confusion and a state of uncertainty affecting many other cases.

16. The *Pepper* case demonstrates that the confusion and legal uncertainty created by a single decision of a Board of Appeal may be comparable to the hypothesis of two conflicting decisions of two Boards of Appeal. The decision in case T 1063/18 concerns points of law of fundamental importance, with serious legal implications for future cases. It conflicts directly with the Implementing Regulations. It has led to the suspension of all examination and opposition proceedings and has generated a state of considerable confusion and uncertainty, jeopardizing the work of the EPO. Article 112(1)(b) EPC was precisely intended as a mechanism to resolve such situations and restore legal certainty.

17. A literal reading of Article 112 (1)(b) EPC which would entirely disregard the function of that provision risks leading to absurd results. To satisfy such a literal reading, the EPO and the entire patent community would have to wait for future decisions of other Boards of Appeal, hoping for a conflict to emerge. If, and as long as, Boards of Appeal (or, more accurately, the only Board where the issue has been raised and is likely to arise, i.e. Technical Board 3.3.04) follow the interpretative approach outlined in case T 1063/18, the President of the EPO would not be able to submit the fundamental point of law to the EBoA, and a string of patents on non-patentable subject matter would be issued.

18. Finally, the European Union notes that in the past, the EBoA has expressed its views on the substance of a referral while declaring the referral inadmissible under Article 112(1)(b) EPC, on the grounds that there was "at least the potential for confusion".[10] It seems undisputable that the situation created by the decision of the Technical Board of Appeal in the Pepper case (T 1063/18) has created significant potential for confusion as regards the scope of patentable subject-matter and the validity of Rule 28(2) EPC.

4. SUBSTANCE – RULE 28(2) DOES NOT "REVERSE" OR "CONFLICT WITH" ART. 53B EPC

19. The European Union supports the argumentation in the Referral, in particular as regards the interpretation of Article 53(b) EPC and the powers of the Administrative Council. It will supplement those arguments with some remarks concerning more specifically the interpretation of the Biotech Directive and its interaction with the legal order of the EPO.

4.1. The Biotech Directive excludes the patentability of plants obtained by essentially biological processes

20. The Biotech Directive harmonises the national laws of the member States of the European Union as regards the patentability of inventions related to biological material. The Directive applies to several categories of biological material, including plants.

21. The European Commission adopted in 2016 a '*Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions*' (attached as **Annex 1**).[11] The Notice addresses *inter alia* the interpretation of Article 4 of the Directive on the patentability of products emanating from essentially biological processes. The Notice is based on the wording of the Biotech Directive read in combination with the *travaux préparatoires* leading to its adoption.

22. Section 1 of the Notice ('*Exclusion from patentability of products obtained by essentially biological processes*') sets out in detail the reasoning leading the Commission to the conclusion that the EU legislator's intention, when adopting the Biotech Directive was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.

23. The Notice, having regard to the preparatory work related to the Directive, explains that certain provisions of the Directive are only consistent if plants/animals obtained by essentially biological processes are understood as being excluded from its scope.

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[10] EBoA, decision G3/08, section 13.5.

[11] See the reference *supra*, note 6.

24. In particular, recital 32 of the Directive implicitly but unambiguously takes as its premise that a plant which is the result of an essentially biological process is excluded from patentability (as explained in § 1.3 of the Notice):

> *"Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process"* (emphasis added)

25. This recital clearly shows the legislator's basic concept – so basic as not to require codification - that the products of essentially biological processes can never be patented. The recital provides that "even" plant varieties resulting "not [from] an essentially biological process but [from] a biotechnological process" cannot be patentable.

26. In addition, the Notice highlights Article 3(2), which states:

> *"Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."*

27. This provision makes sense only if it is understood that plants or animals, which are covered by the generic term 'biological material', but which are obtained by a non-technical process (*i.e.* an essentially biological process), may not be the subject matter of an invention, and thus cannot give rise to a patent.

28. Finally, though not mentioned in the Commission Notice, recitals 52 and 53 of the Directive – related to Article 12 on compulsory cross-licensing – specify the cases where a license may be granted to a patent owner or to a breeder when either the plant variety or the patent depends on a previous patent or plant variety. These recitals only refer to the exploitation of new plant characteristics resulting from genetic engineering and clearly exclude plants obtained by essentially biological processes. It is obvious, in light of these recitals, that the EU legislature did not intend to allow patents for plants obtained by essentially biological processes; had it intended to allow such patents, it would have provided for similar cross-licensing between plant varieties and inventions based on plants obtained by essentially biological processes.

29. The European Union also notes that the correct interpretation of Article 4 (1) (b) of the Biotech directive must take account of the shared understanding of all the EU institutions involved in the law-making process in 1998 that plants and animals obtained by essentially biological processes would at any rate not satisfy the basic conditions to be patentable.

30. In this regard, the Notice, when quoting the European Parliament's report (the "Rothley report") under the heading "1.2 Negotiating of the Directive", refers to the report's statement that essentially biological processes like crossing and selection and their products are not patentable because they are neither inventive nor reproducible.[12]

31. Whether that statement in the Rothley report was factually correct or incorrect in the light of today's knowledge is immaterial. What remains is that the statement quoted in the Notice describes the situation as it was perceived by the legislative bodies. The European Parliament's Rothley report was accepted in full in the subsequent steps of the legislative process. This perception explains why they may have deemed it superfluous to stipulate expressly in Article 4 (1) (b) of the Biotech directive that products obtained by essentially biological processes are not patentable.[13]

4.2. The Notice must be taken into account when interpreting the Biotech Directive

32. It is correct that the CJEU is ultimately competent to adopt an authoritative and binding interpretation Union law. Nevertheless, the Notice is intended to assist in the application of the Directive and may not be disregarded as devoid of any value.

33. In particular, the Notice may not be dismissed as a subjective opinion of the Commission as EU institution. A simple reading of its contents should suffice to disprove such a characterisation. By reference to the negotiating history and to a systematic interpretation, the Notice seeks to ascertain the objective intent of the legislature at the time of the adoption of the Biotech Directive. The Commission Notice was issued by the EU institution that proposed the Directive and participated in all stages of the legislative procedure that resulted in its adoption.

34. The Notice provides an in-depth explanation why the Biotech Directive, and in particular Article 4, cannot be interpreted other than as excluding patentability for products (plants/animals) obtained from essentially biological processes.

35. When interpreting secondary legislation such as a Directive, the CJEU examines its wording, objectives and the context in which the Directive and its specific provisions should be placed.[14] This contextual interpretation includes not only the normative part of

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[12] Notice, footnote 4 and accompanying text.

[13] In addition, the reference to plants and animals in Article 4 (1) (b) of the biotech directive may have been motivated by the concern to avoid misunderstandings between on the one hand, Article 3(2) first alternative (isolation requirement) of the Directive read in conjunction with Article 2 (1) (a) of the Directive, and on the other hand, Article 4 (1) (b) of the Directive.

[14] See e.g. judgment of 18 October 2011, Brüstle, C-34/10, EU:C:2011:669, paragraph 31 (regarding Article 6 of the Biotech Directive). See also Judgments of 17 November 1983, Merck/Hauptzollamt Hamburg-Jonas,

the Directive but also the (legislative) decision-making process that led to the adoption of its provisions. The Court takes into account, in particular, the drafting history of a provision (*travaux préparatoires*),[15] in particular where this drafting history is publicly available. The *travaux préparatoires* of the Biotech Directive have, in this sense, substantive interpretative value.

36. In addition, the CJEU has often referred to Commission Notices and other "soft law" as interpretative tools taken into account when interpreting EU law.[16]

37. Finally, the Notice and its interpretation of Article 4 of the Directive have been expressly endorsed by both EU co-legislators: the Council of the European Union and the European Parliament (cf. § 91 of the referral):

— The Notice was itself a response to an explicit request by the European Parliament in its Resolution of 17 December 2015. This parliamentary Resolution called on the Commission to "*ensure legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes.*"[17]

— On 28 February 2017, the Council of the European Union unanimously adopted Conclusions welcoming the Notice which "*increases clarity in this field within the EU and contributes to restoring an appropriate balance between patent-related rights and plant variety rights*",[18] and urged the European Patent Organisation to act accordingly.

— On 19 September 2019, the European Parliament passed a Resolution on the patentability of plants and essentially biological processes, supporting the Notice and underlining that "*any attempt to patent products derived from conventional*

292/82, EU:C:1983:335, paragraph 12; judgment of 22 November 2012, Brain Products, C-219/11, EU:C:2012:742, paragraph 13 and the case-law cited, and of 12 June 2014, Lukoyl Neftohim Burgas, C-330/13, EU:C:2014:1757, paragraph 59.

15 See e.g. judgment of 17 July 1997, Badische Erfrischungs-Getränke, C-17/96, EU:C:1997:381, paragraph 16. See also, more recently, Judgment of 7 September 2017, Schottelius, C-247/16, EU:C:2017:638, paragraphs 40 and 43.

16 See for example 3 December 1998, Generics (UK), C-368/96, EU:C:1998:583, paragraphs 28, 31-32. See already, in case of the legal effect of Recommendations, Case C-322/88, Grimaldi, ECLI:EU:C:1989:646.; Opinion of Advocate General Kokott in relation to case C-226/11, Expedia Inc. v Autorité de la concurrence, at points 38-39 and 42.

17 European Parliament resolution of 17 December 2015 on patents and plant breeders' rights (2015/2981(RSP), OJ C 399, 24.11.2017, p. 188. See also European Parliament Resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP), O.J. C 261 E 31, of 10.09.2013.

18 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, OJ C 65, 1.3.2017, p. 2 (attached as **Annex 2**).

breeding, including crossing and selection, or on genetic material necessary for conventional breeding undermines the exclusion established in Article 53(b) of the EPC and in Article 4 of Directive 98/44/EC".[19]

38. These statements should be taken into account when considering the intention of the EU legislature. By these statements, the European Parliament and the Council have clarified what their intent was when adopting the Biotech Directive. The CJEU has taken such statements by EU legislators into account when interpreting secondary EU law.[20]

39. Therefore, national authorities should take the Notice into account when interpreting the Biotech Directive. As a matter of fact, the national authorities of the Member States of the EU have done so.

40. Decision T 1063/18 did not see fit to refer to the existence of Council Conclusions unanimously pronounced by the 28 EU Member States, all of which are Members of the European Patent Organisation. Recital 23 of the decision refers to decisions G 2/12 and G 2/13 of the EBoA (both of which were issued on 25 March 2015, before the statements of the European Parliament, the Commission or the Council of the European Union, and before adoption of Rule 28(2) EPC).

41. Ultimately, whatever one may think about the weight to be given to the views of the Commission, the Council and European Parliament, the European Union is not claiming that the Notice must be followed on account of having a "binding" character. The Notice should be followed because it contains a persuasive and convincing inquiry into the legislative intent underlying the Biotech Directive.

42. For reasons that are not easy to understand, the Board of Appeal in case T 1063/18 only saw a risk of misaligning the provisions of the EPC with the Biotech Directive if it were to have followed the Commission's Notice.[21] The European Union notes that disregarding the interpretation in the Commission's Notice does not show any particular deference to the role of the CJEU. Indeed, the Notice reflects the intent of the EU's legislature in adopting the Biotech Directive. It is thus the Board's decision in the *Pepper* case which is very likely to misalign the provisions of the EPC and of the Biotech

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19 European Parliament resolution of 19 September 2019 on the patentability of plants and essentially biological processes (2019/2800(RSP) (attached as **Annex 3**).

20 See for instance judgments of 20 June 2013, Giersch, C-20/12, EU:C:2013:411, paragraphs 54-55, and of 3 December 1998, Generics (UK), C-368/96, EU:C:1998:583, paragraphs 27-28.

21 Decision of the Board of Appeal in case T 1063/18, point 43 ("*adopting the interpretation of the Notice in the absence of a decision of the CJEU on the matter, creates a risk of misaligning the provisions of the EPC with the Biotech Directive, should the CJEU later concur with the analysis of the EBA*").

Directive and, in particular, to conflict with a future decision of the CJEU on the interpretation of the Directive.

4.3. The incorporation of the Biotech Directive in the legal order of the European Patent Organisation

43. By decision of 16 June 1999, the Administrative Council implemented the Biotech Directive into the EPC's Implementing Regulations in order to ensure that the same provisions would apply to national patents on biotechnical inventions granted by either National Patent Offices or the European Patent Office.[22] To this end, most articles of the Directive were *verbatim* transposed into the EPC's Implementing Regulations.

44. Article 3(2) of the Biotech Directive – which states that "*Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature*" – was not literally implemented.

45. Indeed, Rule 27(a) EPC provides that "*Biotechnological inventions shall be patentable, in particular 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* […]".

46. In accordance with Rule 26(1) EPC, Article 3(2) of the Biotech Directive is taken into account in the interpretation of Rule 27(a) EPC so that both provisions have the same meaning. Biological material isolated from its natural environment or produced by a technical process may be the subject of an invention and may therefore be patentable (if the patentability criteria are met). This applies without any doubt, for instance, to the isolation of a gene where a specific function is claimed and could therefore be patentable, or to the insertion of a gene into the genome of a plant conferring it new features which would not occur in nature.

47. However, both provisions do not explicitly cover a third situation where the product is obtained neither by isolation of the biological material nor by means of technical processes, but by essentially biological processes. In such a situation, as abundantly explained in the Commission Notice, such a plant should be excluded from patentability.

48. Following discussions in the Committee on Patent Law, the Administrative Council decided in June 2017 to introduce Rule 28(2) EPC (effective as of 1 July 2017)[23] to

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[22] *Cf.* paragraphs 81-82 of the Referral, with references.

[23] Decision CA/D 6/17 of 30 June 2017, OJ EPO 2017, A 56.

create clarity on the scope of Article 53 (b) EPC. It provides that "*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*". The new Rule was in line with meaning and scope of Article 3(2) of the Biotech Directive.

49. In this respect, paragraphs 46-52 of the Referral recall that the Administrative Council is competent to address issues of substantive law in the EPC's Implementing Regulations, including "detailed guidance on what was patentable and unpatentable", and in particular to clarify the interpretation of Article 53 EPC. The European Union agrees with these explanations.

50. The Referral recalls (paragraphs 80-92) the undisputed intention of the EPC legislator to ensure the uniformity of harmonised European patent law and to fully align the European Patent Convention with the EU Biotechnology Directive. It highlights the need to take into account the intention of the EU legislature, and especially the *travaux préparatoires* of the Directive – '*since the other means of interpretation had not given rise to a clear result*'.

51. It is also worth noting that there are other examples where provisions of the Directive are taken into account in the interpretation and application of the relevant EPC Implementing Rules in order to achieve and ensure the uniformity of harmonised European patent law. For instance, while Rule 26(4) EPC has explicitly incorporated Article 5(2) of Regulation 2100/94[24] on Community Plant Variety Rights (to which Article 2(3) of the Biotech Directive refers), and EPO practice is in line with other parts of said Article 5 such as, for example Article 5(3) of Regulation 2100/94. As explained in the preparatory document underlying the introduction of Rule 28(2) EPC,[25] it corresponds to current EPO practice with regard to the exclusion of plant varieties, based on Article 53(b) EPC, Rule 26(1) and (4) EPC and relevant case law, that an applicant cannot circumvent the prohibition of patenting a plant variety by claiming the seeds or other propagation material instead of the plant variety.

4.4. The interpretation of EU law in the EPC framework

52. It is undisputed that the intention of the EPC legislator is to ensure the uniformity of harmonised European patent law and to fully align the EPC with the Biotech Directive.

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[24] Council Regulation (EC) No 2100/94 on Community plant variety rights, OJ L 227, 1.9.1994, p.1, as amended (hereinafter "**Regulation 2100/94**").

[25] Document CA/56/17, of 06.06.2017, at paragraph 43 (preparatory document to Decision CA/D 6/17, cited *supra* note 23).

The Commission refers to the arguments and reasoning put forward in the Referral, paragraphs 78-84.

53. Rule 26(1) EPC – the validity of which has never been questioned and is accepted by all parties - explicitly states that, in addition to the provisions of Chapter V of the Implementing Regulations, '*Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation*' for European patent applications and patents concerning biotechnological inventions. This implies that, where needed, the Directive may be interpreted in order to properly apply the related EPC provisions, in particular where the rules of the Implementing Regulations have not yielded a clear interpretation of Article 53 (b) EPC.

54. In case T 1063/18, the Board of Appeal came to the conclusion that any possible interpretation of Rule 28(2) of the Implementing Regulations was in conflict with Article 53(b) EPC, thus not leaving any possible scope for the use of Rule 28(2) to clarify the meaning of Article 53 (b) EPC (par. 23-25 of the reasons for the decision).

55. In such a situation, according to Rule 26(1) of the Implementing Regulations, the Board of Appeal and EBoA must refer to the Biotech Directive as a supplementary means of interpretation of the Convention, here of Article 53 (b) EPC.

56. Thus, Rule 28 (2) EPC, which only mirrors the provisions of the Biotech Directive in their correct interpretation, neither "reverses the meaning of Article 53 (b) EPC",[26] nor is it "in conflict with Article 53 (b) EPC".[27] It only clarifies the meaning which must be given to Article 53 (b) EPC anyway, by expressly codifying the non-patentability of plants and animals obtained by essentially biological processes.

57. Within the EPC framework, EU legislation is placed on the same footing as international treaties. The fast track integration of EU legislation takes place under the same conditions and procedure applied to international treaties (cf. Article 33(1)(b) EPC). There is therefore no reason, from an EPC perspective, to interpret EU legislation in a different manner than Treaties.

58. The EBoA has recognised that the principles of the Vienna Convention on the Law of Treaties are applicable to EU legislation on patents:

> "*Although the Directive is not a treaty, the Enlarged Board of Appeal will, in view of the reference in Rule 26(1) EPC (...) and in line with the established case law (see eg G*

[26] Decision in case T 1063/18, paragraph 32.

[27] *Id.*, paragraph 25.

5/83, OJ EPO 1985, 064, G 1/84, OJ 1985, 299, J 16/96, OJ 1998, 347) apply mutatis mutandis the general rules laid down in the Vienna Convention on the Law of Treaties." [28]

59. According to Article 31(1) of the Vienna Convention, a treaty "shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".

60. Article 31(3) of the Vienna Convention specifies that in interpreting a treaty, there shall be taken into account, together with the context, "(a) any subsequent *agreement* between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any *subsequent practice* in the application of the treaty which establishes the agreement of the parties regarding its interpretation" (italics added).

61. The EBoA, when interpreting Article 53(b) EPC, cannot therefore ignore the intentions of the EU legislature, the other provisions of the Biotech Directive and its drafting history, and subsequent agreements and practice of the contracting parties. This is not only the case based on EU law, as explained previously, but also based on international law principles as recognised by the EBoA itself.

62. This does not only refer to the position of the Commission as set out in the Notice. The EBoA must also take into account and give weight to the declarations of the Council and the European Parliament, when examining the existence of "agreements" or "subsequent practices" in the meaning of the Vienna Convention. These statements and practices reveal the concurrent will of at least 28 of the Contracting States of the European Patent Organisation.

63. As indicated earlier, the Commission issued the Notice at the request of the European Parliament, which in a 2015 resolution called on the Commission to make sure that products obtained by conventional breeding, i.e. plants obtained by essentially biological processes, will be excluded from the patentable subject matter.[29] As explained above, the Notice reaches the firm conclusion that the intention of the EU legislature when enacting the Biotech Directive was to exclude patentability in respect of plants or animals obtained by means of an essentially biological process.

64. On 28 February 2017 the Council, unanimously adopted Conclusions in which it welcomed the Notice, which *'increases clarity in this field within the EU and contributes*

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[28] EBoA, decision G 2/06, point 16.

[29] European Parliament Resolution on the patenting of essential biological processes and European Parliament Resolution on patents and breeder's rights, cited *supra* notes 17 and 19.

to restoring an appropriate balance between patent-related rights and plant variety rights'.[30] The Council also urged the European Patent Organisation to act accordingly. Strangely, decision T 1063/18 does not even refer to the existence of these Conclusions of the 28 EU Member States.

65. The EPC bodies (Administrative Council) adopted Rule 28(2) EPC (effective as of 1 July 2017) precisely to address this request, to reflect the position of the Notice and conform to the Biotech Directive.

66. By adopting Rule 28(2) EPC, in full compliance of Article 33(3) EPC, the Administrative Council rightly reflected the correct interpretation of the Biotech Directive regarding the non-patentability of plants obtained by essentially biological processes, and sought to clarify that the EPC and the Directive are aligned in this regard.

67. The adoption of Rule 28(2) EPC is arguably a "subsequent agreement" between the parties to the treaty within the meaning of Article 31(3) of the Vienna Convention, which must be taken into account when interpreting Article 53 (b) EPC. The practices of the Contracting States (see below) can be considered "subsequent practices" in the meaning of Article 31(3)(b) of the Vienna Convention.

4.5. The application of the Biotech Directive in the EPC Contracting States after the publication of the Notice

68. The interpretation of Article 4 set out in the Notice, as recalled in § 40 of the Referral, is shared by the EPC Contracting States. They have either implemented the exclusion from patentability in their national legislation expressly (see also paragraph 108 of the Referral) or their national IP offices or courts apply the prohibition in practice.

69. This is not only the case for the 28 EU Member States but also for the 10 EPC Contracting Parties that are not members of the EU. All these 10 EPC Contracting States not part of the EU voted as well in favour of the introduction of Rule 28(2) EPC. As far as the Commission is aware, every EU Member State (and all other Contracting States of the EPO) excludes patentability for products obtained by essentially biological processes, either expressly in their domestic legislation or in the interpretation adopted in the practice of their patent office.

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[30] Council conclusions cited *supra* note 18.

4.6. The balance between patent-related rights and plant variety rights

70. The aforementioned Council conclusions of 2017 (see, above, note 18) welcomed the Notice as contributing to restore an appropriate balance between patent rights and plant variety rights. That balance, which underlies Article 53(b), risks being jeopardised by a narrow interpretation of the exclusion from patentability.

71. Both Article 4 (1) (a) of the Biotech Directive and Article 53(b) EPC specifically exclude patents for plant varieties. In turn, Article 92 of Regulation 2100/94 prohibits the patenting of any plant variety protected by a Community plant variety right, and any prior patent which has been granted becomes unenforceable while the plant variety right remains effective.

72. Originally, the EPC did not include a definition of 'plant variety'. Such a definition was incorporated into the EPC by virtue of Rule 26(4) which transposes the definition in the UPOV Convention 1991[31] which is the same as in Article 5 of Regulation 2100/94 (to which Article 2(3) of the Biotech Directive refers).

73. A plant variety is a plant grouping "within a single botanical taxon of the lowest known rank" which is defined by the expression of certain characteristics that result from a given genotype or combination of genotypes. To be eligible for protection under plant variety rights, the plant variety must be new, distinct, uniform and stable (Article 6 of Regulation 2100/94).

74. It is generally accepted that patents offer a stronger form of protection than plant variety rights. In particular, plant variety rights do not extend to acts done for experimental purposes and acts done for the purpose of breeding other varieties (Article 15 (c) of Regulation 2100/94). This so-called 'breeders exemption' is an essential cornerstone of the system of plant variety rights (both at EU level and at national level). Preserving free access to biological material without requiring the consent of the right holder is essential for the breeding industry and for the development of plant variety rights.[32]

75. There is a significant interface between patents on plants and plant variety rights.[33] As it has been observed, every patent claim to plants will embrace plant varieties, as a plant

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31 International Convention for the Protection of New Varieties of Plants, 1991 revision, Article 1(vi).

32 Strengthening breeder's rights was 'the main goal' of the revision of the UPOV in 1991, see Summary Minutes, Records of the 1991 Diplomatic Conference, §165.

33 That significant interface and the risk that a shift in the boundary between patents and plant variety rights would affect patents was recognised by the EPO, during the revision of the UPOV in 1991, see Summary Minutes, Records of the 1991 Diplomatic Conference, §76.1.

variety is a plant grouping of the lowest possible rank. When claiming species, or a higher rank, it will always embrace plant varieties (the example of Golden Delicious apples, which is a variety of apples (species) while not all apples are Golden Delicious). Nonetheless, the two systems have co-existed and developed in parallel, without much interference from the other.

76. The first problem with the narrow interpretation of the exclusion contained in Article 53(b), second alternative, EPC is that it blurs the distinction between what may be patentable (plants, traits) and what is not patentable (plant varieties). This is particularly problematic for plants obtained from essentially biological processes because these have overwhelmingly been protected by plant variety rights.[34]

77. The second problem is that a patent claim for a plant (*e.g.*, a trait) may cover and extend to multiple plant varieties. This in turn may well affect plant variety rights because if biological material (products obtained from essentially biological processes) becomes patent protected it will either no longer be available to breeders, or not to the same extent as it is currently the case under the regime of plant variety rights, thus jeopardising the applicability of the 'breeder's exemption' and the development of plant variety rights.

78. The Biotech Directive contains provisions on compulsory cross-licensing in case a plant variety right cannot be exploited without infringing a prior patent concerning a plant, or vice-versa, subject to the applicant demonstrating the dual condition of 'significant technical progress' and 'considerable economic interest' (see, Article 12(3) (b)). Nonetheless, as explained in the Notice[35], these dual conditions are quite restrictive and more difficult to demonstrate for a plant variety right than for a patent. There are also more limited situations (*e.g.*, when a patent claim targets a naïve trait) where the provisions on cross-licensing may not be sufficient to avoid breeders being prevented from developing new varieties by the existence of patents.[36]

79. The Decision in T 1063/18 (point 41) rejected the need to balance the interests of plant breeders to freely perform crossing and selection without being hampered by patents,

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[34] It has been observed that "*the objects of pvr (plant variety rights) protection, new varieties of plants, are mostly the result of the application of traditional breeding techniques. Only in a few cases has the CPVO received applications for plant variety right protection in respect of genetically modified varieties*." See, Bart Kiewiet, "Relation between PVR and Patents on Biotechnology (2003), p.3, available at https://cpvo.europa.eu/en/news-and-events/articles/relations-between-plant-variety-protection-and-patents-biotechnology. This remains the case today. In over 24 years of existence, the EU's Community Plant Variety Office ('CPVO') has received 67.586 applications for plant variety rights, of which only little more than 100 were for genetically modified plant varieties.

[35] See Notice, p.7-8.

[36] See Notice, p.8.

with the interests of inventors to benefit from their work and the encouragement of technical development. According to the Decision, this was *'a matter for the legislative body'*. However, this balancing is what underpins the exclusion from patentability of plant varieties in Article 53 (b) EPC. The historic reason for excluding plant varieties from patentability appears to have been that these were protected by plant variety rights in Contracting States when Article 53(b) EPC was enacted.[37]

80. This balancing between plant variety rights and patents on plants was also made by the EU legislator in the Biotech Directive, and it is enshrined in Article 4(2) of that Directive. Regulation 2100/94 also refers to this balancing in recitals 22 and 23, where it acknowledges the need *'to ensure that the full application of the principles of the Community plant variety rights system is not impaired by the effects of other systems'* and moreover, to the fact that it is *'indispensable to examine whether and to what extent the conditions for the protection of accorded in other industrial property systems, such as patents, should be adapted or otherwise modified for consistency with the Community plant variety rights system'*. (emphasis added)

81. The narrow interpretation of the exclusion contained in Article 53(b), second alternative, EPC does not accord with the need to balance patent rights and plant variety rights, which balance is intrinsic to this provision of the EPC, also when read in light of the Biotech Directive and Regulation 2100/94 on the Community plant variety rights. The potential consequences of that imbalance may affect access by breeders to biological material and the development of plant variety rights.

4.7. On the application of the principle of effectiveness to the interpretation of Article 53(b) EPC

82. The principle of effectiveness (*ut res magis valeat quam pereat*), following from Article 31 of the Vienna Convention and generally recognised as a fundamental tenet of treaty interpretation, holds that an interpretation which renders part of a treaty redundant is to be rejected. This principle was also reiterated by the EBoA, which affirmed the importance of interpreting a provision 'in such a manner that it takes its effect fully and achieves the purpose for which it was designed' (G 1/07).

83. A narrow interpretation of the exclusion contained in Article 53(b), second alternative, EPC would render that provision redundant, insofar as essentially biological processes

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[37] See Bart Kiewiet, "Relation between PVR and Patents on Biotechnology (2003), p.2.

(as natural phenomena)[38] would not fulfil the general patentability criteria of novelty and inventiveness required by Article 52(1) EPC. This is particularly evident with reference to the legislative history of Article 53(b) EPC as reconstructed by the EBoA in case G 1/08, where it was clarified that "*the legislator's intention was to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time*". Conventional methods known at the time would by definition not have fulfilled the criteria of novelty and inventiveness, and therefore would not have required a specific provision excluding them from patentability as such, unless it was intended that this exclusion should also extend to the products obtained by such methods.

84. In this regard, it could be objected that the EBoA noted in case G 2/12 (Reasons, point V11.22b) that:

> 'if it were not for the process exclusion in Article 53(b) EPC, patenting of an essentially biological process for the production of plants or animals would mean that the protection conferred by a process claim extended to the product directly obtained by such process (Article 64(2) EPC), which could well encompass a plant or animal variety. In consequence, irrespective of the distinction between the subject-matter of a patent claim and the protection conferred by it, the process exclusion is inevitable to avoid a contradiction. From this it further could be deduced as part of a systematic approach to Article 53(b) EPC that the second exclusion is aimed at averting an inconsistency with regard to the first group of exclusions. '
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> [However, this consideration seems to be contradicted by the argument put forth by the EBoA in case G 1/98 (also referenced in G 2/12) that 'in conformity with the established case law . . . the protection conferred by a process patent is extended to the products obtained directly by the process, even if the products are not patentable per se.' Therefore Art. 53(b), second alternative, does not seem to perform the function of avoiding the possibility that the protection conferred by a process claim could be extended to a plant variety obtained by such process.]

85. A fortiori, however, if the process exclusion in Article 53(b) EPC is to be interpreted according to case G 2/12 as aimed at preventing that the protection conferred by a process claim for an essentially biological process could be extended to the product thereof ('which could well encompass a plant or animal variety'), then it should also be noted that this provision refers to essentially biological processes for the production of 'plants or animals', and not for the production of 'plant or animal varieties'. If— as appears to be suggested by the EBoA in the reasoning above — the aim of the provision is to prevent the extension of the protection conferred by a process claim to the product

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[38] According to Rule 26(5) EPC, "[a] *process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection*".

thereof (for which a product claim is already excluded by means of the first part of Article 53 (b)), then in order for the difference in wording between the first and the second part of Article 53(b) EPC to be meaningful, the second part of Article 53(b) EPC ought to be interpreted in the sense of excluding the patentability of plants and animals resulting from essentially biological processes, regardless of their qualification as plant or animal varieties.

5. CONCLUSIONS

86. As regards the alleged conflict between Rule 28(2) EPC and Article 53(b) EPC, the European Union fully supports the conclusions and shares the arguments put forward in the Referral.

87. The European Union agrees that Rule 28(2) of the Implementing Regulations to the EPC, having regard to EU law, does not conflict with Article 53(b) EPC where it excludes plants and animals from patentability if obtained by means of an essentially biological process.

88. When assessing this Referral, the EBoA must take into account the Commission Notice, as well as the consensus position of the Contracting Parties to the EPC. After the Board of Appeal decision in case T 1063/18, the February 2019 meeting of the Committee on Patent Law (PLC) of the European Patent Organisation witnessed undivided support for the substance of the Notice by all the contracting States, including those which are not Member States of the EU.[39]

89. Based on the above, the European Union submits that the first question and the second question raised in the Referral by the President of the EPO should both be answered in the affirmative.

Eric GIPPINI FOURNIER Flor CASTILLA CONTRERAS

Agents of the Commission

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[39] See minutes of the meeting of the European Patent Organisation's 'Patent Law Committee' of 19-20.2.2019 (attached as **Annex 4**) confirming that practically all of the 38 contracting states of the Organisation support the views expressed in the Commission Notice of 2016 and the continued application of Rule 28.2 EPC (§ 37: "It had become clear that the member states continued to broadly support the European Commission Notice and the amendment of Rule 28(2) EPC."). Support was expressed again by numerous delegations during the meeting of the Administrative Council of 27-28.3.2019 (see minutes attached as **Annex 5**, § 88 *et seq.*).

6. SCHEDULE OF ANNEXES

ANNEX	TITLE
1.	European 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'.
2.	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.
3.	European Parliament resolution of 19 September 2019 on the patentability of plants and essentially biological processes (2019/2800(RSP).
4.	Minutes of the meeting of the European Patent Organisation's 'Patent Law Committee' of 19-20.2.2019.
5.	Minutes of the meeting of the Administrative Council of the EPO of 27-28.3.2019.