**CA/PL 4/20**

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SUBJECT: Exception to patentability under Article 53(b) and Rule 28(2) EPC of plants and animals exclusively obtained by means of an essentially biological process following opinion G 3/19 of the Enlarged Board of Appeal

SUBMITTED BY: President of the European Patent Office

ADDRESSEES: Committee on Patent Law (for information)

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SUMMARY

In opinion G 3/19 (Pepper) of 14 May 2020, triggered by a referral from the President of the European Patent Office (EPO) in April 2019, the Enlarged Board of Appeal held that plants and animals exclusively obtained by essentially biological processes are not patentable under the European Patent Convention (EPC). The EPO has implemented the clarifications provided in opinion G 3/19 in the practice of examining and opposition divisions. For European patent applications with an effective filing date on or after 1 July 2017, the EPO has resumed its practice based on Rule 28(2) EPC introduced by the Administrative Council in June 2017. The contracting states will be regularly informed about the implementation of opinion G 3/19 and the EPO's examination practice concerning plant- and animal-related inventions.


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## I. STRATEGIC/OPERATIONAL

1. Operational.

## II. RECOMMENDATION

2. The Committee on Patent Law is requested to take note of the information provided by the Office on opinion G 3/19 of the Enlarged Board of Appeal of the European Patent Office (EPO) and its impact with regard to the examination of inventions concerning plants and animals.

## III. MAJORITY NEEDED

3. N/A.

## IV. CONTEXT

4. Under Article 53(b) of the European Patent Convention (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. Article 4(1)(b) of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions ("EU Biotechnology Directive") contains an identically worded provision.

5. In combined decisions G 2/12 and G 2/13 of 25 March 2015 ("Tomatoes II" and "Broccoli II"; OJ EPO 2016, 27 and 28) the Enlarged Board of Appeal found that Article 53(b) EPC was not unambiguous with regard to the question of whether the exception to patentability covers product claims directed to plants or plant material such as a fruit generated by an essentially biological process for the production of plants.

6. In November 2016, the European Commission published a notice on certain articles of the EU Biotechnology Directive (Official Journal of the EU C 411/03 of 8 November 2016; "Commission Notice") in which it took the view that the EU legislator's intention when adopting the directive was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.

7. Based on a proposal by the Office (CA/56/17), the Administrative Council introduced with effect from 1 July 2017 a new paragraph 2 in Rule 28 of the Implementing Regulations to the EPC stipulating that under Article 53(b) EPC European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process. In accordance with Article 3 of the Administrative Council's decision (CA/D 6/17), Rule 28(2) EPC was to apply to European patent applications filed on or after 1 July 2017 as well as to European patent applications and European patents pending at that time.

8. Many contracting states of the European Patent Organisation ("contracting states") introduced a similar patentability exception in their national patent acts; some declared their national law and/or practice to be in line with Rule 28(2) EPC.

9. In decision T 1063/18 of 5 December 2018, a technical board of appeal of the EPO found that Rule 28(2) EPC was in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13. The case was remitted to the examining division for further prosecution.

10. On 4 April 2019 the EPO President, under Article 112(1)(b) EPC, referred questions related to Rule 28(2) EPC and decision T 1063/18 to the Enlarged Board of Appeal (G 3/19 – "Pepper"). The measure was supported by the contracting states in discussions in the Committee on Patent Law in February 2019 and in the Administrative Council in March 2019. On 9 April 2019, the EPO President decided to stay, *ex officio*, all proceedings before examining and opposition divisions in which the decision depended entirely on the Enlarged Board of Appeal's opinion on referral G 3/19 (OJ EPO 2019, A34).

11. More than 40 *amicus curiae* statements were submitted to the Enlarged Board of Appeal on the points of law referred to it by the EPO President, including from many contracting states and the EU.

12. On 14 May 2020, the Enlarged Board of Appeal issued opinion G 3/19 and concluded that plants and animals exclusively obtained by essentially biological processes are not patentable.

13. The Enlarged Board of Appeal held the referral to be admissible based on the grounds cited by the EPO President that decision T 1063/18 differed from decisions of other boards of appeal with regard to the question of whether an amendment to the EPC Implementing Regulations could have an impact on the interpretation of an article of the EPC, irrespective of a particular interpretation given to the latter in an earlier decision of the boards of appeal.

14. On the substance of the questions referred to it by the EPO President, the Enlarged Board of Appeal endorsed both the conclusions and the reasoning of decisions G 2/12 and G 2/13 but at the same time clarified that these decisions did not settle the meaning of Article 53(b) EPC once and for all. According to the Enlarged Board of Appeal, a particular interpretation which has been given to a legal provision can never be taken as being set in stone because the meaning of the provision may change or evolve over time in view of subsequent legal, or even practical or factual, developments.

15. The Enlarged Board of Appeal found that the Administrative Council's decision to introduce Rule 28(2) EPC constituted a new aspect or consideration which could not be ignored when interpreting Article 53(b) EPC. Taking into account the almost unanimous adoption of Rule 28(2) EPC by the Administrative Council as well as the wording and the *travaux préparatoires* of this rule, the Enlarged Board of Appeal accepted that it was the EPC legislator's intention to establish, through the introduction of Rule 28(2) EPC, a special meaning and particular interpretation of Article 53(b) EPC which is that the non-patentability of essentially biological processes for the production of plants or animals also extends to plant or animal products that are exclusively obtained by means of an essentially biological process. The Enlarged Board of Appeal, in addition, saw the contracting states' intention and aims with regard to Article 53(b) EPC demonstrated by the fact that a significant number of them had aligned their national provisions to the content of Rule 28(2) EPC.

16. In view of this clear legislative intent of the EPC legislator and of the contracting states represented in the Administrative Council, the Enlarged Board of Appeal concluded that new Rule 28(2) EPC allowed and indeed called for a dynamic interpretation of Article 53(b) EPC. In adopting this dynamic interpretation, the Enlarged Board of Appeal abandoned its earlier interpretation of Article 53(b) EPC in decisions G 2/12 and G 2/13. It held that, in the light of Rule 28(2) EPC, Article 53(b) EPC is to be understood and applied as extending to product claims or product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process.

17. The Enlarged Board of Appeal also clarified that there is no conflict, within the meaning of Article 164(2) EPC, between Rule 28(2) EPC and Article 53(b) EPC, and confirmed the powers of the Administrative Council as the legislative body of the Organisation to interpret the EPC.

18. In order to ensure legal certainty and to protect the legitimate interests of patent proprietors and applicants, the Enlarged Board of Appeal considered it appropriate that the new interpretation of Article 53(b) EPC given in opinion G 3/19 should have no retroactive effect on European patents granted before 1 July 2017, or on pending European patent applications with a date of filing or, if priority has been claimed, a priority date before that date.

19. In opinion G 3/19, the Enlarged Board of Appeal also confirmed its earlier decisions, and the conclusions underlying these decisions, concerning the interpretation of Article 53(b) EPC, namely the definition of the term "essentially biological processes for the production of plants or animals" given in combined decisions G 2/07 and G 1/08 (OJ EPO 2012, 130 and 206) and the scope of the patentability exception for plant varieties as clarified in decision G 1/98 (OJ EPO 2000, 111).

20. With regard to the delimitation between the judicial function of the boards of appeal (judicial interpretation) and the legislative power of the Administrative Council (regulatory interpretation) in general, the Enlarged Board of Appeal confirmed that the Administrative Council could adopt an EPC rule which concerns the interpretation of an EPC article given by the boards. In particular, the Enlarged Board of Appeal considered that the adoption of Rule 28(2) EPC by the Administrative Council was in accordance with both the separation of powers principle, to which the European Patent Organisation is bound, and the Organisation's duty of loyalty to all its organs and bodies. According to the Enlarged Board of Appeal, the question of whether a change of interpretation effected by an amendment of the EPC Implementing Regulations complied with the rule of law, in the sense that it remained within the legal limits set by the relevant article of the EPC, was a separate matter related to the hierarchy of norms principle set out in Article 164(2) EPC.

## V. ARGUMENTS

### A. INTRODUCTION

21. Opinion G 3/19 confirms that under the EPC plants and animals exclusively obtained by essentially biological processes are not patentable. This understanding is in line with the law and practice of the contracting states and the view taken in the Commission Notice, thereby safeguarding the uniform application of harmonised European patent law. Having regard also to the confirmation of earlier decisions G 2/07, G 1/08 as well as G 1/98 of the Enlarged Board of Appeal, opinion G 3/19 provides legal certainty for users and a solid basis for the EPO's examination practice concerning plant- and animal-related inventions.

22. As in the case of earlier decisions and opinions of the Enlarged Board of Appeal, the Office has acted in accordance with the clarifications provided in opinion G 3/19 and started to implement them in its examination practice, commencing with setting aside the stay of proceedings.

23. The stay of proceedings implemented while referral G 3/19 was pending before the Enlarged Board of Appeal was lifted with effect from 15 May 2020 (OJ EPO 2020, A79). Affected proceedings are gradually being resumed.

24. Following discussions with the users in the SACEPO Working Party on Guidelines, a revised draft of the relevant parts of the Guidelines for Examination in the EPO ("Guidelines") was prepared to reflect the clarifications provided by the Enlarged Board of Appeal in opinion G 3/19. Since the Guidelines were adapted to Rule 28(2) EPC back in 2017 and 2018, only minor additions were required as a consequence of opinion G 3/19, in particular the inclusion of a reference to the opinion. The lack of retroactivity of the new interpretation of Article 53(b) EPC to patents granted before 1 July 2017, or to pending European patent applications filed or which claimed a priority date before that date, was also reflected. Following finalisation of the texts, the amended Guidelines will be published and enter into force in March 2021, according to the new revision cycle.

## B. PRACTICE FOR APPLICATIONS WITH AN EFFECTIVE FILING DATE ON OR AFTER 1 JULY 2017

### a) No European patents in respect of plants and animals exclusively obtained by means of essentially biological processes

25. For applications with an effective filing date on or after 1 July 2017, the practice based on Rule 28(2) EPC implemented since the entry into force of that provision on 1 July 2017 can be continued. In line with this practice, plants and animals exclusively obtained by means of an essentially biological process are excluded from patentability and no European patent covering such a plant or animal is granted.

### b) Plants obtained by technically induced mutagenesis; use of disclaimers

26. In view of the confirmation in opinion G 3/19 of both the validity of Rule 28(2) EPC and the relevant case law concerning the definition of "essentially biological processes", the EPO can continue its practice relating to the examination of inventions concerning plants obtained by technically induced mutagenesis. Mutant plants obtained by technical processes are not covered by the patentability exception of Article 53(b) and Rule 28(2) EPC provided that the claim to such plants explicitly mentions, by means of a so-called disclaimer, that it does not cover plants exclusively obtained by means of an essentially biological process. Such a disclaimer is required in all cases in which a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, can be the result of either a technical intervention or an essentially biological process (a natural allele).

*27.* The disclaimer requirement is set out in the Guidelines as follows (section G-II, 5.2 and 5.4): "*If a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, might be the result of either a technical intervention (e.g. directed mutagenesis) or an essentially biological process (a natural allele), a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product in order to comply with the requirements of Art. 53(b) and Rule 28(2). Otherwise the application is considered to relate to excluded subject-matter and is to be refused on the basis of Art. 53(b) in conjunction with Rule 28(2). A disclaimer is required in all cases and, in particular, even if the description only mentions a technical method of production and is silent on the use of an essentially biological process."* The Guidelines (section G-II, 5.4.2.1) also give an example for the use of the disclaimer: "*A cultivated pepper plant expressing a mutated AHAS enzyme with the proviso that the plant is not exclusively obtained by means of an essentially biological process*."

28. Some stakeholders, in particular NGOs, consider that random mutagenesis constitutes an essentially biological process for the production of plants in the sense of Article 53(b) EPC and thus no European patents should be granted in respect of processes of random mutagenesis and the plants obtained thereby. The practice of the EPO is based on the *travaux préparatoires* for Rule 28(2) EPC (CA/56/17; CA/PL 4/17) as well as combined decisions G 2/07 and G 1/08 which provide support for the view that processes of either targeted mutagenesis (such as, for example, Zinc Finger Nucleases, CRISPR, TALEN and oligonucleotide directed mutagenesis) or random mutagenesis (such as, for example, mutagenic radiation – e.g. UV light – and chemical mutagenesis) as well as the plants obtained by such processes are technical and thus not excluded from patentability.

29. In the preparatory documents for the amendment of Rule 28(2) EPC submitted to the Committee on Patent Law (CA/PL 4/17) and the Administrative Council (CA/56/17), it was acknowledged that mutagenesis is considered to be a technical process which modifies the genetic characteristics of the plant, and that this applied to traditional (i.e. random) methods and modern (i.e. targeted molecular) methods of mutagenesis (CA/PL 4/17, point 82; CA/56/17, points 32 and 40).

30. This is in line with the Enlarged Board of Appeal's decisions in combined cases G 2/07 and G 1/08 which have been explicitly confirmed by the Enlarged Board of Appeal in opinion G 3/19. In these decisions the Enlarged Board of Appeal clarified that 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 which do not themselves change the characteristics of the plant (such as, for example, the use of molecular markers for the selection of the desired plant). However, if a step of a technical nature 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 as long as no step of sexual mixing of whole genomes is claimed as part of the process.

31. When discussing the legislative history of Article 53(b) EPC in decisions G 2/07 and G 1/08, the Enlarged Board of Appeal made explicit reference to processes of irradiation, as follows: "*The explanations given in the comments on the Draft Convention specify that (…) patents will still have to be granted for processes which, while being applicable to plants, are of a technical nature, e.g. processes for producing new plants by irradiation of the plants themselves or the seeds with isotopes (…)."* (point 6.4.2.2 of the Reasons for the decision).

32. The Enlarged Board of Appeal likewise clarified that in determining whether a process was characterised as being essentially biological it was irrelevant whether the process was considered as "traditional" or "classical". It is not because steps taken in a breeding process are known that they can no longer serve to confer a technical character on the process (see point 6.4.1 of the Reasons for the decision). Rather, the essential question is whether the characteristic of the plant is exclusively brought about by an essentially biological process or the consequence of a technical process. As stated above and acknowledged in the preparatory documents underlying the introduction of Rule 28(2) EPC, in the case of mutagenesis – whether targeted or random – the modification in the genome of the plant is brought about by a technical process such as, for example, mutagenic radiation (e.g. UV light) or chemical mutagenesis and is not exclusively brought about by crossing plants.

33. 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).[1] The trigger point for ensuring the patentability of either a plant or an animal is thus the technical process used[2] so that plants and animals produced by technical processes which modify the genetic characteristics of the plant or animal are in principle patentable in accordance with the EU Biotechnology Directive.

34. In judgment C-528/16 of 25 July 2018[3], the Court of Justice of the European Union ruled, with regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms within the meaning of that directive. This applies to both new techniques/methods of direct mutagenesis as well as processes of mutagenesis which have conventionally been used in a number of applications and have a long safety record (although the latter are excluded from the scope of the directive). According to the Court's reasoning, techniques/methods of mutagenesis lead to alterations in the genetic material of a plant.[4] In this context, the Court makes explicit reference to techniques/methods involving the use of chemical or physical mutageneous agents.[5] It is to be noted that the judgment does not concern or deal with the EU Biotechnology Directive or with questions related to the exception from patentability of essentially biological plant breeding processes and the plants exclusively obtained by means of such processes.

**c) Plant cells which are propagation material**

35. In accordance with decision G 1/98 of the Enlarged Board of Appeal (OJ EPO 2000, 11, 5.2 of the Reasons for the decision), which has been explicitly confirmed in opinion G 3/19, plant cells or cell populations which are the subject of in vitro culture are treated like microorganisms since they are comparable to unicellular organisms. Thus, in vitro plant cells are in principle regarded as patentable. This was also acknowledged in the preparatory document underlying the introduction of Rule 28(2) EPC (CA/56/17, point 51).

[1] See Commission Notice, section 1.3.
[2] See Commission Notice, section 1.3, tenth paragraph
[3] Judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583.
[4] Idem, paragraph 28.
[5] Idem, paragraph 29.

36. At the same time, in the framework of introducing Rule 28(2) EPC it was acknowledged that plant parts which are propagation material (i.e. from which a whole plant can be regenerated) would be treated in the same manner as the plants themselves and thus be excluded from patentability if exclusively obtained by means of an essentially biological process (CA/PL 4/17, point 84; CA/56/17, point 43). This is in line with the clarification provided by the Enlarged Board of Appeal in opinion G 3/19 that the patentability exception under Article 53(b) and Rule 28(2) EPC covers not only plants but also plant material exclusively obtained by means of an essentially biological process.

37. Plant cells or tissues are usually totipotent and are able to regenerate the full plant. Therefore, even if plant cells or cell cultures can be regarded as the product of a microbiological process, plant material which is able to propagate the full plant is excluded from patentability in accordance with opinion G 3/19 if the plant from which the material originates has been exclusively produced by an essentially biological process.

## C. STATUS OF PROCEEDINGS TO WHICH RULE 28(2) EPC DOES NOT APPLY

38. Based on the consideration of the Enlarged Board of Appeal in opinion G 3/19 with regard to protecting the legitimate interests of patent proprietors and applicants, Rule 28(2) EPC cannot be applied by the EPO to pending European patent applications filed or claiming a priority date before 1 July 2017 and European patents granted before that date.

39. This concerns about 310 European patent applications pending in examination and approximately 10 European patents pending in opposition with a filing or priority date before 1 July 2017. About half of these 320 applications and patents relate to plants exclusively obtained by means of an essentially biological process which would be refused or revoked within the scope of Rule 28(2) EPC (see point 25 above). The other half concerns plants produced by technically-induced mutagenesis which, if Rule 28(2) EPC applied, would only be considered patentable subject to the introduction of a disclaimer (see point 26 above). No European patent applications or European patents relating to animals exclusively obtained by means of an essentially biological process are pending at the EPO.

40. The non-applicability of Rule 28(2) EPC to the above-mentioned cases means that the invention in question cannot be considered as excluded from patentability on the ground that it relates to plants exclusively obtained by means of an essentially biological process, and that in the case of plants obtained by technically-induced mutagenesis the introduction of a so-called disclaimer cannot be made a requirement. In accordance with standard practice, subject-matter not excluded from patentability has to be examined with regard to the patentability requirements of novelty, inventive step, industrial application, sufficient disclosure and clarity (Articles 54, 56, 57, 83, 84 and 123 EPC). Under Article 97(1) EPC and Article 101(3) EPC, a European patent is granted or maintained if the European patent application or European patent and the related invention fulfil all requirements of the EPC.

41. Following lifting of the stay of proceedings by the EPO President (see point 23 above), proceedings in the affected cases are gradually being resumed. Subject to the circumstances of each case, the examining or opposition division in charge sends an examination report or summons to oral proceedings (whichever is applicable) in which the compliance of the application or patent with all EPC requirements is discussed, and the applicant or parties is/are given the opportunity to comment within (normally) a four-month time limit. Whether the applications or patents affected will be withdrawn or lapse due to the non-payment of renewal fees may only become apparent at a later stage.

42. At the time of publication of opinion G 3/19 in May 2020, 18 appeal cases were pending with the relevant technical board of appeal concerning decisions of EPO examining and opposition divisions based on Rule 28(2) EPC in relation to European patent applications filed before 1 July 2017 or European patents granted before that date.

## D. EUROPEAN PATENTS AFTER GRANT

43. After grant, a European patent falls within the competence of national authorities and courts, in accordance with Articles 2, 64, 65 and 138 EPC and the applicable national law.[6] Without prejudice to Article 65 EPC (and the Agreement dated 17 October 2000 on the application of Article 65 EPC, London Agreement, OJ EPO 2001, 549), the grant of a European patent takes automatic effect and confers on its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin in each contracting state in respect of which it is granted the same rights as would be conferred by a national patent granted in that state. Under Article 138(1) EPC, a European patent may be revoked with effect for a contracting state only on the grounds stipulated in that provision. The effect of an interpretation or explanation of the EPC contained in a decision or opinion of the Enlarged Board of Appeal on the application of Article 138(1) EPC by the authority or court of a contracting state is subject to the law and practice of that state (see the information provided on this by contracting states published as CA/PL 4/16 with addenda 1-4).

## E. FURTHER DEVELOPMENTS

44. The Office will regularly inform contracting states about the implementation of opinion G 3/19 and its practice concerning the examination of inventions related to plants or animals.

45. The EPO recognises the societal and economic implications related to the patentability of plants and animals and is continuing discussions with various stakeholder groups, including NGOs, industry and EU institutions, such as the Community Plant Variety Office.

## VI. ALTERNATIVES

46. N/A.

## VII. FINANCIAL IMPLICATIONS

47. N/A.

[6] The authority vested in the EPO for opposition, limitation and revocation proceedings remains unaffected.

## VIII. LEGAL BASIS

48. N/A.

## IX. DOCUMENTS CITED

49. CA/56/17; CA/D 6/17; CA/PL 4/17; CA/PL 4/16 with addenda 1-4.

## X. RECOMMENDATION FOR PUBLICATION

50. Yes.