

Referral of a point of law
to the Enlarged Board of Appeal
by the President of the European Patent Office
(Article 112(1)(b) EPC)

Under Article 112(1)(b) EPC the President of the European Patent Office refers the following points of law to the Enlarged Board of Appeal:

1. Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being *a priori* limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal?
2. If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?

A. Admissibility of the referral

1. According to Article 112(1)(b) EPC, in order to ensure the uniform application of the law, or if a point of law of fundamental importance arises, the President of the European Patent Office may refer a point of law to the Enlarged Board of Appeal where two Boards have given different decisions on that question.
2. The requirement of “different decisions” is fulfilled in the present case since there is conflicting case law with regard to the way Boards of Appeal have assessed the EPC Rules which implement Article 53 EPC under Article 164(2) EPC (below I.).
3. On this basis question 2 is also admissible, since it is directly related to the different application of Article 164(2) EPC as exemplified in the specific case of Rule 28(2) EPC. In the alternative, question 2 should be considered admissible based on an analogous application of Article 112(1)(b) EPC (below II.).

I. Different decisions of two Boards of Appeal

4. Decision T 1063/18 differs from earlier case law with regard to the way in which an EPC Rule which clarifies the meaning and scope of Article 53 EPC is assessed under Article 164(2) EPC.
5. In decision T 1063/18 the Technical Board of Appeal found that Rule 28(2) EPC is in conflict with the meaning of Article 53(b) EPC “*as interpreted by the Enlarged Board of Appeal*”.¹ This conclusion is based, inter alia, on a statement from decision T 39/93 cited by the Board according to which “*the meaning of an Article of the EPC [...], on its true interpretation as established by a ruling of the Enlarged Board of Appeal cannot, [...] be overturned by a newly drafted Rule of the Implementing Regulations, the effect of which is to conflict with this interpretation.*”² To give effect to such a Rule change “*would reverse the meaning of Article 53(b) EPC as interpreted by the EBA [...] (scil.: and) represent an amendment of an Article of the Convention.*”³
6. It follows from this conclusion and the underlying reasoning that in decision T 1063/18 the Technical Board of Appeal assessed the conformity of Rule 28(2) EPC, which implements Article 53(b) EPC, in relation to an interpretation of said Article in an earlier decision of the Enlarged Board of Appeal. The Board thus equated law, i.e. “provisions of this Convention” within the meaning of Article 164(2) EPC, with case law, i.e. the interpretation of Article 53(b) EPC in an earlier decision of the Enlarged Board of Appeal. Following this decision a clarification of the meaning and scope of Article 53 EPC by means of an EPC Rule would therefore not only be limited by law, i.e. Article 53 EPC itself, but also by case law, i.e. an interpretation of Article 53 EPC given in an earlier decision of the Enlarged Board.

¹ Not published in the OJ EPO, points 23, 25 and 46 of the [Reasons for the Decision](#).

² See [idem](#), point 26 of the Reasons for the Decision, citing decision [T 39/93](#), OJ EPO 1997, 134, point 3.2 of the Reasons for the decision. See in this regard also [T 83/05](#) of 22.05.2007, OJ EPO 2007, 644, point 57 of the Reasons for the Decision.

³ See [idem](#) points 32 and 35 of the Reasons for the Decision.

7. In this context the Board considered it irrelevant that the earlier decision of the Enlarged Board of Appeal did not and could not take into account the Administrative Council's implementation of Article 53 EPC in an EPC Rule since the Enlarged Board's interpretation would exclude any subsequent clarification by means of a Rule which would conflict with said interpretation.
8. This approach differs from other decisions, namely the case law relating to the implementation of Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions (hereafter referred to as "EU Biotechnology Directive") into the EPC.
9. In decision T 315/03 (relating to what has become Rule 28(1)(d) EPC) the Board fully acknowledged the Administrative Council's competence to interpret Article 53(a) EPC by amendment to the Implementing Regulations based on Article 33(1)(c) EPC without being limited in this regard by an interpretation of the Article set forth in earlier case law.
10. In particular, the Board found in point 7.3 of the Reasons for the Decision: "*An administrative action or rule of subsidiary legislation is ultra vires if it falls outside the scope of a law which precludes or limits the legal power of the person or body doing the act or making the rule which is consequently invalid - the term ultra vires denotes an "excès de pouvoir". That is quite clearly not the case here. The law in question, Article 53(a) EPC, contains nothing which precludes or limits its own subsequent interpretation whether by case-law [...] or by legislation [...]. The respondent appears to have argued that the law in question is not simply Article 53(a) EPC but that Article as interpreted in T 19/90. Not only is this a legal impossibility - one cannot combine a legislative provision with case-law interpretation to construct an artificial vires by which to judge an action or rule as ultra vires [...]*" (emphasis added).
11. In decision T 272/95 (relating to what has become Rule 29(1) EPC) the Board, too, fully acknowledged the Administrative Council's competence to give "a more detailed interpretation of the meaning of Article 53 EPC".⁴ On this basis the Board examined under Article 164(2) EPC the validity of the new Rule with Article 53(a) EPC in assessing whether it was "*in conformity with said Article*" (emphasis added). The Board concluded that the new Rule was applicable for the purposes of interpreting the Convention. The same conclusion was later reached in decisions T 666/05⁵ and T 1213/05.⁶
12. In decision G 2/07⁷ the Enlarged Board of Appeal also followed an approach under Article 164(2) EPC which differs from the one underlying decision T 1063/18 as well as decision T 39/93 on which the Technical Board of Appeal relied for its conclusion. Namely, the Enlarged Board of Appeal did not endorse the reasoning underlying decision T 39/93 that under Article 164(2) EPC a previous interpretation of Article 53 EPC by the Enlarged Board of Appeal would *a priori* preclude its clarification by means of a newly drafted Rule of the Implementing Regulations.

⁴ See [T 272/95](#) of 23.10.2002, not published in the OJ EPO, point 4 of the Reasons for the Decision.

⁵ Not published in the OJ EPO, point 75 of the [Reasons for the Decision](#).

⁶ Not published in the OJ EPO, point 44 of the [Reasons for the Decision](#).

⁷ [OJ EPO 2012, 130](#).

13. The Enlarged Board held in point 2.4 of the Reasons for the Decision that: “[b]ased on the assumptions that the approach to the interpretation of Article 53(b) EPC adopted by the boards of appeal prior to the introduction of Rule 23b(5) EPC 1973 reflected the true meaning of that Article, and that Rule 23b(5) EPC 1973 was aimed at a very narrow construction of Article 53(b) EPC 1973, and one which was hardly to be reconciled with the previous interpretation of that Article, the referring Board considers that Rule 23b(5) EPC 1973 is in conflict with Article 53(b) EPC 1973, contrary to Article 164(2) EPC. Reference is made by the referring Board to decision T 39/93 (OJ EPO 1997, 134, point 2.3 of the Reasons), in which it was held that, in view of Article 164(2) EPC, the meaning of an Article of the EPC on its true interpretation as established - in that case - by a ruling of the Enlarged Board of Appeal cannot be overturned by a newly drafted rule of the Implementing Regulations. As will be set out below, this reasoning is based on assumptions which are not endorsed by the Enlarged Board, so that a problem of conflict between Rule 26(5) EPC and Article 53(b) EPC in the sense described by the referring Board does not arise. (emphasis added).”
14. It is acknowledged that the Enlarged Board of Appeal is not a “Board of Appeal” within the meaning of Article 112(1)(b) EPC. “Different decisions” between a Board of Appeal and the Enlarged Board of Appeal can normally not arise since a Board shall refer the matter to the Enlarged Board if it considers it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier opinion or decision of the Enlarged Board of Appeal.⁸ In decision T 1063/18 the Board did not consider a referral “to be justified”⁹ although, it is submitted, the decision deviated from the above-mentioned statement and interpretation of Article 164(2) EPC underlying decision G 2/07 which did not endorse decision T 39/93. In view of this, it is considered appropriate to take into account decision G 2/07, too, in establishing the existence of conflicting case law in the sense of Article 112(1)(b) EPC.
15. In assessing the conformity of a Rule of the EPC the above-mentioned decisions took into account the available guidance from the Enlarged Board of Appeal and the Boards of Appeal on the interpretation of Article 53 EPC.¹⁰ The difference, though, is that unlike T 1063/18 none of these decisions considered an earlier interpretation of Article 53 EPC to impose an absolute bar on its implementation by a newly drafted EPC Rule subsequently adopted by the Administrative Council. In a nutshell, none of these decisions considered it decisive under Article 164(2) EPC whether a Rule was in conflict with an Article “as interpreted by the Enlarged Board of Appeal”¹¹ in an earlier decision and thus whether the Rule was in conflict with case law.

⁸ See Article 21 of the [Rules of Procedure of the Boards of Appeal](#).

⁹ See point 39 of the [Reasons for the Decision](#).

¹⁰ See, for example, [T 315/03](#), OJ EPO 2006, 15, point 7.6 of the Reasons for the Decision.

¹¹ See decision [T 1063/18](#), not published in the OJ EPO, points 23, 25 and 46 of the Reasons for the Decision.

16. The difference is substantial and not just of theoretical nature, as demonstrated in detail in section B. If, as in the case of Article 53 EPC, an Article does not explicitly exclude certain subject matter (or, in the words of the Enlarged Board of Appeal in decision G 2/12, “does not have a negative effect on the allowability”¹² or does not cover “directly”¹³ certain subject-matter) and is thus open to different interpretations, there is *a priori* no conflict between a Rule excluding said subject-matter and the Article. The case law contrasted above then suggests a different approach which may lead to a different result: In decision T 1063/18 the Technical Board of Appeal departed from the existence of a conflict under Article 164(2) EPC of a Rule adopted by the Administrative Council with an earlier Enlarged Board decision and then examined whether it could be resolved by way of interpretation. Under the approach underlying the other decisions, the Article first needs to be interpreted by considering all elements relevant to its interpretation¹⁴, including not only earlier case law from the Boards of Appeal and in particular the Enlarged Board of Appeal but also the Administrative Council’s implementation (i.e. interpretation and clarification) of said Article. Only in relation to this interpretation can it be concluded whether the Rule is in conflict with the Article in the sense of Article 164(2) EPC.
17. It may be noted that some legal scholars have also suggested that the approach underlying decision T 39/93 and followed in decision T 1063/18 is in conflict with other case law.¹⁵
18. In conclusion, there is different case law on the way the existence of a conflict between Article 53 EPC and a Rule which clarifies its meaning and scope is examined under Article 164(2) EPC. Thus, question 1 is clearly admissible. Question 2 should be considered admissible too on the same basis. The conflict of Rule 28(2) EPC with Article 53(b) EPC found in decision T 1063/18 is the direct consequence of the different approach taken to the examination under Article 164(2) EPC in a specific case. Both questions are directly related since the compliance of Rule 28(2) EPC with Article 53(b) EPC depends on whether the earlier interpretation of said Article in decisions G 2/12 and G 2/13 is seen as precluding the Administrative Council’s clarification of Article 53(b) EPC. For these reasons, the admissibility of question 2 should follow from the admissibility of question 1.

¹² See decision [G 2/12](#), OJ EPO 2016, A27, point 1 of the Order of the Decision.

¹³ [Idem](#), point VII. 6. (3) of the Reasons for the Decision.

¹⁴ See, for example, decision [J 16/96](#), OJ EPO 1998, 347, point 2.3 of the Reasons for the Decision in which the Legal Board of Appeal decided that this even included a decision of the Administrative Council *on the interpretation* of an EPC Rule, hence *a fortiori* a Rule change adopted by the latter.

¹⁵ See Benkard/*Schäfers/Henke*, EPC, 3rd edition (2019), Article 164, at 30.

II. Application of Article 112(1)(b) EPC by analogy

19. In the event that the Enlarged Board of Appeal does not agree on the admissibility of question 2 based on the above-presented grounds, it should be considered admissible under Article 112(1)(b) EPC by analogy.

a) The application of Article 112(1)(b) EPC by analogy is not excluded

20. The general rules of interpretation followed by the Boards of Appeal do not exclude an analogous application of Article 112(1)(b) EPC.¹⁶ In cases G 1/97¹⁷ and G 2/02¹⁸ the Enlarged Board of Appeal explicitly acknowledged that “[i]n a codified legal system such as the EPC the judge [...] may certainly find occasion to fill lacunae in the law, in particular where situations arise for which the legislator has omitted to provide.”

21. There is also no general principle that Article 112(1)(b) EPC must be interpreted in a restrictive manner. In decision G 3/08¹⁹ a limitative interpretation of the term “different decisions” was adopted insofar as required by the legislative object and purpose of Article 112(1)(b) EPC to prevent a President’s referral on abstract points of law, which is however not at issue here (see below point 26.).

22. The application of Article 112(1)(b) EPC in the present case is not excluded by other case law from the Enlarged Board of Appeal on the presidential right of referral either. While decision G 4/98 suggests that a conflict between, on the one hand, the general practice of the Office *based on instructions set forth in the Guidelines for Examination* and a decision of a Board of Appeal, on the other hand, does not comply with Article 112(1)(b) EPC²⁰, the decision does not exclude the (analogous) application of Article 112(1)(b) EPC where the Office practice is based on the implementation of an EPC Article in a Rule of the Implementing Regulations to the EPC.

23. On the contrary, decision G 4/98 emphasizes the need for a broad interpretation of Article 112(1)(b) EPC if otherwise the President would be prevented from making a referral in situations intended to be covered by Article 112(1) EPC. In this decision the Enlarged Board of Appeal acknowledged that Article 112(1) EPC must not be interpreted in such a way as to unduly restrict its effect and the presidential right of referral.²¹

¹⁶ See *Schachenmann*, Die Methoden der Rechtsfindung der Großen Beschwerdekammer, GRUR Int. 2008, 702, section IV. with several case law references.

¹⁷ [OJ EPO 2000, 322](#), point 3(b) of the Reasons for the Decision.

¹⁸ [OJ EPO 2004, 483](#), point 8.8 of the Reasons for the Decision.

¹⁹ [OJ EPO 2011, 10](#).

²⁰ [OJ EPO 2001, 131](#), point 1.1 of the Reasons for the Decision; see also Schulte/*Moufang*, Patent Act with EPC, 10th edition (2017), Article 112 EPC, at 36.

²¹ [OJ EPO 2001, 131](#), point 1.2 of the Reasons for the Decision.

b) The effect of decision T 1063/18 is comparable to the situation where two Boards have given different decisions

24. The purpose of the President's right of referral under Article 112(1)(b) EPC is to establish uniformity of law and legal certainty within the European patent system.²² A referral enables the Office to apply the law in a uniform manner, notably when it is difficult if not impossible to bring its examination practice into line with the case law.²³ This difficulty or impossibility exists in case of differences in the rulings of two Boards of Appeal. Whichever interpretation of the point of law at issue is followed by examining and opposition divisions, at least some of the decisions will be set aside on appeal if attributed to a Board which follows the different interpretation.
25. The "different decisions" criterion set forth in Article 112(1)(b) EPC further serves the purpose to prevent the President from consulting the Enlarged Board whenever he so wishes in order to clarify *abstract points of law*.²⁴ While the introduction of a broad right of referral covering abstract points of law was considered in the discussions leading to adoption of Article 112 EPC 1973 it was ultimately decided to exclude such a possibility, inter alia on the ground that the President could make use of the Office's legal departments for this purpose.²⁵
26. The present situation is not related to the cases in which the legislator intended to exclude a referral by the President to the Enlarged Board of Appeal. It does not concern an abstract legal question, but a concrete question which has arisen or may arise in a significant number of pending cases. There are currently about 18 appeals pending against decisions based on Rule 28(2) EPC and about 250 examination and about 7 opposition proceedings in which the application of Rule 28(2) EPC has or may become decisive.
27. On the contrary, the case at issue is most closely comparable to those in which the legislator has foreseen a presidential right of referral under Article 112(1)(b) EPC. In the case explicitly foreseen in Article 112(1)(b) EPC, the right of referral arises due to two different Board of Appeal decisions which, although only binding in the specific case at issue (see Article 111(2) EPC) make it impossible for the Office to align its examination practice with both decisions (see above point 24.).
28. In the present situation Rule 28(2) EPC is generally binding for examining and opposition divisions. As held in decision G 3/08²⁶, it is a fundamental principle of the European Patent Organisation's legal order that the Office as executive organ is bound by the law. There is no legal basis not to apply a provision enacted by the Administrative Council on the basis of a single decision of one Technical Board of Appeal which is only binding in the specific case at issue (Article 111(2) EPC) and in the absence of a decision of the Enlarged Board of Appeal on the conformity of Rule 28(2) EPC with Article 53(b) EPC. This is

²² See [G 4/98](#), OJ EPO 2001, 131, point 1.2 of the Reasons for the Decision; see also Case Law of the Boards of Appeal of the EPO, 8th edition (2016), chapter [IV.F.2.4.3](#).

²³ See [G 3/08](#), OJ EPO 2011, 10, point 7.2.6 of the Reasons for the Decision.

²⁴ [Idem](#), point 7.2.5 of the Reasons for Decision.

²⁵ See, for example, documents BR/12 e/69 ern/PA/mk and BR/26 e/70 kel/PA/mk, as well as decision [G 3/08](#), OJ EPO 2011, 10, point 7.2.5 of the Reasons for Decision.

²⁶ [OJ EPO 2011](#), 10, point 7.2.3. of the Reasons for the Decision.

reinforced by the consideration that according to case law of the Boards of Appeal the Administrative Council has the competence under Article 33(1)(c) EPC to implement, i.e. interpret the Articles of the Convention.²⁷

29. In decision T 1063/18 the Board concluded that Rule 28(2) EPC is in conflict with the meaning of Article 53(b) EPC as interpreted by the Enlarged Board of Appeal and on this ground set aside the examining division's decision based on Rule 28(2) EPC.²⁸ This means that decision T 1063/18 differs from the interpretation of Article 53(b) EPC set forth in Rule 28(2) EPC.
30. If a presidential right of referral exists in case of divergent interpretations of the EPC in two Board of Appeal decisions with *inter partes* effect, it must all the more exist in case of a divergence between the interpretation of an EPC Article in a single Board of Appeal decision and its implementation (i.e. interpretation) with *erga omnes* effect set forth in an EPC Rule adopted by the Administrative Council (*argumentum a fortiori*). In other words, where the impossibility for the Office to bring its examination practice in line with the law results from a conflict between an EPC Rule and a single decision of one Board of Appeal which did not consider a referral to the Enlarged Board justified, the situation is comparable to the case explicitly covered by Article 112(1)(b) EPC.

c) The point of law raised in decision T 1063/18 is of fundamental importance and requires clarification from the Enlarged Board of Appeal in accordance with Article 112(1) EPC

31. The Enlarged Board of Appeal is "*the highest judicial authority of the EPO*".²⁹ Under Article 22(1)(a) and (b) together with Article 112(1) EPC it is responsible for deciding and giving opinions on points of law of fundamental importance in order to ensure the uniform application of the law. In the context of referrals by the Boards of Appeal and the President of the EPO under Article 112(1) EPC the Enlarged Board of Appeal has interpretative supremacy with regard to the EPC.³⁰ Its decisions have a *de facto* binding effect on the Boards of Appeal who may not deviate therefrom.³¹
32. The Enlarged Board's status and its specific role and competence are a clear indication of the significance for legal certainty and uniformity that, in those cases foreseen by Article 112(1) EPC, the Enlarged Board of Appeal indeed has the possibility to clarify the point of law at issue or, in the Enlarged Board's own words "*to take action*".³²

²⁷ See above A. I. and in more detail in section B.

²⁸ Not published in the OJ EPO, points 23, 25 and 46 of the [Reasons for the Decision](#).

²⁹ See decision [G 2301/16](#), not published in the OJ EPO, point 42 of the Reasons for the Decision.

³⁰ [G 3/08](#), OJ EPO 2011, 10, points 7.2.3 and 7.2.5 of the Reasons for the Decision. (The competence for petitions for review under Article 112a EPC is not relevant in the present context.)

³¹ See Article 21 [Rules of Procedure of the Boards of Appeal](#): "*Should a Board consider it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier opinion or decision of the Enlarged Board of Appeal, the question shall be referred to the Enlarged Board of Appeal.*"

³² [G 3/08](#), OJ EPO 2011, 10, point 7.2.5 of the Reasons for the Decision.

33. Pursuant to Article 112(1) EPC, this is the case whenever a point of law of fundamental importance or a question relevant for ensuring the uniform application of the law arises in a decisive manner in a concrete case. The case law of the Boards of Appeal and of the Enlarged Board of Appeal has defined several criteria for assessing whether this requirement for a referral to the Enlarged Board is fulfilled.
34. One of the decisive criteria is whether the question can be answered beyond all doubt by reference to the EPC.³³ It also needs to be taken into account whether the question is relevant for a large number of similar cases so that settling the point of law is important not only to the users of the European patent system but also to the department of first instance in examination and opposition proceedings.³⁴
35. Regarding the specific case of a new referral to the Enlarged Board of Appeal, it was held in decision T 297/88 that in view of Article 112(1) EPC resubmitting to the Enlarged Board a question already decided by it was in general necessary and appropriate if legal developments which had occurred since the earlier decision let it appear desirable in the public interest to have the issue re-assessed by the Enlarged Board of Appeal.³⁵
36. It is submitted that the present situation falls within the category of cases in which Article 112(1) EPC requires the Enlarged Board of Appeal to consider the point of law at issue.
37. The validity of Rule 28(2) EPC in view of Article 164(2) and Article 53(b) EPC is not only a point of law of fundamental importance but also a question which cannot be resolved by reference to the EPC without doubt. While earlier decisions of the Boards of Appeal have dealt with the conformity of a Rule of the Implementing Regulations to the EPC with the Convention³⁶, the non-applicability of an EPC Rule due to a perceived conflict with an Article of the EPC is in general a legal question of fundamental importance. In the specific case at issue it raises fundamental questions of legal interpretation, i.e. the impact of subsequent legal developments on the interpretation of Article 53(b) EPC and the significance of an earlier decision of the Enlarged Board of Appeal on the operation of Article 164(2) EPC.

³³ See Case Law of the Boards of Appeal of the EPO, 8th edition (2016), chapter [IV.F.2.3.2](#) with reference to decision [T 1242/04](#), as well as chapter [IV.F.2.3.7](#) with reference to decisions [J 5/81](#), [J 14/91](#), [T 39/05](#), [T 1196/08](#), [T 1676/08](#) and [T 2477/12](#).

³⁴ Idem, chapter [IV.F.2.3.7](#) with reference to decisions [G 1/12](#), [G 1/13](#), [T 271/85](#), OJ EPO 1988, 341, [T 1242/04](#), OJ EPO 2007, 421 and [T 1676/08](#).

³⁵ Not published in the OJ EPO, point 2.4 (ii) and (iii) of the [Reasons for the Decision](#). The original German text reads: “*Eine erneute Vorlage an die Große Beschwerdekammer sollte nach Meinung der Kammer nur dann erfolgen, wenn die beschließende Kammer nach Abwägen aller Umstände zur Überzeugung gelangt, [...] daß es [...] seither eingetretene rechtliche und/oder technische Entwicklungen im öffentlichen Interesse wünschenswert erscheinen lassen könnten, die Frage nochmals durch die Große Beschwerdekammer prüfen zu lassen.*“

³⁶ For an overview see, for example, Benkard/Schäfers/Henke, EPC, 3rd edition, 2019, Article 164, at 14 et seq.

38. The issue at stake also concerns fundamental questions of legal uniformity. Rule 28(2) EPC was adopted by the Administrative Council in order to align the EPC with the EU Biotechnology Directive.³⁷ The Administrative Council and the EPC Contracting States have attached utmost importance to the uniform interpretation and application of harmonised European patent law. This can be derived not only from Rule 26(1) EPC (according to which the EU Biotechnology Directive shall be used as a supplementary means of interpretation for the EPC) but also from the *travaux préparatoires* relating to the implementation of the EU Biotechnology Directive into the EPC in 1999³⁸ and to the adoption of Rule 28(2) EPC in 2017.³⁹ The Boards of Appeal, too, have recognised the significance of a uniform interpretation of harmonised European patent law.⁴⁰
39. The point of law is relevant for a large number of similar cases. Currently, about 250 examination and about 7 opposition proceedings are pending in which the application of Rule 28(2) EPC may or already has become relevant. Settling the point of law by a *de facto* binding decision of the Enlarged Board of Appeal is thus of great interest and importance for applicants as well as examining and opposition divisions. In the absence of a decision from the Enlarged Board of Appeal the general applicability of Rule 28(2) EPC for examining and opposition divisions creates legal uncertainty and inefficiencies for users and the Office alike.
40. Important legal developments have occurred since the Enlarged Board's earlier decisions in cases G 2/12 and G 2/13 of March 2015. In November 2016 the European Commission issued a Notice on the interpretation of certain articles of the EU Biotechnology Directive⁴¹. This Notice was in line with the position adopted in the European Parliament⁴² and endorsed by the EU Council of Ministers in February 2017.⁴³ Contracting States of the European Patent Convention have meanwhile aligned their law with the interpretation set forth in the European Commission Notice⁴⁴ or have declared their law and practice to be fully in line with it.⁴⁵ Last but not least, in June 2017 the Administrative Council decided to clarify the meaning and scope of Article 53(b) EPC by introducing Rule 28(2) EPC.⁴⁶ Thus, all Contracting States consider the

³⁷ See [CA/56/17](#), section V. A.

³⁸ See the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, [OJ EPO 1999, 573](#), as well as decision [G 2/06](#), OJ EPO 2009, 306, points 5 and 12 of the Reasons for the Decision.

³⁹ See documents CA/PL 4/17 and [CA/56/17](#).

⁴⁰ Established case law since decision [G 5/83](#), OJ EPO 1985, 64; see also [G 2/06](#), OJ EPO 2009, 306, points 5 and 16 of the Reasons for the Decision.

⁴¹ [Official Journal of the EU C 411/3 of 8 November 2016](#).

⁴² See [European Parliament resolution of 10 May 2012](#) on the patenting of essential biological processes (2012/2623(RSP)), as well as [European Parliament resolution of 17 December 2015](#) on patents and plant breeders' rights, 2015/2981(2015/2981(RSP)).

⁴³ See [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.

⁴⁴ Since March 2015 AT, BE, FR, PT and RS have amended their national patent acts accordingly, and similar legislative initiatives are under way in HR, PL and SI; see in detail infra section B. II.

⁴⁵ See in detail infra section B. II.

⁴⁶ See [CA/D 6/17](#) based on preparatory document [CA/56/17](#).

products (plants and animals) of essentially biological processes to be excluded from patentability under harmonised European patent law.

41. The aforementioned legal developments could not be taken into account by the Enlarged Board of Appeal in the interpretation of Article 53(b) EPC made in decisions G 2/12 and G 2/13 in 2015. In light of Article 112(1) EPC and decision T 297/88 it would appear justified for the Enlarged Board of Appeal itself to clarify the potential impact of these subsequent legal developments for the interpretation of Article 53(b) EPC.
42. The significant attention which political, economic and societal stakeholders have attributed to the legal developments related to the patentability of conventional plants under European patent law since at least 2015 is a clear indication for the public interest to have the issue re-assessed by the Enlarged Board of Appeal in light of these subsequent legal developments.
43. The present situation is thus most closely comparable to the one explicitly foreseen in Article 112(1)(b) EPC. The legislator cannot be presumed to have advertently left out the possibility of a presidential referral in the present scenario, taking into account that under the intended operation of Article 112(1) EPC a situation as the one at stake would have been presumed to give rise either to different Board of Appeal decisions as explicit basis for a presidential referral or to a referral by one of several Boards of Appeal under Article 112(1)(a) EPC.
44. The admissibility of question 2 at least based on an analogous application of Article 112(1)(b) EPC thus appears expedient and justified.

B. Substantive considerations

I. Question 1: Assessment under Article 164(2) EPC of a Rule which clarifies the meaning and scope of Article 53 EPC

45. The correct approach to follow under Article 164(2) EPC when examining the conformity of a Rule which implements Article 53 EPC should be the one underlying decisions T 315/03 and T 272/95 (together with decisions T 666/05 and T 1213/05) of the Boards of Appeal as well as decisions G 2/06 and G 2/07 of the Enlarged Board of Appeal, i.e. a Rule clarifying the meaning and scope of Article 53 EPC is not *a priori* limited by earlier case law from the Boards of Appeal or the Enlarged Board of Appeal.

a) The Administrative Council is competent to implement Article 53 EPC

46. Pursuant to Article 33(1)(c) EPC the Administrative Council is competent to amend the Implementing Regulations to the EPC. This competence covers the possibility to implement the Articles of the Convention – including those related to substantive patentability requirements – by interpreting and clarifying their meaning and scope. This competence has been widely recognised in the case law of the Boards of Appeal.

47. In decision G 2/07 (point 2.2 of the Reasons) the Enlarged Board of Appeal held: “*The Enlarged Board is not aware of any ground which would justify such a general assumption (scil.: that the Implementing Regulations may not deal with (core) issues of substantive law) and the referring Board has also given none. It is the function of the Implementing Regulations to determine in more detail how the Articles should be applied and there is nothing in the Convention allowing the conclusion that this would not also apply in the case of Articles governing issues of substantive patent law (emphasis added).*” The Enlarged Board went on stating that “*the legislator is entitled to provide for issues of substantive law in the Rules of the Implementing Regulations (scil.: as long as) such Rule (scil.: is) [...] clear enough to indicate to those applying it in what way the legislator intended the Article to be interpreted by means of that Rule.*”

48. This was confirmed in decisions G 2/12 and G 2/13 in which the Enlarged Board reiterated that “*the Administrative Council of the European Patent Organisation as legislator may amend the Implementing Rules in respect of matters of both procedure and substance*”.⁴⁷

49. In decision G 2/06, too, the Enlarged Board of Appeal acknowledged the Administrative Council’s competence to introduce in the Implementing Regulations “*detailed guidance on what was patentable and unpatentable*” under the Articles of the Convention.⁴⁸

50. In decision T 315/03 the Board of Appeal acknowledged the Administrative Council’s power to establish Rules in the Implementing Regulations to the EPC in order to “*supply provisions for the application and interpretation of pre-existing provisions of the EPC*”.⁴⁹

⁴⁷ OJ EPO 2016, A27 and A28, point VII. 2. (4) (a) of the [Reasons for the Decision](#).

⁴⁸ OJ EPO 2009, 306, point 13 of the [Reasons for the Decision](#).

⁴⁹ OJ EPO 2006, 15, points 5.1 and 7.7 of the [Reasons for the Decision](#).

51. In decision T 272/95 the Board concluded that the Administrative Council has the power to give a more detailed interpretation of the meaning of Article 53 EPC in the Implementing Regulations to the EPC.⁵⁰
52. The Administrative Council's competence to clarify the meaning and scope of EPC Articles by amendments to the Implementing Regulations has also been recognised in case law of the Boards of Appeal not specifically related to the incorporation of the EU Biotechnology Directive into the EPC. In decision J 20/84 the Legal Board of Appeal not only recognised the Administrative Council's power to implement Articles of the Convention, but even implied that a Rule may exclude a legal effect provided for in the Convention on the condition that it was "unambiguous both in its wording and as regards the recognisable intention of the legislator" (emphasis added).⁵¹ In decision T 991/04 the Board found that the Administrative Council can adopt EPC Rules to the effect that "*the Implementing Regulations to the Convention stipulate an authentic interpretation within the framework set by the Convention*".⁵²
- b) Article 164(2) EPC does not provide a basis to a priori exclude the Administrative Council's interpretation and implementation of Article 53 EPC because it deviates from an earlier interpretation of the Enlarged Board of Appeal
53. As confirmed in all of the above-mentioned decisions dealing with the Administrative Council's competence to implement an Article of the Convention, the Administrative Council is thereby limited only by the hierarchy of laws laid down in Article 164(2) EPC.⁵³ In other words, the applicability of a Rule adopted by the Administrative Council is limited to the extent that it conflicts with an Article of the Convention.
54. However, under Article 164(2) EPC the Administrative Council's power is not limited by an interpretation of the Article in question in an earlier decision of the Enlarged Board of Appeal. Article 164(2) EPC does not provide a basis to examine the compatibility of an EPC Rule with earlier case law.
55. This follows first of all from the wording of Article 164(2) EPC which refers to "provisions of this Convention" but not to an earlier interpretation by case law. The wording provides no basis to equate "law" with "case law".
56. It is further supported by the provision's context and *telos*. As a provision of part XII of the European Patent Convention Article 164(2) EPC concerns the relation between Articles adopted (in the first place⁵⁴) by the Diplomatic Conference and Implementing Regulations adopted by the Administrative Council but does

⁵⁰ Not published in the OJ EPO, point 4 of the [Reasons for the Decision](#).

⁵¹ OJ EPO 1987, 95, point 5 of the [Reasons for the Decision](#).

⁵² Decision [T 991/04](#) of 22.11.2005, not published in the OJ EPO, point 6 of the Reasons for the Decision.

⁵³ See, for example, decision [G 2/12](#), OJ EPO 2016, A27, point VII. 2. (4) (a) of the Reasons for the Decision.

⁵⁴ See, however, [Article 33\(1\)\(b\) EPC 2000](#).

not concern the relation between interpretation in case law and the legislative implementation of an Article of the Convention by the Administrative Council.⁵⁵

57. This approach under Article 164(2) EPC is also in line with the role and function of the Boards of Appeal and the Enlarged Board of Appeal. As derivable from Articles 112 and 112a EPC and confirmed inter alia in decision G 3/08, the Enlarged Board of Appeal is not a constitutional court and its decisions or holdings do not have the force of law. Its decisions have a *de facto* binding effect based on Article 21 of the Rules of Procedure of the Enlarged Board of Appeal, but do not *per se* preclude a development in the law or its interpretation. This was confirmed by the Enlarged Board of Appeal in cases G 9/93 and G 2/08 in which it overturned its earlier decisions in cases G 1/84 and G 5/83 respectively and made a clear distinction between the law on the one hand and its interpretation on the other.⁵⁶
58. As regards the Boards of Appeal, they have interpretative supremacy with regard to the EPC; it derives from Articles 21 to 23 EPC⁵⁷ and is beyond any doubt. But neither these provisions nor Article 164(2) EPC provide the basis for disregarding a Rule correctly enacted by the Administrative Council on the sole basis that it deviates from an earlier interpretation in case law. This has been confirmed, in particular, in decisions T 315/03 and T 991/04.
59. In decision T 991/04 the Board stated: *“In general, the interpretation of legal terms lies within the competence of the Boards of Appeal because of their judicial function unless the Implementing Regulations to the Convention stipulate an authentic interpretation within the framework set by the Convention because the Boards of Appeal are not only bound by the European Patent Convention but also by the Implementing Regulations as part of the Convention according to Article 23(3) EPC. The framework set by the Convention means that, if any provision of the Implementing Regulations violates a procedural principle laid down in the Convention itself, such a provision has to be disregarded by the Board of Appeal according to Article 164(2) EPC but otherwise the Board of Appeal has to apply all provisions of the Implementing Rules. (emphasis added).”*⁵⁸
60. In decision T 315/03 the Board clarified: *“Article 164(2) EPC provides that, in the case of conflict between the EPC and the Implementing Regulations, the EPC shall prevail. Thus, Article 164(2) EPC might, in the event of such a conflict, affect the application of the new Rules but it does not and cannot affect how changes in the law may be made, namely by amending Articles of the EPC and/or by amending the Implementing Regulations. Further, in the absence of any such provision, the Boards of Appeal have no power within their existing jurisdiction to pronounce upon such matters. The Boards do have jurisdiction inter alia to interpret the EPC - whether Articles enacted by the Contracting States in conference or Rules enacted by the Administrative Council [...] The Boards also have jurisdiction to give effect to Article 164(2) EPC - to refuse*

⁵⁵ See in this regard also Benkard/Schäfers/Henke, EPC, 3rd edition (2019), Article 164, at 30. See in this context also [Article 150\(2\) sentence 3 EPC](#).

⁵⁶ See [G 9/93](#), OJ EPO 1994, 891, point 6 of the Reasons for the Decision and [G 2/08](#), OJ EPO 2010, 456, point 7.1.4 of the Reasons for the Decision.

⁵⁷ See [G 3/08](#), OJ EPO 2011, 10, points 7.2.1 and 7.2.2 of the Reasons for the Decision.

⁵⁸ See point 6 of the [Reasons for the Decision](#).

*enforcement of a Rule of the Convention which conflicts with an Article. But none of these powers mean that the Boards have any power, express or necessarily implied, to prevent the operation of correctly enacted legislation and, as regards the passage of legislation, the choice between Articles and Implementing Regulations is one exclusively for the legislator.*⁵⁹

61. Thus, it is in line not only with Article 164(2) EPC but also with the interpretative supremacy of the Boards of Appeal that a Rule implementing Article 53 EPC must be taken into account and cannot be *a priori* disregarded on the grounds that it deviates from an earlier interpretation in case law. Exceptions are only conceivable in extreme and obvious cases of conflict, i.e. if the Rule and Article 53 EPC would have mutually exclusive legal consequences.⁶⁰
62. If under Article 164(2) EPC an EPC Rule had to be examined for compatibility in relation to earlier case law, the Administrative Council's competence under Article 33(1)(c) EPC would depend on whether or not the Article in question was already interpreted by case law, in particular by the Enlarged Board of Appeal, before the Council's implementation. Where the Enlarged Board overturns its earlier interpretation of an Article, for example, as in case G 9/93, a Rule clarifying said Article (and, to stay with the example, allowing self-opposition by the proprietor) would at one point in time conflict with the Article and at another point in time not. However, such a "dynamic element" would seem to run counter to any reasonable interpretation of Article 164(2) EPC (and Article 33(1)(c) EPC).

c) Correct approach under Article 164(2) EPC confirmed by predominant case law

63. The approach under Article 164(2) EPC set out above finds confirmation not only in decisions T 315/03 and T 272/95 (as well as T 666/05 and T 1213/05) but also in case law not specifically related to Article 53 EPC and above all in decisions from the Enlarged Board of Appeal.
64. Namely, the approach suggested in decision T 39/93 and relied on by the Board in decision T 1063/18 was explicitly discarded by the Enlarged Board of Appeal in decision G 2/07 as being "*based on assumptions which are not endorsed by the Enlarged Board*".
65. On the contrary, in case G 2/07 as well as in all other pertinent decisions the Administrative Council's clarification was taken into account in the interpretation of the Article in question.
66. In decision G 2/07 the Enlarged Board stated with regard to Rule 26(5) EPC introduced by the Administrative Council in order to clarify the meaning and scope of Article 53(b) EPC that it constituted "*an important addition to the legal texts to be considered in the matter*" (emphasis added).⁶¹ The Enlarged Board further noted that an Article had to be interpreted in light of a Rule of the Implementing Regulations as long as the latter was clear enough.⁶²

⁵⁹ OJ EPO 2006, 15, point 5.8 of the [Reasons for the Decision](#).

⁶⁰ See [G 2/95](#), OJ EPO 1996, 555, point 1 of the Reasons for the Decision.

⁶¹ See point 4.4 of the [Reasons for the Decision](#).

⁶² [Idem](#), point 5 of the Reasons for the Decision.

67. In decisions G 2/06, G 2/12 – G 2/13 as well as T 315/03 the Enlarged Board of Appeal and the Board of Appeal respectively took into account the Rules enacted by the Administrative Council when interpreting Article 53 EPC.
68. In decision J 16/96 the Legal Board of Appeal confirmed that in the examination under Article 164(2) EPC the Boards of Appeal have to consider all elements relevant to interpretation, including *a fortiori* an amendment of the Implementing Regulations by the Administrative Council.⁶³
69. In view of all this the first question should be answered in the positive.

⁶³ See point 2.3 of the [Reasons for the Decision](#).

II. Question 2: Conformity of Rule 28(2) with Article 53(b) EPC

70. Having regard to Article 164(2) EPC, Rule 28(2) EPC is in conformity with Article 53(b) EPC based on at least one of the following considerations.

a) Article 53(b) EPC does not preclude its application to the subject-matter defined in Rule 28(2) EPC

71. In decisions G 2/12 and G 2/13⁶⁴ the Enlarged Board – in accordance with the principles provided for in Articles 31 and 32 of the Vienna Convention on the Law of Treaties – interpreted Article 53(b) EPC in respect of, primarily, its wording and, secondarily, considered also the legislator's intention and the aspects of systematic and historical interpretation.
72. On this basis the Enlarged Board did not conclude or even imply that Article 53(b) EPC itself explicitly acknowledges the patentability of plants (or plant material such as fruit) exclusively generated by an essentially biological process, as it is the case for example for microbiological processes and the products of such processes according to Article 53(b) *ad fine* EPC, or for medical substances or compositions according to Article 53(c) *ad fine* EPC. It was only by reference to Rule 27 EPC that the Enlarged Board considered that Article 53(b) EPC was to be interpreted on account of a “*rather wide notion of the patentability of biotechnological inventions concerning plant-related processes and products other than plant varieties*”.
73. As concerns Article 53(b) EPC itself, the Enlarged Board acknowledged that it is open to different interpretations and that in principle more than one meaning could be attributed to it. At the same time, the Enlarged Board did not consider Article 53(b) EPC to be sufficiently obvious, to provide explicit support or a solid basis to extend the process exclusion also to the products obtained by such processes.
74. On two occasions the Enlarged Board also made reference to the issue of a legislative clarification of the patentability exclusion for essentially biological processes for the production of plants (or animals).⁶⁵
75. Three conclusions may be drawn therefrom:
- Article 53(b) EPC itself does not explicitly allow the patentability of plants (or animals) exclusively obtained by essentially biological processes.
 - Article 53(b) EPC (itself and as interpreted by the Enlarged Board in decisions G 2/12 and G 2/13) leaves room for its further clarification by means of Implementing Regulations to the EPC.
 - The other means of interpretation (applied by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13) do not provide a clear result.

⁶⁴ [OJ EPO 2016, A27 and A28.](#)

⁶⁵ [G 2/12](#), OJ EPO 2016, A27, points VIII. 1. (2) and VIII. 2. (6) (d) of the Reasons for the Decision.

76. On this basis, Rule 28(2) EPC is a permissible clarification of the meaning and scope of Article 53(b) EPC as explained in section I. above. It is also in conformity with Article 53(b) EPC which neither explicitly, nor when interpreted in accordance with established principles, precludes its application to plants and animals exclusively obtained by means of an essentially biological process via an Implementing Rule.

b) Article 53(b) EPC is to be interpreted as excluding the subject-matter explicitly mentioned in Rule 28(2) EPC

77. In the event that the Enlarged Board of Appeal would not agree that Article 53(b) EPC leaves the patentability of plants and animals exclusively obtained by essentially biological processes open for clarification by an Implementing Rule, it should be considered that Article 53(b) EPC itself as interpreted in the light of the clarified legislative intent excludes said subject-matter from patentability.

i) The EPC legislator's intention to interpret Article 53(b) EPC in line with the EU Biotechnology Directive

78. The legislative intent is one element to be taken into account in the interpretation of a provision. This results clearly from the case law of the Boards of Appeal⁶⁶ as well as Articles 31 and 32 of the Vienna Convention on the Law of Treaties.

79. Specifically in decisions G 2/12 and G 2/13 the Enlarged Board of Appeal referred to the legislative intent when interpreting Article 53(b) EPC.⁶⁷ Based on earlier decisions G 2/07 and G 2/08 the Enlarged Board concluded that the *ratio legis* behind the patentability exclusion for essentially biological processes for the production of plants or animals was “*not sufficiently obvious*”⁶⁸ and that the *travaux préparatoires* did not provide a clear result either.⁶⁹

80. What is clear, though, and has not been questioned in said or any other decision is the 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.

81. By decision of 16 June 1999⁷⁰ the Administrative Council of the European Patent Organisation decided to implement the EU Biotechnology Directive into the EPC. In view of the Administrative Council's power to clarify and interpret the provisions of the European Patent Convention in its Implementing Regulations⁷¹, it was decided to incorporate the EU Biotechnology Directive into the EPC Rules and that no changes to the EPC Articles were required.

⁶⁶ See Case Law of the Boards of Appeal of the EPO, 8th edition, 2016, chapter [III. H. 1.1.2](#) and [1.2](#).

⁶⁷ [OJ EPO 2016, A27 and A28](#), points VII. 3. and 5. of the Reasons for the Decision.

⁶⁸ [Idem](#), point VII. 3. (3) of the Reasons for the Decision.

⁶⁹ [Idem](#), point VII. 5. (5) of the Reasons for the Decision.

⁷⁰ See CA/D 10/99 based on preparatory document CA/7/99.

⁷¹ See CA/7/99, at 14.

82. The aim of the Administrative Council's decision was to align the EPC to the EU Biotechnology Directive. This becomes apparent from the *travaux préparatoires*⁷² and has been recognised in the case law of the Enlarged Board of Appeal.⁷³ It is also explicitly reflected in Rule 26(1) EPC according to which the EU Biotechnology Directive shall be used as a supplementary means of interpretation when applying and interpreting the relevant provisions of the European Patent Convention.
83. As suggested in decisions G 2/12 and G 2/13⁷⁴, this intention, reflected in Rule 26(1) EPC, may be considered to amount to a subsequent agreement between the parties regarding the interpretation of Article 53(b) EPC within the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties. In this regard it is worth noting that the Conference of the Contracting States (Article 172 EPC), too, when adopting the revised EPC 2000 did not consider any amendment to the Articles of the Convention necessary as it was already considered to be in line with the EU Biotechnology Directive. This can only be understood to mean that also the Contracting States represented in the Diplomatic Conference were of the view and in agreement that, following the implementation of the EU Biotechnology Directive into the EPC, the Articles of the Convention (in particular Article 53 EPC) would be applied and interpreted in line with the EU Biotechnology Directive.
84. Thus, in 1999/2000 all Contracting States to the EPC, even those not members of the EU, indicated their clear will and intention that when considering whether or not a European patent should be granted the relevant provisions of the European Patent Convention be interpreted in the same manner as the corresponding provisions of the EU Biotechnology Directive.⁷⁵

ii) Intention of the EU legislator behind Article 4(1)(b) EU Biotechnology Directive

85. In the European Commission's Notice of 8 November 2016 it is stated that "[t]he Commission takes the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes."⁷⁶

⁷² See, for example, the notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, [OJ EPO 1999, 573](#).

⁷³ See, for example, decision [G 2/06](#), OJ EPO 2009, 306, points 5 and 12 of the Reasons for the Decision.

⁷⁴ [OJ EPO 2016, A27 and A28](#), point VII. 4. (1) of the Reasons for the Decision.

⁷⁵ [Idem](#), points 5 and 16 of the Reasons for the Decision.

⁷⁶ See [Official Journal of the EU C 411/3 of 8 November 2016](#), section 1.3. The view expressed in the Notice was subsequently confirmed by the European Commission at various occasions, for example most recently in the European Commission's reply to parliamentary question P-000180/2019, http://www.europarl.europa.eu/doceo/document/P-8-2019-000180-ASW_EN.pdf.

86. In its conclusions welcoming the European Commission Notice the EU Council of Ministers recalled in February 2017 that *“the EU legislator’s intention when adopting Directive 98/44/EC was to exclude from patentability products obtained through essentially biological processes”*.⁷⁷
87. Already in December 2015 the European Parliament set forth in a resolution that *“Article 4 (scil.: of Directive 98/44/EC) [...] states that products obtained from essentially biological processes shall not be patentable.”*⁷⁸
88. In decision T 1063/18 the Board found that the European Commission Notice *“has no legal authority”*.⁷⁹ No reference was made to the conclusions of the EU Council of Ministers or the resolution of the European Parliament.
89. The European Commission Notice *“sets out the Commission’s view on the patentability of products emanating from essentially biological processes (addressed in Article 4 of the Directive). [...] The Notice is intended to assist in the application of the Directive, and does not prejudice any future position of the Commission on the matter. Only the Court of Justice of the European Union is competent to interpret Union law.”*⁸⁰
90. Thus, the Notice sets forth one element relevant for the interpretation of Article 4 of the EU Biotechnology Directive. Namely, it specifically sets out the Commission’s view on the EU legislator’s intention regarding the patentability of products (plants and animals) of essentially biological processes in order to assist in the application of the EU Biotechnology Directive.
91. In this regard the European Commission Notice should be considered to carry weight, in particular in view of its endorsement by the EU Council of Ministers and the European Parliament. The EU Biotechnology Directive was adopted in 1998 by the European Parliament and the Council of Ministers, based on a proposal from the European Commission. Thus, the same three institutions competent for the legislative procedure leading to the adoption of the EU Biotechnology Directive have provided information on the legislator’s intention at the time, i.e. that the legislator intended to exclude from patentability the products (plants and animals) of essentially biological processes.
92. In result, the circumstance – acknowledged in the Commission Notice – that it does not set forth a binding interpretation of Article 4 of the EU Biotechnology Directive should not lead to disregarding the conclusions set forth in the Notice altogether. Rather, the statements of the EU legislative institutions as to the legislative intent should be taken into account.

⁷⁷ See point 4 of the 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.

⁷⁸ See second indent of the [European Parliament resolution of 17 December 2015](#) on patents and plant breeders' rights, 2015/2981(2015/2981(RSP))

⁷⁹ See point 29 of the [Reasons for the Decision](#).

⁸⁰ See Introduction, paragraph 6.

iii) Interpretation of Article 53(b) EPC taking into account the legislative intent

93. Taking into account the EU legislator's intention is not barred by decisions G 2/12 and G 2/13. When interpreting Article 4(1)(b) of the EU Biotechnology Directive in these decisions the Enlarged Board of Appeal looked at the provision's wording and context. It did not refer to the *travaux préparatoires* relating to Article 4(1)(b) of the Directive or reach any conclusion as to the EU legislator's intent which would be at odds with the views expressed by the EU institutions.
94. Considering the EPC legislator's intention to fully align the EPC with the EU Biotechnology Directive and the fact that 15 of the 19 Contracting States⁸¹ at the time were the same that as EU Member States had shortly before adopted the EU Biotechnology Directive, it can only be assumed that the EPC legislator had the same intent as the EU legislator when incorporating the EU Biotechnology Directive into the EPC.⁸² For the specific question at issue this should mean that the EPC legislator agreed that, based on Rule 26(1) EPC, Article 53(b) EPC be interpreted on account of the legislative intent that the products (plants and animals) exclusively obtained by essentially biological processes shall not be patentable.
95. As acknowledged above the legislative intent is only one element to be taken into account in the interpretation of a provision. The result of applying the other means of interpretation in the analysis of Article 53(b) EPC derives from decisions G 2/12 and G 2/13.
96. With regard to the grammatical interpretation the Enlarged Board found that "*more than one meaning could in principle be attributed to the wording*".⁸³ Concerning systematic interpretation, the Enlarged Board concluded that it "*does not support giving the process exclusion a broad meaning*".⁸⁴ Based on a teleological interpretation the Enlarged Board arrived at the conclusion that "*the object and purpose of the exclusion under Article 53(b) EPC is not sufficiently obvious*" with regard to the exclusion from patentability of products (plants and plant material) of essentially biological processes.⁸⁵ It follows that Article 53(b) EPC itself is in principle open to different interpretations on this question and that the provision's ordinary meaning, context, object and purpose are not sufficiently clear.
97. Where the other means of interpretation leave the meaning and scope of a provision ambiguous or obscure, the legislative intent should be attributed significant weight. This finds support in decisions G 2/12 and G 2/13 in which the Enlarged Board ultimately tried to establish the legislator's intent based on the *travaux préparatoires* since the other means of interpretation had not given rise to a clear result.⁸⁶

⁸¹ The European Patent Organisation counted 19 Contracting States when the EU Biotechnology Directive was incorporated into the EPC, namely the 15 EU Member States at the time (AT, BE, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, NL, PT, SE) as well as CH, CY, LI and MC.

⁸² See in this regard also the preparatory document underlying the introduction of Rule 28(2) EPC, CA/PL 4/17, points 52 and 53.

⁸³ [Idem](#), point VII. 1. (3) of the Reasons for the Decision.

⁸⁴ [Idem](#), point VII. 2. (5) of the Reasons for the Decision.

⁸⁵ [Idem](#), point VII. 3. (3) of the Reasons for the Decision.

⁸⁶ [Idem](#), section VII. 5. of the Reasons for the Decision.

98. Taking into account the EPC legislator's intent derivable from the incorporation of the EU Biotechnology Directive into the EPC Article 53(b) EPC is to be interpreted as excluding from patentability also the products (plants and animals) of essentially biological processes.
99. According to Rule 28(2) EPC European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process. Based on the above-proposed interpretation of Article 53(b) EPC in light of the legislative intent derivable from the incorporation of the EU Biotechnology Directive into the EPC, Rule 28(2) EPC is fully in line with Article 53(b) EPC and a question of conflict within the meaning of Article 164(2) EPC does not arise.

iv) Subsequent agreement and practice by the EPC Contracting States

100. The following agreement between and practice of the Contracting States of the European Patent Convention should in addition be taken into account in the interpretation of Article 53(b) EPC.
101. When the Enlarged Board of Appeal issued the decisions in consolidated cases G 2/12 and G 2/13, the situation in and the views of the 38 Contracting States with regard to the patentability of plants and animals exclusively obtained by essentially biological processes was not yet fully aligned.
102. Following an invitation from the Office in 2016, the Contracting States provided information on the patentability of plants and animals under their respective national laws.⁸⁷ In the 46th meeting of the Committee on Patent Law, its Chairman summarised the information provided as follows: "*The broad message coming through was that one third of delegations formed a group where the law and/or practice was very different from that decided by the Enlarged Board (scil.: in decisions G 2/12 and G 2/13) [...]; one third was where practice was consistent with the Enlarged Board of Appeal and finally one third were in a middle category of not having many cases and not having a very clear position. Like in other fields, there were clear legal inconsistencies across member states.*"⁸⁸
103. However, since the European Commission Notice was published in November 2016, all 38 Contracting States of the European Patent Convention have indicated and declared that under their national law and practice the products (plants and animals) of essentially biological processes are excluded from patentability.

⁸⁷ See documents CA/PL 4/16, CA/PL 4/16 Add. 1, CA/PL 4/16 Add. 2, CA/PL 4/16 Add. 3 and CA/PL 4/16 Add. 4.

⁸⁸ See CA/PL PV 46, at 23.

104. The 28 EPC Contracting States which are members of the EU have declared their national law and practice to be in line with the interpretation of Article 4(1)(b) of the EU Biotechnology Directive set forth in the European Commission Notice. This results in the first place from the conclusions of the EU Council of the Ministers in which the Commission Notice was welcomed.⁸⁹
105. The 10 EPC Contracting States which are not members of the EU, too, have indicated that under their national law and practice plants and animals obtained by essentially biological breeding processes are not patentable. All these 10 Contracting States voted in favour of the introduction of Rule 28(2) EPC in June 2017.⁹⁰ In view of the harmonising effect of the EPC and the high degree of alignment which has been *de facto* achieved⁹¹ this amounts to a clear indication that the national law and practice is the same as set forth in Rule 28(2) EPC.
106. In RS Article 9(1) item 3 of the national patent act was amended with effect of 16 December 2018 to prescribe that patents shall not be granted in respect of *“a plant variety or animal race or an essential biological process for the production of plants or animals, as well as plants or animals obtained exclusively by means of a substantially biological procedure”*.
107. In NO the examination guidelines of the Norwegian Intellectual Property Office were amended in August 2017 in order to clarify that the practice is in conformity with amended Rule 28(2) EPC. The relevant part of section C - chapter IV - 2a.3.2 reads in translation: *“Plants and animals that are the result of such essentially biological process are also exempted from patenting.”*⁹²
108. In addition, based on Article 4(1)(b) EU Biotechnology Directive several Member States have introduced, or are in the process of introducing, a patentability exclusion for the products (plants and animals) of essentially biological processes in their national law:
- Already since the implementation of the EU Biotechnology Directive, Article 3(1)(d) of the Dutch Patent Act provides:

“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 (emphasis added).”

⁸⁹ See the 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.

⁹⁰ See in this regard also decision [G 2/06](#), OJ EPO 2009, 306, point 5 of the Reasons for the Decision.

⁹¹ See in this regard decision [J 9/07](#), not published in the OJ EPO, point 20 of the Reasons for the Decision; see also Haertel, Die Harmonisierungswirkung des europäischen Patentrechts, GRUR Int. 1981, 479, 488, at No. 3.

⁹² Original text available at https://www.patentstyret.no/tjenester/patent/patentretningsslinjer/utvalg/del-c/del-c-realtetsbehandling-kap-iv---vurdering-av-patenterbar/#_Toc532812123.

- Article 81^{quater} (e) of the Italian Industrial Property Code provides since 2010:

“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, [...] (emphasis added).”
- With effect from 2013 § 2a (1) Nr. 1 of the German Patent Act was amended to provide as follows:

“No patents shall be granted for [...] essentially biological processes for the production of plants and animals as well as plants or animals exclusively obtained by means of such processes; (emphasis added).”
- In a similar manner, § 2 (2) S. 1 of the Austrian Patent Act sets forth since 2016:

“No patents shall be granted for [...] essentially biological processes for the production of plants and animals as well as plants or animals exclusively obtained by means of such processes; (emphasis added).”
- An amendment of L 611-19 I. 3^obis of the French Code de la Propriété Intellectuelle which entered into force in 2016 provides as follows:

“Not patentable are: [...] The products exclusively obtained by essentially biological processes defined in paragraph 3 [...] (emphasis added).
- In PT Article 52(3)(B) of the Código da Propriedade Industrial has been amended with effect from 1 July 2019:

“No patents shall also be granted for [...] essentially biological processes for the production of plants or animals and the plants or animals obtained exclusively by means of such processes (emphasis added).”
- In BE Article XI.5 1^{er} of the Code de droit économique has been amended with effect from 1 April 2019:

“Not patentable are [...] plants and animals exclusively obtained by processes according to paragraph 2 [i.e. essentially biological processes for the production of plants and animals], [...] (emphasis added).”
- In PL the legislator is discussing an amendment of Article 29(1) item 2 of the Polish Industrial Property Act to read:

“Patents shall not be granted for: [...] essentially biological methods of breeding plants or animals, as well as products obtained by these methods (emphasis added).”
- Similar legislative initiatives are under way in HR and SI.

109. The fact that under the national law and practice of all 38 Contracting States of the European Patent Convention the products (plants and animals) of essentially biological processes are excluded from patentability was not yet established and could not be known to the Enlarged Board of Appeal when deciding the questions referred in cases G 2/12 and G 2/13. Also, while in these decisions the Enlarged Board made reference to the national laws of Germany and The Netherlands, it could not yet take into account the changes and forthcoming amendments to the national patent acts of AT, BE, FR, HR, PL, PT, RS and SI.
110. It is recognised that the EPC on the one hand and the national laws of the Contracting States on the other are a different legal source.⁹³ Still, there are strong formal links between both legal orders.⁹⁴ Pursuant to Article 1 EPC a system of law, common to the Contracting States, for the grant of patents for invention is established by the European Patent Convention. Under Article 2(2) EPC the European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, subject of other provisions in the Convention. For issues of infringement of European patents Article 64(3) EPC refers to the applicable national law. Article 138 EPC relates to revocation grounds to be taken into account in national proceedings.
111. Also in light of this the agreement between and practice of the 38 Contracting States of the European Patent Convention in relation to the patentability of the products (plants and animals) of essentially biological processes should be taken into account in the interpretation of Article 53(b) EPC to the effect that under the Convention, too, these products should be considered excluded from patentability.
112. These considerations further support the conclusion suggested above that, having regard to Article 164(2) EPC, Rule 28(2) EPC is in conformity with Article 53(b) EPC.

⁹³ Article 31(3)(a) and (b) of the [Vienna Convention](#) refer to an agreement or practice regarding the interpretation/application “*of the treaty*”.

⁹⁴ See in this regard also decision [J 9/07](#), not published in the OJ EPO, point 20 of the Reasons for the Decision.