Dear Sirs,

The Chartered Institute of Patent Attorneys (CIPA) is the professional and examining body for patent attorneys (also known as patent agents) in the United Kingdom. The Institute was founded in 1882 and was incorporated by Royal Charter in 1891. It represents virtually all of the 2,400 registered patent attorneys in the United Kingdom, whether they practice in industry or private practice. The total membership is approximately 4,000 and includes trainee patent attorneys and other professionals with an interest in intellectual property matters. CIPA maintains the Register of Patent Attorneys under statutory authority on behalf of the UK Department of Trade and Industry and reports to the Comptroller-General of Patents, Trade Marks and Designs at the UK Intellectual Property Office. Nearly all registered patent attorneys in the UK are also professional representatives before the EPO (i.e. they are also European patent attorneys).

Enclosed is an *amicus curiae* brief that is submitted pursuant to Article 10 of the Rules of Procedure of the Enlarged Board of Appeal that that represents CIPA's position on G 3/19.

Yours faithfully,

Simon Wright
Chair, Life Sciences Committee
Chartered Institute of Patent Attorneys

Enc:  *Amicus curiae* brief
**Amicus curiae brief in case G 3/19 (Article 164(2) EPC)**

by the Chartered Institute of Patent Attorneys

In accordance with Article 10 of the Rules of Procedure of the Enlarged Board of Appeal, we hereby make the following statement in connection with case G 3/19.

Table of Contents

1. The Questions Referred
2. CIPA's Views on the Referral
   2.1. Executive Summary
   2.2. Inadmissibility of the Referral: General Points
      2.2.1. As originally conceived, the Referral was improperly based
      2.2.2. The Referral attempts to circumvent the separation of powers principle
      2.2.3. Question 1 of the Referral does not refer to any objective evidence of divergent applications of the law
      2.2.4. Question 1 is misleading and should be reinterpreted
   2.3. Questions 1 and 2 are Inadmissible
      2.3.1. The Boards of Appeal have applied a consistent approach to Article 164(2) EPC
      2.3.2. Question 1 is inadmissible because there are no “different” decisions
      2.3.3. The President’s arguments based upon T 315/03 are unfounded
      2.3.4. T 272/95 contradicts the President’s interpretation of Article 164(2) EPC
      2.3.5. The President’s arguments based upon G 2/07 are unfounded
      2.3.6. Question 1 is inadmissible because Question 2 fails G 3/08 admissibility standards
      2.3.7. Question 2 is inadmissible because there are no “different” decisions
      2.3.8. The EC interpretative notice does not cure the inadmissibility of Question 2
      2.3.9. Application of Article 112(1)(b) EPC by analogy is excluded
   2.4. The Need for a Clarifying Statement Regarding the EC Notice
   2.5. Discussion of Points of Law Underlying Questions 1 and 2
      2.5.1. Prohibitions against retroactivity in certain cases
      2.5.2. Provisions governing amendments to the Implementing Regulations
      2.5.3. The combined effects of Articles 33, 35 and 164 EPC
      2.5.4. Grounds for departure from an earlier EBA interpretation
      2.5.5. Subsequent agreement or practice in the sense of Article 31(3) VCLT
      2.5.6. Developments alleged to represent subsequent agreement or practice
      2.5.7. The AC decision does not qualify as subsequent agreement or practice
      2.5.8. The EC Notice does not qualify as subsequent agreement or practice
      2.5.9. Amendments to national laws do not qualify as subsequent agreement or practice
      2.5.10. The cited developments do not jointly qualify as subsequent agreement or practice
      2.5.11. A “dynamic” interpretation of Article 53 EPC
      2.5.12. The reasoning in G 2/12 and G 2/13
      2.5.13. Significance of certain provisions of EU law
   2.6. CIPA’s Proposed Answer to Questions 1 and 2
1. **The Questions Referred**

The President of the EPO has pursuant to Article 112(1) (b) EPC, referred the following questions to the Enlarged Board of Appeal (EBA).

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?

The document submitted by the president that contains these questions shall hereinafter be referred to as “the Referral”.

2. **CIPA’s Views on the Referral**

2.1. **Executive Summary**

For reasons explained in more detail below, CIPA’s views on the Referral are as follows.

- Question 1 is seeking to obtain a “second opinion” from the EBA upon the basis of views expressed by bodies that are not law-making bodies for the EPC (i.e. the European Commission, the EU Council and the European Parliament) or, in the case of the EPO’s Administrative Council, that do not have the necessary authority to amend Article 53 EPC in circumstances where neither the requirements of Article 33(1)(b) nor of Article 35(3) EPC have been satisfied).

- The Referral is inadmissible because each of Questions 1 and 2 fails the test for admissibility under Article 112(1)(b) EPC.

Questions 1 and 2 both relate to points of law for which:
- there are no “different” decisions in the sense of Article 112(1)(b) EPC; and
- there is already legal certainty and uniformity by virtue of the decisions of the EBA in G 2/12 and G 2/13 as followed in T1063/18.

Further answers from the EBA are not required to establish legal certainty or uniformity.

- The EC Notice is not a relevant “legal development” because it has no legal authority. That Notice therefore does not cure the inadmissibility of Question 2.

- The interpretative supremacy afforded to the Boards of Appeal means that the interpretation afforded to an Article of the EPC by the Boards of Appeal shall prevail in

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1 Since this paper was prepared CIPA has seen the EU Parliament resolution “P9_TA-PROV(2019)0020 Patentability of plants and essentially biological processes. European Parliament resolution of 19 September 2019 on the patentability of plants and essentially biological processes (2019/2800(RSP))”. This appears merely to repeat comments made earlier. The Parliament is not a law making body for the EPC, as appears above and hereafter.

the event of any divergence in views between the AC and the Boards of Appeal. There is therefore no basis in the EPC for application of Article 112(1)(b) EPC “by analogy”.

- Even if the EBA agrees that the Referral is inadmissible, CIPA is of the view that there is a pressing need for the EBA to make a clear statement to the effect that the EC Notice is not “an international treaty relating to patents or European Community legislation relating to patents” in the sense of Article 33(1)(b) EPC and therefore cannot be relied upon to justify an amendment of Article 53 EPC by the AC.

For the reasons outlined above (and discussed in detail in Section 2.3 below), CIPA is firmly of the view that the Referral is inadmissible. Nevertheless CIPA has the following comments.

- A “conflict” in the sense of Article 164(2) EPC automatically arises for any Implementing Regulation amended by the AC under Article 33(1)(c) EPC that purports to override the prevailing interpretation of an Article of the EPC, as established in the case law of the Boards of Appeal.

This conclusion is based upon principles established in the case law of the EPC. The interpretative supremacy afforded to the Boards of Appeal and/or the separation of powers principle prohibit the AC from replacing a Board of Appeal, let alone an EBA, interpretation of the EPC with a different interpretation. Such replacement is also contrary to the principle of protection of legitimate expectations.

- The AC is empowered to amend Articles of the EPC only when the requirements of both of Articles 33(1)(b) and 35(3) EPC have been satisfied.

- There are no reasons to depart from the interpretation of Article 53 EPC in G 2/12 and G 2/13, as followed in T1063/18.

In particular, there is no subsequent agreement or practice in the sense of Article 31(3) Vienna Convention on the Law of Treaties (VCLT) that justifies departing from the EBA’s interpretation.

Further, no considerations have arisen subsequent to the signing of the Convention that provide reasons to believe that a literal interpretation of Article 53 EPC would conflict with the legislator’s aims.

Finally, there is no fundamental flaw in the reasoning in G 2/12 and G 2/13 (which reasoning needs to be upheld in order to avoid a breach by the EU Member States of their obligations under Article 267 TFEU).

2.2. Inadmissibility of the Referral: General Points

Whilst admissibility can only be determined by reference to the EPC (e.g. the interpretation of Article 112(1)(b) EPC in G 3/08), CIPA is of the view that the genesis of G 3/19 justifies a view that the reference is not admissible.

2.2.1. As originally conceived, the Referral was improperly based

The Referral is a reaction to decision T 1063/18, which was published on 5 February 2019.

The Office’s initial reaction to T 1063/18 is illustrated by reports of the outcome of the meeting of the Committee on Patent Law (CPL) that took place on 19 and 20 February 2019.
The first such report is the Office’s 20 February 2019 news item3 entitled “EPO member states discuss patentability of plants obtained by essentially biological processes”:

“In the meeting of the Committee on Patent Law, the Office and the representatives of the 38 EPO Contracting States, together with the European Commission as observer, had a first exchange of views on possible next steps following the recent decision T 1063/18 of an EPO Board of Appeal on plant patentability. The Committee addressed different potential options for the way forward and particularly supported measures to obtain an opinion from the Enlarged Board of Appeal on the matter. The need for legal certainty in the interest of the users of the European patent system and the general public was strongly underlined in the debate. Discussions will continue with the intention to find a solution in the short term”.

The second report can be found in point 17 of document CA/26/19 (dated 7 March 2019):

“In the meeting of the Administrative Council in December 2018 some delegations commented on case T 1063/18. Following a presentation by the Office, an initial discussion on decision T 1063/18 and potential options for next steps took place in the meeting of the Committee on Patent Law on 19 February 2019. The Committee expressed broad support for measures to obtain an opinion from the Enlarged Board of Appeal on the matter and requested the Office to prepare an analysis for the Administrative Council meeting in March 2019 as basis for the further discussions”.

Whilst these reports indicate that the CPL perceived a “need for legal certainty”, they are silent upon the issues of:
- why the CPL perceived that the decision in T 1063/18 gave rise to any uncertainty; and
- the grounds for the CPL’s belief that a referral to the EBA would be possible.

Whilst representing the opinion of the President (and not the CPL), document CA/26/19 contains further information on the latter point. That is, points 25 and 26 of CA/26/19 indicate that, in the President’s view:
- according to decision T 297/88 “a Board of Appeal should refer a question already decided by the Enlarged Board of Appeal again to the latter if, weighing all circumstances, it considers amongst other things that legal developments which have 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”; and
- “In the situation brought about by decision T 1063/18 a referral by the President under Article 112(1)(b) EPC would give the Enlarged Board of Appeal an opportunity to assess itself the potential impact of the Administrative Council’s decision to introduce Rule 28(2) EPC and of the conclusions set forth in the European Commission Notice of 2016 for the interpretation of Article 53(b) EPC”.

Document CA/26/19 therefore establishes that, as recently as 7 March 2019, the President was prepared to make a referral under Article 112(1)(b) EPC for the sole purpose of giving the EBA an opportunity to reconsider its ruling in G 2/12 and G 2/13, in the light of the “legal developments” of Rule 28(2) EPC and the EC Notice.

In other words, the President’s statements in CA/26/19 confirm that, as originally conceived, the Referral was not the result of two Boards of Appeal having given different decisions as required by Article 112(1)(b) EPC. That is, the clear objective of the Referral was to obtain a “second opinion” from the EBA on a point of law decided in G 2/12 and G 2/13 and followed

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in T 1063/18 (i.e. the determination that the EC Notice “cannot be seen as a relevant development because it has not been confirmed in a legally binding way” and that it therefore has “no legal authority” under the EPC).

The basis of the Referral is also evident in the Office’s 29 March 2019 news item⁴ entitled “EPO Contracting States discuss next steps regarding the patentability of plants obtained by essentially biological processes”, wherein it is stated that:

“In the 159th meeting of the Administrative Council, the representatives of the 38 EPO Contracting States together with the European Patent Office discussed the need to find a solution in the short term following the decision T 1063/18.

The Contracting States expressed their concerns with regard to the legal uncertainty caused by decision T 1063/18. The President of the EPO expressed his view that a President’s referral of the case to the Enlarged Board of Appeal is justified and necessary. The aim is to obtain an opinion from the Enlarged Board of Appeal on the patentability of plants exclusively obtained by essentially biological processes, hereby considering recent legal developments (interpretations and statements of the European Commission, the EU Council, European Parliament and EPO’s Administrative Council on the interpretation of the European Patent Convention and the EU Bio-Directive, all of them concluding that there should be no patentability in these cases).

The President’s proposal received broad and overwhelming support from almost all Contracting States. President António Campinos announced that the EPO will proceed swiftly to submit the referral. The EPO endeavours to restore legal certainty fully and speedily in the interest of the users of the European patent system and the general public” (emphasis added).

2.2.2. The Referral attempts to circumvent the separation of powers principle

Despite discussing the possibility of a referral by the President to the EBA, the written record outlined above (the reports of the CPL meeting and the discussion in CA/26/19) makes no mention of Article 164(2) EPC. The first ever public mention of that Article by either the President or the Office is therefore in the documents submitted to the EBA on 5 April 2019, which form the basis of the Referral.

In document point 23 of CA/PL 4/17 (dated 23 March 2017), the President of the EPO acknowledged that, in view of T 39/93, application of Article 164(2) EPC by the Boards of Appeal would mean that:

“an amendment of the EPC Implementing Regulations is only effective if it does not conflict with the meaning of an article of the EPC on its true interpretation as established by a ruling of the Enlarged Board of Appeal” (emphasis added).

This point is apparently no longer conceded by the President. That is, in the Referral, the President instead argues that there are decisions that are “different” to T 39/93 with respect to the interpretation of Article 164(2) EPC. Indeed, in point 15 of the Referral, the President retreats so far from the position set out in CA/PL 4/17 as to suggest that, with regard to the allegedly “different” decisions:

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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” in an earlier decision.

The decisions cited by the President as allegedly being “different” (i.e. T 315/03, T 272/95 and G 2/07) were all available to the President and his legal advisors at the time that document CA/PL 4/17 was drafted. The availability (or otherwise) of those decisions therefore does not explain the marked change, between 23 March 2017 and 5 April 2019, in the position of the President with regard to the interpretation of Article 164(2) EPC.

In this context, and bearing in mind the original basis for the Referral discussed at Section 2.2.1 above, CIPA’s view is that there is a concern that Question 1 represents an attempt to circumvent the principle of separation of powers, by asking the EBA to replace an interpretation of the EPC provided by the Boards of Appeal of the EPO with a different interpretation based upon an opinion expressed by the European Commission (and by the EU Council, the European Parliament and the EPO’s Administrative Council).

2.2.3. Question 1 of the Referral does not refer to any objective evidence of divergent applications of the law.

According to point 7.2.6 of G 3/08, what matters for admissibility is objective evidence of divergent applications of the law. CIPA’s view is that the above-mentioned written record makes it clear that Question 1 does not represent a point of law upon which the EBA can be properly be asked to provide an opinion.

In this respect, and for the reasons outlined in Section 2.3 below, CIPA’s view is that Question 1 is intended to obtain a “second opinion” from the EBA on the interpretation of Article 53 EPC provided in G 2/12 and G 2/13 as followed in T 1063/18 solely upon the grounds of contrary opinions expressed by bodies that:
- are not law-making bodies for the EPC (i.e. the European Commission, the EU Council and the European Parliament); or
- in the case of the EPO’s Administrative Council, do not have the necessary authority to amend Article 53 EPC in circumstances where neither the requirements of Articles 33(1)(b) nor of Article 35(3) EPC have been satisfied.

2.2.4. Question 1 is misleading and should be reinterpreted

Question 1 asks whether the meaning and scope of Article 53 EPC can be “clarified” in the Implementing Regulations (i.e. by Rule 28(2) EPC). In this respect, CIPA’s view is that Question 1 is misleading. This is because it mischaracterises:
- the relationship between Article 53 EPC and Rule 28(2) EPC; and/or
- the respective roles of the Administrative Council and the Boards of Appeal.

According to point 7.2.2 of G 3/08, the EPO’s Boards of Appeal are assigned interpretative supremacy with regard to the EPC.

“Like the judiciary of any democratic entity based on the separation of powers principle, the EPO’s Boards of Appeal as an independent judiciary guarantee the due process of law within the Organisation. They are also assigned interpretative supremacy with regard to the EPC in terms of its scope of application”.

Thus, whilst Article 33(1)(c) EPC 2000 (which corresponds to Article 33(1)(b) EPC 1973) provides the AC with competence to amend the Implementing Regulations, the separation of
powers principle means that this competence does not (and cannot) override the interpretative supremacy assigned to the Boards of Appeal.

Indeed, the limits of the AC’s powers is a point that is addressed in point 4 of the reasons for the decision in G 6/95:

“According to Article 33(1)(b) EPC, the Administrative Council is competent to amend the Implementing Regulations. There are obviously limits to the exercise of its powers, however. In fact, Article 164(2) EPC states that: "In the case of conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail”. Therefore, the Administrative Council may not amend the Implementing Regulations in such a way that the effect of an amended Rule would be in conflict with the EPC itself ("this Convention")” (emphasis added).

Given that the Boards of Appeal are assigned interpretative supremacy with regard to the EPC, the practical effect of the principle established in in G 6/95 is that the AC may not amend the Implementing Regulations as interpreted by the Boards of Appeal in such a way that the effect of an amended Rule would be in conflict with the EPC as interpreted by the Boards of Appeal.

Rule 28(2) EPC was designed to exclude from patentability certain plants and animals (those exclusively obtained by means of an essentially biological process; see point 11 of CA/26/19). As concluded in T 1063/18, this is a result that directly contradicts the EBA’s interpretation of Article 53 EPC in G 2/12 and G 2/13.

Thus, unless and until the BoA and the EBA deviates from the EBA’s rulings in G 2/12 and G 2/13 (or interprets Rule 28(2) EPC in a manner that is consistent with those rulings), it is inaccurate to describe Rule 28(2) EPC as doing anything other than purportedly changing the meaning and scope of Article 53 EPC. To suggest otherwise would be to assume that either:
- the EBA will overrule G 2/12 and G 2/13; or
- the separation of powers principle upon which the EPO is modelled (as confirmed in G 3/08) can be disregarded with respect to Article 53 EPC.

Neither of these assumptions can be justified. Therefore, to ensure that Question 1 is not tainted by such unjustifiable assumptions, CIPA’s view is that the point of law addressed by Question 1 should be interpreted to have the following meaning.

Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be modified/clarified in the Implementing Regulations to the EPC without this modification/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?

This reinterpretation of Question 1 also has the advantage of better reflecting the fact that, in view of the interpretative supremacy assigned to the Boards of Appeal, the “meaning and scope” of an Article of the EPC is synonymous with the interpretation afforded to said Article by the Boards of Appeal. That is, it avoids giving the misleading impression that an Article of the EPC can have a meaning and scope other than that afforded to it by way of the prevailing interpretation in the case law of the Boards of Appeal.
2.3. **Questions 1 and 2 are Inadmissible**

In this section, we will outline the reasons why each of Questions 1 and 2 fail the test for admissibility under Article 112(1)(b) EPC. In particular, we will demonstrate that Questions 1 and 2 both relate to points of law:

- where the Boards of Appeal apply a uniform approach;
- for which allegations of “different” decisions in the sense of Article 112(1)(b) EPC are either unfounded or contradicted by the cited case law; and
- for which an opinion of the EBA is not required in order to establish legal certainty or uniformity

We shall also demonstrate that the EC Notice does not cure the inadmissibility of Question 2, and that application of Article 112(1)(b) EPC “by analogy” is excluded.

2.3.1. **The Boards of Appeal have applied a consistent approach to Article 164(2) EPC**

When assessing whether there is a “conflict” in the sense of Article 164(2) EPC (between a higher status provision of the EPC and an amended, lower status provision of the EPC), the Boards of Appeal of the EPO have applied a consistent approach. That is, in all cases (*including* T 1063/18, T 315/03, T 272/95 and G 2/07) the Boards have adopted the following approach.

(a) Interpreting the higher status provision according to the principles of interpretation enshrined in the VCLT.

(b) Interpreting the amended lower status provision in question, again according to the principles of the VCLT.

(c) Comparing the results of the interpretations from (a) and (b).

The principles of the VCLT include the possibility to take account of developments subsequent to the conclusion of a treaty (see, for example, VCLT Article 31(3) and Article 32). However, there is no fixed answer to the question of whether an amendment to a lower status provision reflects a “subsequent development” that can influence the interpretation of a pre-existing higher status provision. This is because it must be determined, on a case-by-case basis, whether the facts support the contentions that:

- there is a relevant “subsequent development” in the sense of the VCLT (that justifies a change to the interpretation of the higher status provision); and
- the amendment to the lower status provision reflects that development.

Possible conclusions from the analysis outlined at (a) to (c) above include the following.

(A) A finding of no conflict, on the grounds that the scope and effect of the lower status provision falls within the scope and effect of the higher status provision on its proper interpretation (and *without* reference to the lower status provision).

(B) A finding of no conflict, on the grounds that the lower status provision reflects a “subsequent development” in the sense of the VCLT that can be taken into account for the interpretation of the higher status provision.

(C) A finding of conflict between the higher and lower status provisions.

Further, in cases under scenario (C) above, the Boards have resolved the conflict between the higher and lower status provisions in an entirely logical manner (and in accordance with Art 164 (2)), namely by:
(1) reinterpreting the lower status provision to remove the conflict with the higher status provision (as in G 2/95, G 6/95, J 14/91, J 15/02, J 7/07, T 556/95 and T 708/00); or, where this is not possible
(2) disregarding the lower status provision (as in T 1063/18).

It is therefore perfectly understandable that different facts underlying different alleged conflicts between higher and lower status provisions have resulted in Boards of Appeal:
- reaching different conclusions; and, where relevant
- resolving any conflict identified in different ways.

However, such differences are wholly attributable to differences in underlying facts and not any divergence or conflict with regard to the interpretation of Article 164(2) EPC.

2.3.2. Question 1 is inadmissible because there are no “different” decisions

In point 16 of the Referral, it is asserted that the Board in T 1063/18 did not interpret Article 164(2) EPC “by considering all elements relevant to its interpretation, 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”.

As will be demonstrated below, this assertion is incorrect.

Point 20 of T 1063/18 quotes Article 21 of the Rules of Procedure of the Boards of Appeal, which states that:

“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”.

Points 26 to 39 of T 1063/18 then:
- discuss in detail the question of whether there are any reasons to deviate from the G 2/12 and G 2/13; and
- conclude that there are no such reasons, and that it is therefore “not necessary to deviate from the interpretation of Article 53(b) EPC given by the EBA in decisions G 2/12 and G 2/13”.

The Board in T 1063/18 therefore interpreted Article 164(2) EPC in a manner entirely consistent with all other Boards, namely by applying the approach outlined at (a) to (c) above.

Further, it is clear that the Board in T 1063/18 gave detailed consideration to the question of whether Rule 28(2) EPC reflected a “subsequent development” in the sense of the VCLT that can be taken into account for the interpretation of Article 53(b) EPC (see, in particular, points 28 to 37 of T 1063/18).

Thus, contrary to the assertion in point 16 of the Referral, the Boards in T 315/03, T 272/95 and G 2/07 applied an identical approach to the Board in T 1063/18, with the consequence that there are no “different” decisions regarding the interpretation / application of Article 164(2) EPC.

5 As held in point 35 of T2477/12, “The application of the same legal principles and criteria may lead to different results in different cases. This is a consequence of the specific facts of each individual case and not, however, an indication of a contradictory interpretation or an inconsistent application of the law.”
In this respect, we point out that T 315/03, T 272/95 and G 2/07 are all cases falling under Category (A) above. That is, they are cases in which:

- the Boards did not find any conflict at step (c); and
- the absence of conflict was evident from a “stand-alone” interpretation of the higher status provision, i.e. an interpretation without reference to the amended lower status provision.

In other words, those allegedly non-uniform decisions merely concern "a different legal situation" (in the sense of points 1.5 and 1.6 of T 137/09) to that in T 1063/18. This is evident, for example, from the following.

Point 7.4 of T 315/03:
“Second, the respondent said Rule 23(d) EPC broadens the exclusion in Article 53(a) EPC contrary to the principle of narrow construction of exclusions and thus inventions which might have satisfied the T 19/90 test may now fail the Rule 23(d) test. In the Board's opinion, it is only correct to say the Rule broadens the Article 53(a) EPC exclusion in as much as the Rule now specifies four limited categories of inventions which are deemed to fall within that Article. However, since it is unimaginable that cases within those four categories would not always have been considered under Article 53(a) EPC, it would be incorrect to say that the new Rule broadens the law as regards the exclusion of such cases” (emphasis added).

Point 7.6 of T 315/03:
“As mentioned above (see paragraph 5.8), Article 164(2) EPC provides that, in the case of conflict between the EPC and the Implementing Regulations, the EPC shall prevail. Thus it is clear that, in T 272/95, Board 3.3.4 posed the question whether the new Rules were consistent with Article 53(a) EPC and, relying as one would only expect on available guidance from the Enlarged Board, found that the new Rules were so consistent”.

Point 5 of T 272/95:
“Having regard to Article 164(2) EPC, the Board has to examine whether or not the new rules insofar as they relate to Article 53(a) EPC are in conformity with this article. In decision G 1/98 (OJ EPO 2000, 11, point 5.3) dealing with the interpretation of Article 53(b) EPC, the EBA stated that Article 4(1)b and (3) of the EU biotechnology directive 98/44 (see supra) was intended to be interpreted in the same sense as the EBA interpreted the scope of Article 53(b) EPC (G 1/98, points 3.10, 5 and 6, see supra). This latter interpretation corresponds entirely to the new Rule 23(c) adopted by the Administrative Council, which in turn is based on the EU directive. The EBA, thus, found this Rule related to Article 53(b) EPC to be only interpretative. The present Board adopts this view, considers that the same holds true for the new rules as far as they relate to the interpretation of Article 53(a) EPC and, thus, will apply Rules (e) and (d) to the present case” (emphasis added).

Point 6.4.2.3 of G 2/07:
“Hence, in more general terms, the conclusion to be drawn is that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC”.
Nevertheless, the Boards in T 315/03, T 272/95 and G 2/07 still answered the question of whether there was a “conflict” in the sense of Article 164(2) EPC by using the same general approach as in T 1063/18, i.e. by applying steps (a) to (c) above.

2.3.3. The President’s arguments based upon T 315/03 are unfounded

The arguments in points 9 and 10 of the Referral are based upon a fundamental misunderstanding of the point of law addressed in point 7.3 of T 315/03. In particular, those arguments erroneously conflate unenforceability of an Implementing Regulation on two distinct grounds, namely:

- invalidity on the grounds that the AC exceeded its powers (i.e. acted in an ultra vires manner) by promulgating the Implementing Regulation in question; and
- conflict (in the sense of Article 164(2) EPC) of the Implementing Regulation in question with an Article of the EPC.

The difference between these two grounds for unenforceability of an Implementing Regulation is best illustrated by considering the respective legal consequences.

An Implementing Regulation deemed invalid is a legal nullity (i.e. it is deemed never to have existed). On the other hand, an Implementing Regulation deemed to conflict with an Article of the EPC may still (validly) produce legal effects. This is because, as in cases such as G 2/95, G 6/95, J 14/91, J 15/02, J 7/07, T 556/95 and T 708/00, it is often possible for conflict to be resolved by way of a reinterpretation that subtly modifies, rather than entirely eviscerates or negates, the legal effects of the Implementing Regulation.

Point 7.3 of the reasons for the decision in T 315/03 only addresses the question of whether, Rule 23d(d) EPC 1973 was invalid for being ultra vires (i.e. on the grounds that, when promulgating that Rule, the AC was acting “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”).

There is nothing in Article 164(2) EPC that “precludes or limits” the AC from promulgating amendments to the Implementing Regulations. Instead, that Article merely:

- establishes an order of precedence between the Implementing Regulations and the Articles of the EPC; and
- enables Boards of Appeal to disregard (or adopt a non-conflicting interpretation of) any Implementing Regulation amended by the AC whose “normal” interpretation conflicts with an Article of the EPC.

In other words, point 7.3 of the reasons for the decision in T 315/03 says nothing whatsoever about the interpretation (or application) of Article 164(2) EPC. The arguments in points 9 and 10 of the Referral are therefore unfounded, as they are based upon statements in T 315/03 that are irrelevant to Article 164(2) EPC (and hence also to the question of whether there are any “different” decisions in the sense required by Article 112(1)(b) EPC).

2.3.4. T 272/95 contradicts the President’s interpretation of Article 164(2) EPC

In point 11 of the Referral, a statement from T 272/95 is quoted in order to support the assertion that “the Board, too, fully acknowledged the Administrative Council’s competence to give “a more detailed interpretation of the meaning of Article 53 EPC”.

However, when viewed in its proper context, it can be seen that the statement from T 272/95 in fact contradicts the President’s position regarding the interpretation of Article 164(2) EPC.
Point 4 of the reasons for the decision in T 272/95 reads as follows.

“After the Directive 98/44/EC of 6 July 1998 was passed by the European Parliament, the Administrative Council of the EPO in its decision of 16 June 1999 amended the Implementing Regulations of the European Patent Convention by adding to Part II of these Regulations a Chapter VI - Biotechnological inventions – comprising Rules 23(b) to 23(e), for the purpose of applying and interpreting the provisions of the Convention relevant to European patent applications and patents concerning biotechnological inventions. Article 2 of this decision states that it shall enter into force on 1 September 1999; the decision itself does not contain transitional provisions. **The Board concludes from the absence of transitional provisions that the Administrative Council must have been of the opinion that Rules 23(b) to 23(e) EPC only gave a more detailed interpretation of the meaning of Article 53 EPC as intended from its inception, and hence were also applicable to cases already pending before 1 September 1999 such as the present case**” (emphasis added).

Thus, from the text emboldened above, it can be seen that the Board in T 272/95 was operating upon the assumption that the absence of transitional provisions for Rules 23b to 23e meant that:
- the meaning and scope of Article 53 EPC was unchanged (i.e. it had the same meaning and scope as intended from its inception); and
- Rules 23b to 23e merely provided further details regarding how Article 53 EPC should be interpreted within its original meaning and scope.

Thus, the passage quoted from T 272/95 does not support the President’s interpretation of Article 164(2) EPC. That passage instead supports a very different position, namely the conclusion that the Board in T 272/95 found that the Implementing Regulations in question did not conflict with the original interpretation of Article 53 EPC (i.e. Scenario (A) from Section 2.3.1 above).

2.3.5. The President’s arguments based upon G 2/07 are unfounded

Contrary to the assertion in point 12 of the Referral, the EBA in G 2/07 did **not** reject the reasoning underlying decision T 39/93.

In the broader context of points 2.4 and 2.5 of G 2/07 (see below), it is evident that the “reasoning” mentioned at the end of point 2.4:
- is reasoning of the **referring** Board (i.e. not the Board in T 39/93); and
- relates to assumptions regarding the interpretation of Article 53(b) EPC.

In this respect, we refer to the following passages from points 2.4 and 2.5 of G 2/07:

“**Based 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.

... The same applies with respect to the further, related argument raised by the referring Board concerning the principle of protection of legitimate expectations. On the assumption that the introduction of Rule 23b(5) EPC 1973 changed the law by narrowing the scope of the process exclusion contained in Article 53(b) EPC 1973 and thus expanded the area of patentable subject-matter, it might be necessary to consider whether third parties should be protected in their expectation that an activity which amounted to an essentially biological process under the previous law could not be made the subject-matter of a patent resulting from an application filed before the entry into force of Rule 23b(5) EPC 1973” (emphasis added).

In other words, G 2/07 does not explicitly address the issue of whether the reasoning underlying decision T 39/93 was endorsed by the EBA.

Nevertheless, we note that the EBA in G 2/07 dealt with arguments based upon T 39/93:
- by explaining why there was no “conflict” in the sense of Article 164(2) EPC; and
- not by (also) criticising any of the reasoning underlying or the conclusion that “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” in T 39/93.

It is also important to note that, in common with the Board in T 39/93, the EBA in G 6/95 concluded that amended Rule 71a should be interpreted in a manner that avoided “conflict” in the sense of Article 164(2) EPC with a higher status provision (in that instance, the longer-standing provision of Article 11(2) RPBA).

In the light of the above, it is clear that:
- there is no indication whatsoever that the EBA in G 2/07 took issue with the reasoning underlying T 39/93; and
- the arguments at points 12 to 14 of the Referral are therefore unfounded.

2.3.6. Question 1 is inadmissible because Question 2 fails G 3/08 admissibility standards

Any answer from the EBA to Question 1 would not have a direct impact upon the Office’s granting practice. This is because the Office does not examine patents or patent applications for compliance with Article 164(2) EPC.

Thus, in the context of the Referral, it is only possible for answers from the EBA to affect the granting practice of the Office if those answers relate to a provision of the EPC that the Office: (I) uses to examine the validity of patents or patent applications; and (II) is uncertain how to interpret, in the light of an apparent “conflict” (in the sense of Article 164(2) EPC) with a lower status provision of the EPC.

As is evident from the Referral, the only Article of the EPC for which both of these criteria are satisfied is Article 53(b) EPC, namely the provision that is the subject of Question 2.
Therefore, with regard to the established interpretation of the “different decisions” criterion (i.e. the interpretation from G 3/08), the admissibility of Question 1 is inextricably linked to the admissibility of Question 2. This is because:

- the interpretation of the “different decisions” criterion in G 3/08 requires not just the existence of divergent or conflicting decisions of different Boards of Appeal but also an impact of that divergence upon the granting practice of the Office; and

- in the light of points (I) and (II) above, it is only possible to assess Question 2 for compliance with that criterion.

G 3/08 contains the following statements of principle regarding the impact upon the granting practice of the office that allegedly diverging / conflicting decisions must have in order for a reference under Article 112(1)(b) to be admissible.

“The “different decisions” criterion would appear to show that the President is only intended to be allowed to refer a question to the Enlarged Board when there is a divergence or, better, conflict in the case law making it difficult if not impossible for the Office to bring its patent granting practice into line with the case law of the Boards of Appeal” (point 7.2.6; emphasis added).

“A referral is justified only if at least two Board of Appeal decisions come into conflict with the principle of legal uniformity” (point 7.3.1).

“Hence the President has no right of referral under Article 112(1)(b) EPC simply in order to intervene, on whatever grounds, in mere legal development if on an interpretation of the notion of "different decisions" in the sense of conflicting decisions there is no need for correction to establish legal certainty” (point 7.3.8).

Applying these principles to Question 2 leads to the following conclusions.

Firstly, the case law of the Boards of Appeal is consistent with respect to the interpretation of Article 53(b) EPC. This is because no Board has interpreted Article 53(b) EPC in a manner that deviates from G 2/12 and G 2/13.

Thus, answers from the EBA to the questions referred by the President are not required to establish legal certainty or uniformity.

Secondly, with respect to Article 53(b) EPC, it is neither difficult nor impossible for the Office to bring its patent granting practice into line with the case law of the Boards of Appeal.

All that the Office need do to align it practice with the case law is to apply the interpretation of Article 53(b) EPC from G 2/12 and G 2/13 (and not the conflicting interpretation of Rule 28(2) EPC). There are no legal or practical barriers to the Office taking this step.

At point 28, the Referral asserts that “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”. However, that assertion is incorrect. There is nothing in the EPC that prevents the Office from not applying a lower status provision of the EPC that has been held by a Board of Appeal to conflict with a higher status provision of the EPC. Indeed, Article 164(2) EPC mandates that the Office take such an approach.
According to point 7.2.2 of G 3/08 (cited in Section 2.2.4 above), and as acknowledged in points 31 and 58 of the Referral, the Boards of Appeal are assigned interpretative supremacy with regard to the EPC in terms of its scope of application. Thus, in the absence of any diverging or conflicting Board of Appeal decisions regarding Rule 28(2) EPC, there is no legal justification for the Office interpreting Article 53(b) EPC in any manner other than as set out in G 2/12, G 2/13 as applied correctly in T 1063/18.

Alternatively, or additionally, there is nothing to stop the President from working to bring the wording of the Implementing Regulations into line with the established (i.e. G 2/12, G 2/13 and T 1063/18) interpretation of Article 53(b) EPC, for example by submitting a proposal to the Administrative Council to amend Rule 28 EPC by deletion of paragraph (2) (with a consequential amendment to Rule 27 EPC, thereby returning Rules 27 and 28 EPC to the form that they took prior to 1 July 2017).

In the light of the above, it can be seen that:
- Question 2 is clearly inadmissible because it does not satisfy the G 3/08 interpretation of the “different decisions” criterion; and
- because its admissibility is inextricably linked to that of Question 2, Question 1 is inadmissible for the same reason.

2.3.7. Question 2 is inadmissible because there are no “different” decisions

As mentioned above, the case law of the Boards of Appeal is entirely consistent in that no Board has interpreted Article 53(b) EPC in a manner that deviates from G 2/12 and G 2/13.

Question 2 is therefore inadmissible on the grounds that there are no “different” decisions on Article 53(b) EPC (regardless of whether or not the “different decisions” criterion is interpreted according to G 3/08).6

2.3.8. The EC interpretative notice does not cure the inadmissibility of Question 2

Points 40 to 44 of the Referral cite a number of non-judicial “legal developments” as possible justifications for the admissibility of Question 2. Foremost amongst those developments is a Notice issued by the European Commission on the interpretation of certain articles of the EU Biotechnology Directive

However, CIPA’s view is the “legal developments” cited in points 40 to 44 of the Referral do not cure the inadmissibility of Question 2. As discussed below, the reasons for this include, in particular, the fact that the EC Interpretative Notice is the non-binding opinion of an executive body.

As pointed out by the Board in T 1063/18, the EC Notice has no legal authority under the EPC (inter alia because the interpretation set out in that Notice has not been confirmed by the Court of Justice of the EU).

In this respect, we note that the Board in T 1063/18 only reached this conclusion after giving detailed consideration, at points 26 to 39 of the reasons for the decision, to the question of whether Rule 28(2) EPC, or the EC Interpretative Notice upon which that Rule was based, provided any reasons to deviate from G 2/12 and G 2/13. (As a consequence, the assertion

6 We also note that, in comments on cases G2/12 and G2/13, the former President of the EPO argued for an interpretation of Article 53 EPC that is entirely in accordance with the decision in T 1063/18, namely that “Article 53(b) EPC did not have a negative effect on the allowability of product claims to plants. Any extension of an exclusion from patentability in this respect was a matter for the legislator to decide” (see point V 2(1) of G 2/12 and G 2/13).
at point 7 of the Referral is incorrect, as the Board in T 1063/18 did not make any statement to the effect that it was “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”.

Moreover, we submit that the conclusion of the Board in T 1063/18 with regard to the absence of legal authority (under the EPC) for the EC Notice is supported by the following statement of principle in point 7.2.7 of G 3/08:

“Given its object and purpose, the right of referral does not extend to allowing the President, for whatever reason, to use an Enlarged Board referral as a means of replacing Board of Appeal rulings on CII patentability with the decision of a putatively higher instance. For example, a presidential referral is not admissible merely because the European Parliament and Council have failed to adopt a directive on CII patenting or because consistent Board rulings are called into question by a vocal lobby (cf. the present referral, page 2, Section 1, paragraph 3). Even the essentially commendable desire for harmonisation expressed by Lord Justice Jacob in the Aerotel/Macrossan judgment can be taken up by the Enlarged Board only to the extent possible under the EPC, even if his suggestion might significantly advance the cause of legal uniformity in Europe. When judiciary-driven legal development meets its limits, it is time for the legislator to take over” (emphasis added).

This is because if, as stated in G 3/08, the President cannot use a decision of a “putatively higher instance” to replace a Board of Appeal ruling, then there is no doubt that he cannot use the non-binding opinion of a non-judicial body to replace an Enlarged Board of Appeal ruling.

Thus, even accounting for the possibility for a referral to be based upon public interest in the light of subsequent “legal developments” does not cure the inadmissibility of Question 2. This is because the cited “legal developments” do not alter the interpretation of Article 53 EPC (see also the more detailed discussion in Sections 2.5.4 to 2.5.12 below).

2.3.9. Application of Article 112(1)(b) EPC by analogy is excluded

As discussed in Section 2.2.4 above, the interpretative supremacy assigned to the Boards of Appeal with regard to the EPC means that the practical effect of the principle established in in G 6/95 is that the AC may not amend the Implementing Regulations as interpreted by the Boards of Appeal in such a way that the effect of an amended Rule would be in conflict with the EPC as interpreted by the Boards of Appeal.

In other words, in the event of a divergence in views between the AC and the Boards of Appeal regarding the interpretation of an Article of the EPC, the interpretation of the Boards of Appeal shall prevail. For this reason, application of Article 112(1)(b) EPC “by analogy” is excluded.

2.4. The Need for a Clarifying Statement Regarding the EC Notice

We note that the EPO and the AC have relied upon the EC Notice:

- to impose an ex officio stay of “all proceedings in examination and opposition cases in which the invention is a plant or animal obtained by an essentially biological process” (announcement dated 12 December 2016);

- as the basis for Rule 28(2) EPC; and
- to impose a further *ex officio* stay of all proceedings before the EPO examining and opposition divisions in which the decision depends entirely on the outcome of the EBA’s decision in connection with the Referral.

As a result of these actions, the proprietors of patents and applications containing claims directed to a “plant or animal obtained by an essentially biological process” have been prevented, for a period approaching three years, from either obtaining or upholding patent protection according to the interpretation of Article 53(b) EPC set out in G 2/12 and G 2/13.

In this respect, CIPA notes that points 28 to 33 of CA/26/19 explicitly discuss amendment of Article 53(b) EPC by the AC (under Article 33(1)(b) EPC, and based upon the EC Notice) as an alternative option for achieving the objective set out in that document.

Thus, if the EBA finds the Referral to be inadmissible (or that Rule 28(2) EPC conflicts with Article 53(b) EPC), it is still possible that the Office will not examine patents and applications in accordance with the interpretation of Article 53(b) EPC set out in G 2/12 and G 2/13, but will instead work with the AC to pursue the alternative option of amending Article 53(b) EPC.

As discussed elsewhere herein, CIPA’s view is that the EC Notice has no legal authority under the EPC. CIPA is therefore of the view that, even if the EBA agrees that the Referral is inadmissible, there is a pressing need for the EBA to make a clear statement to the effect that the EC Notice:
- is not “an international treaty relating to patents or European Community legislation relating to patents” in the sense of Article 33(1)(b) EPC; and
- therefore cannot be relied upon to justify an amendment of Article 53 EPC by the AC.

Further, should the EBA agree with CIPA’s submissions with regard to inadmissibility and/or CIPA’s proposed answers to Questions 1 and 2 of the Referral, CIPA is of the view that it would be helpful for the EBA to confirm the correctness of the decision of the Board of Appeal in T 1063/18.

Similarly, CIPA is of the view that the examination (and, if relevant, grant) of patents and applications that are consistent with G 2/12 and G 2/13 should not be subject to any unnecessary (or unjustified) delays, whether by way of the present Referral or otherwise.

**2.5. Discussion of Points of Law Underlying Questions 1 and 2**

For the reasons outlined above, CIPA is firmly of the view that the Referral is inadmissible. Nevertheless, in case the EBA is inclined to admit or comment on the Referral, we discuss below the points of law underlying Questions 1 and 2 and demonstrate that:
- the meaning and scope of an Article of the EPC, as established in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal, cannot be modified by way of an Implementing Regulation to the EPC that is deemed applicable to patents and applications filed before the date of entry into force of that Implementing Regulation, and also cannot only be modified by the Administrative Council other than by way of amendments (to Parts II to VIII and Part X of the EPC) that satisfy the requirements of *both* of Articles 33(1)(b) and 35(3) EPC; and
- there are no reasons to depart from the interpretation of Article 53 EPC in G 2/12 and G 2/13 (which reasoning needs to be upheld in order to avoid a breach by the EU Member States of their obligations under Article 267 TFEU).
2.5.1. **Prohibitions against retroactivity in certain cases**

An amendment to the Implementing Regulations may, on occasion, be afforded “retroactive” effect. That is, an amended Implementing Regulation may be deemed applicable to patents and applications filed before the date of entry into force of the relevant amendment.

However, where an amendment to an Implementing Regulation pursuant to Article 33(1)(c) EPC purports to change the interpretation of an Article of the EPC (relative to that established in the case law of the Boards of Appeal) and is applied to patents and applications filed before the date of its entry into force, CIPA’s view is that a conflict in the sense of Article 164(2) EPC automatically arises. That is, in such a situation, a conflict in the sense of Article 164(2) EPC can be established solely upon the basis of legal principles underpinning the rule of law (and without any need to give detailed consideration to any purported legal basis for the amendment to the Implementing Regulation).

This is firstly because such an amendment in essence amounts to an attempt by the AC to replace the Board of Appeal’s (or EBA’s) interpretation of the EPC with their own. In other words, it represents an attempt by the AC to disregard the interpretative supremacy afforded to the Boards of Appeal and/or the separation of powers principle.

Secondly, such an amendment is contrary to the principle of protection of legitimate expectations as established in the case law of Boards of Appeal. In this respect, and in accordance with J 25/95, we note that particular prominence is afforded to expectations based upon decisions of the Enlarged Board of Appeal:

“The users’ confidence in the continuity of a practice based on a decision of the Enlarged Board may be considered particularly legitimate since all Boards of Appeal are expected to follow the Enlarged Board’s interpretation of the EPC” (see point 4.3.4 of J 25/95).

In this regard, we note that even in cases where the EBA has overturned one of its own judgements (such as in G 9/93 and G 2/08), the EBA has protected legitimate expectations established by its earlier decision by declining to apply its new ruling in a retroactive manner. Thus, an amendment to the Implementing Regulations pursuant to Article 33(1)(c) EPC that does not protect legitimate expectations (e.g. as established by an earlier EBA decision) must be seen to give rise to a conflict in the sense of Article 164(2) EPC.

We also note that such an amendment arguably breaches case law of the European Court of Human Rights relating to the right to peaceful enjoyment of property (including intellectual property) that is enshrined in Article 1 of Protocol 1 to the European Convention on Human Rights (and in Article 17 of the Charter of Fundamental Rights of the EU). This is because that case law recognises a potentially protectable, legitimate expectation of obtaining (intellectual) property, for example as described in paragraph 65 of Anheuser-Busch Inc. v. Portugal (ECHR, Application no. 73049/01):

“However, in certain circumstances, a “legitimate expectation” of obtaining an “asset” may also enjoy the protection of Article 1 of Protocol No. 1. Thus, where a proprietary interest is in the nature of a claim, the person in whom it is vested may be regarded as having a “legitimate expectation” if there is a sufficient basis for the interest in national law, for example where there is settled case-law of the domestic courts confirming its existence (see Kopecký v. Slovakia [GC], no. 44912/98, § 52, ECHR 2004-IX). However, no legitimate expectation can be said to arise where there is a dispute as to the correct interpretation and application of domestic law and the applicant’s submissions are subsequently rejected by the national courts (see Kopecký, cited above, § 50)”. 

18
In this respect, we note that G 2/12 and G 2/13 represent “settled” case law regarding the interpretation of Article 53 EPC. Further, as confirmed by T 1063/18, there is no dispute (amongst the Boards of Appeal) as to the correct interpretation of Article 53 EPC.

2.5.2. Provisions governing amendments to the Implementing Regulations

Because Questions 1 and 2 concern amendments to the Implementing Regulations to the EPC, it is necessary to consider:
- the identity of the legislator that made the amendment (i.e. whether the AC, in accordance with Article 33 EPC, or the Conference of the Contracting States convened in accordance with Article 172 EPC); and
- if the legislator is the AC, the subsection of Article 33 EPC under which the AC made the amendment (e.g. whether Article 33(1)(a), (b) or (c) EPC).

This is because the EPC:
- by way of Article 33 EPC, imposes limits upon the legislative powers of the AC;
- by way of Article 35 EPC, specifies different voting rules for amendments under different subsections of Article 33(1) EPC; and
- by way of Article 164(2) EPC, enables the Boards of Appeal in appropriate circumstances to limit or override the legal effects of amendments to the Implementing Regulations.

However, for the sake of completeness, it is also necessary to consider the possibility that the interpretation of an Article of the EPC might not be static, for example in view of a “subsequent agreement” according to Article 31(3)(a) VCLT, or “subsequent practice” according to Article 31(3)(b) VCLT.

We shall therefore address the questions of whether an amendment to the Implementing Regulations under Article 33(1)(c) EPC can modify the meaning and scope of an Article of the EPC (relative to the interpretation of said Article in an earlier EBA decision) in view of:
- the combined effects of Articles 33, 35 and 164 EPC; or
- the existence of reasons to depart from the interpretation in the earlier EBA decision.

2.5.3. The combined effects of Articles 33, 35 and 164 EPC

The AC is competent to amend the Articles of the EPC only in the circumstances specified in Article 33(1)(b) EPC.

Thus, as a matter of principle, amendments to the Implementing Regulations by the AC under Article 33(1)(c) EPC cannot have the effect of amending an Article of the EPC.

Article 164(2) EPC is the safeguard incorporated into the EPC that enables the Boards of Appeal to enforce this principle. However, it is also important to note that Articles 33(1)(b) and 35(3) EPC provide further safeguards.

Firstly, Article 33(1)(b) EPC can only be used to bring Parts II to VIII and Part X of the EPC “into line with an international treaty relating to patents or European Community legislation relating to patents”. This safeguards against amendments that are not based upon the provisions of either “an international treaty relating to patents” or “European Community legislation relating to patents”.

Secondly, Article 35(3) EPC safeguards, inter alia, against amendments under Article 33(1)(b) EPC that do not receive the unanimous support of the Contracting States at an AC meeting in which all Contracting States are represented. (This contrasts with the much lower bar set
by Article 35(2) EPC in connection with amendments to the Implementing Regulations under Article 33(1)(c) EPC, namely a majority of three-quarters of the votes of the Contracting States represented.)

In this respect, the combined effects of Articles 33, 35 and 164 EPC is to ensure that the AC cannot (effectively) amend Articles of the EPC except when the requirements of both of Articles 33(1)(b) and 35(3) EPC have been satisfied.

2.5.4. Grounds for departure from an earlier EBA interpretation

As mentioned in Section 2.5.2 above, the interpretation of an Article of the EPC might not be static, in that there may be reasons why a Board of Appeal will wish to depart from an interpretation given in an earlier EBA decision.

We shall therefore discuss below possible reasons for departure from the interpretation of Article 53 EPC in G 2/12 and G 2/13 and shall demonstrate that:
- there is no subsequent agreement or practice in the sense of Article 31(3) VCLT that justifies departing from the EBA's interpretation;
- no considerations have arisen subsequent to the signing of the Convention that provide reasons to believe that a literal interpretation of Article 53 EPC would conflict with the legislator's aims; and
- there is no fundamental flaw in the reasoning in G 2/12 and G 2/13.

2.5.5. Subsequent agreement or practice in the sense of Article 31(3) VCLT

The wording of Articles 31(3)(a) and (b) VCLT is as follows.

“(a) Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.

(b) Any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation”.

Thus, an agreement only qualifies as a “subsequent agreement” in the sense of Article 31(3)(a) VCLT if it is:
(1) an agreement between the parties to the treaty; and
(2) an agreement regarding the interpretation of the treaty or the application of its provisions.

Further, it is clear from this wording of Article 31(3)(b) VCLT that not all practice subsequent to the conclusion of a treaty can be considered as “subsequent practice” that is relevant to the interpretation of a treaty. That is, “subsequent practice” can only be considered under Article 31(3)(b) VCLT if it satisfies all of the following four criteria.

(3) It must be subsequent practice of the parties to the treaty.
(4) It must be subsequent practice in the application of the treaty.
(5) It must be subsequent practice that establishes an agreement between the parties to the treaty.
(6) It must be subsequent practice regarding the interpretation of the treaty.

2.5.6. Developments alleged to represent subsequent agreement or practice

Bearing in mind the conclusions in Section 2.5.5 above, as well as the provisions of the EPC, we shall now consider whether any of the developments mentioned in points 100 to 112 of the
Referral are relevant (under Article 31(3)(a) or (b) VCLT) the to the interpretation of Article 53 EPC.

The developments in question are:
- the AC decision introducing Rule 28(2) EPC;
- the EC Notice (and the EU Council conclusions on that Notice);
- (prospective) amendments to national patent acts; and
- amendments to national examination guidelines.

2.5.7. The AC decision does not qualify as subsequent agreement or practice

As a first point, CIPA’s view is that, as a matter of principle, an amendment to the Implementing Regulations under Article 33(1)(c) EPC cannot, on its own, constitute a relevant development (i.e. subsequent agreement or subsequent practice) in the sense of the VCLT.

Allowing an Article of the EPC to be “reinterpreted” in the light of an amendment by the AC to the Implementing Regulations under Article 33(1)(c) EPC would effectively render Article 164(2) EPC devoid of any meaning. That is, it would make all amendments under Article 33(1)(c) EPC permissible, even those that effectively amend Articles of the EPC, on the grounds that “conflict” in the sense of Article 164(2) EPC would never arise if the Articles of the EPC were reinterpreted in the light of amendments to Implementing Regulations.

If the drafters of the EPC had not intended to impose limits on the practical effects of the AC’s legislative powers, then they would not have incorporated Article 164(2) into the Convention (nor retained that provision in EPC 2000). It can therefore be assumed that the drafters of the EPC did not intend Article 164(2) to be rendered meaningless by allowing Articles of the EPC to be effectively amended by the AC under Article 33(1)(c) EPC (i.e. by permitting reinterpretation of the Articles in the light of Implementing Regulations amended by the AC under Article 33(1)(c) EPC). Indeed, this assumption is particularly strong with regard to the exclusions from patentability in Article 53 EPC, as the travaux préparatoires for EPC 1973 (the Minutes of the 10 September to 5 October 1973 Diplomatic Conference in Munich, at page 28, point 33) include the statement that:

“The Swiss delegation was also against transferring the three provisions mentioned to the Implementing Regulations. It emphasised that if the CNIPA proposal were adopted, the Administrative Council would also be afforded the possibility, which nobody wanted, of adding new conditions relating to patentability to the Convention and of amending the grounds for revocation connected with Article 50” (emphasis added).

For the sake of completeness, we also note that the representatives to the AC are not the parties to the EPC. Thus, any position agreed at an AC meeting (as opposed to at a Conference of the Contracting States convened in accordance with Article 172 EPC), does not qualify as either a “subsequent agreement” or “subsequent practice” in the sense of Articles 31(3)(a) and (b) VCLT.

2.5.8. The EC Notice does not qualify as subsequent agreement or practice

CIPA’s view is that the EC Notice is not relevant to the interpretation of the EPC (as subsequent agreement or practice in the sense of Article 31(3) VCLT).

This is because the EC Notice does not meet any of criteria (1) to (6) set out in Section 2.5.5 above.
For example, the EC Notice represents the non-binding opinion of an executive body formed under a different treaty. In this respect, it does not represent an “agreement”, let alone an agreement between the parties to the EPC.

Further, the EC Notice does not concern the interpretation of the EPC. Indeed, we note that section 1.1 of the EC Notice draws a clear distinction between interpretation of the EPC and interpretation of EU law (the Biotech Directive):

“From its analysis of the official background documents for the negotiation leading to the EPC in 1973, the Enlarged Board determined that nothing could be interpreted in the sense that plants or plant materials obtained through essentially biological processes were to be excluded from patentability.

While these decisions of March 2015 are in line with the intentions of the drafters of the EPC, it is questionable whether the same result would have been reached in the EU context” (emphasis added).

In this respect, we note that, in a report dated 17 May 2016 relating to on the development and implications of patent law in the field of biotechnology and genetic engineering (Ref. Ares(2016)5165507), the European Commission’s Biotech Expert Group reached the following conclusion.

“When discussing plant-related patents, the discussion often centres on plants obtained by genetic engineering. Indeed, the number of patents on plant-related inventions increased when this technology became available. It should be kept in mind, however, that the entry into force of the European patent convention predates the first transgenic plant by 10 years, meaning that the legislator could not have had the intention to limit patentability of plant related inventions to transgenic plants and processes of genetic modification” (see the paragraphs spanning pages 11 and 12 of the report).

In other words, European Commission’s Biotech Expert Group identified a clear reason why Article 53(b) of the European Patent Convention 1973 cannot possibly be afforded the same interpretation as set out in the EC Notice for Article 4(1)(b) of the Biotech Directive. In view of the fact that Article 53 was not amended in EPC 2000, the same conclusion applies to Article 53(b) EPC 2000.

The conclusions of the EU Council on the EC Notice also suffer from the same failings as the EC Notice. In addition, we note that:
- it is not clear whether the conclusions of the EU Council represent the unanimous view of the representatives to the EU Council; and
- in point 3, and in common with the EC Notice, makes it clear that the conclusions are “without prejudice to potential future rulings of the Court of Justice of the European Union” (i.e. are not finally legally binding, even under EU law).

2.5.9. Amendments to national laws do not qualify as subsequent agreement or practice

Amendments to national laws (or examination guidelines) are unilateral acts of individual countries. Those amendments therefore do not qualify as “agreements”, let alone subsequent agreements in the sense of Article 31(3)(a) VCLT.

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8 We also note that, despite the rulings in G 2/12 and G 2/13, the Expert Group recommended taking no action with regard to the Biotech Directive (see sections 3.4 and 3.5 of the report of the Expert Group)
Further, not all parties to the EPC have made relevant amendments to their national laws (or examination guidelines). Thus, those amendments do not satisfy either of criteria (3) and (5) above and for at least this reason do not represent subsequent practice in the sense of Article 31(3)(a) VCLT.

We also take this opportunity to point out that, as acknowledged in introduction to the EC Notice, only the Court of Justice of the European Union (CJEU) is competent to interpret Union law. In this respect, it is not yet clear whether the CJEU’s interpretation of Article 4(1)(b) (if and when the CJEU provides such an interpretation) will align with the amended national laws and examining guidelines cited in the Referral. Indeed, it is perfectly possible that the CJEU’s interpretation will not align with those laws and guidelines.

Thus, the amendments to national laws and examination guidelines do not represent subsequent practice in the sense of Article 31(3)(a) VCLT on the further grounds that they have not been confirmed (by the CJEU) as being compliant with the Biotech Directive.

2.5.10. The cited developments do not jointly qualify as subsequent agreement or practice

For the sake of completeness, we point out that, even if viewed as together as a “mosaic” of related developments, the developments cited in the Referral still do not qualify as subsequent development or practice in the sense of Articles 31(3)(a) and (b) VCLT.

For example, the AC decision is the sole development that potentially qualifies as an “agreement”. Thus, the other cited developments cannot compensate for the failure of the AC decision to satisfy criteria (1) and (2) above.

Further, even when taken together, the cited developments do not meet criterion (5) above, in that they do not establish an agreement between the parties to the EPC. The reasons for this include the facts that:
- none of the European Commission, the European Council and the representatives to the AC are the parties to the EPC; and
- the amendments to national patent laws are both unilateral and piecemeal, and so do not establish an agreement between all of the parties to the EPC (let alone an agreement regarding the interpretation of the EPC).

2.5.11. A “dynamic” interpretation of Article 53 EPC

CIPA’s view is that, in G 2/12 and G 2/13, the EBA was correct to observe that:
- subsequent developments in the field of plant breeding techniques did not prompt the legislator to revise (during the EPC 2000 reform) the exclusion of Article 53(b) EPC such that it was extended to plant products obtained by essentially biological processes; and
- the legislator’s decision not to amend Article 53(b) EPC can neither be ignored when interpreting Article 53(b) EPC, nor be reversed by means of a dynamic interpretation.

CIPA is also of the view that no additional considerations have arisen subsequent to the EBA’s ruling that provide reasons to believe that a literal interpretation of Article 53 EPC would conflict with the legislator's aims.

Thus, CIPA’s view is that a “dynamic” interpretation of Article 53 EPC does not give rise to any grounds to depart from the EBA’s interpretation in G 2/12 and G 2/13.
2.5.12. The reasoning in G 2/12 and G 2/13

According to G 9/93, the EBA may depart from an interpretation that it provided in an earlier ruling in situations “where there are very clear reasons for not following the earlier interpretation”.

As discussed in Sections 2.5.5 to 2.5.11 above, no grounds have arisen subsequent to G 2/12 and G 2/13 that justify departure from the EBA’s interpretation of Article 53 EPC in those decisions. Thus, the only possibility remaining for departing from the interpretation in G 2/12 and G 2/13 would be (very clear) flaws in the EBA’s reasoning in those decisions.

In the Referral, the President has not pointed to any flaws in the reasoning of the EBA in G 2/12 and G 2/13. However, an implied criticism of the EBA’s reasoning can be found at point 93 of the Referral, where it is stated that the EBA “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”.

We shall therefore address the question of whether the travaux préparatoires for the Biotech Directive give rise to very clear reasons for not following the interpretation of Article 53 EPC in G 2/12 and G 2/13.

In this context, we firstly note that Article 4 of the 1995 proposal for a Biotech Directive included language that could be interpreted to exclude from patentability those plants and animals obtained by essentially biological processes:

1. The subject of an invention shall not be considered unpatentable merely on the grounds that it is composed of, uses or is applied to biological material.

2. Biological material, including plants and animals, as well as elements of plants and animals obtained by means of a process not essentially biological, except plant and animal varieties as such, shall be patentable (emphasis added).

However, the final wording for Article 4 of the Biotech Directive that was approved by the European Parliament was markedly different:

1. The following shall not be patentable:
(a) plant and animal varieties;
(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process”.

Relative to the 1995 proposal, the most striking difference in text of the 1998 Directive is that the exclusion from patentability is limited to just the two alternatives of Articles 4(1)(a) and (b), neither of which relate to plants and animals that are the products of essentially biological processes. This gives rise to the conclusion that the EU legislator consciously abandoned the scope of the exclusion from original Article 4(2) that is not found in any express or implied provisions of the Biotech Directive.
We note that the EC Notice attempts to rebut this conclusion by referring to:

- various provisions of the Biotech Directive (recital 32, as well as Articles 3(2), 4(1) and 4(3)).

However, for the reasons outlined below, we believe that the arguments set out in the EC Notice are unfounded, and therefore fail to rebut the conclusion that the EU legislator did not intend to exclude from patent protection under EU law any plants and animals other than varieties (or plants and animals whose commercial exploitation would contravene Article 6 of the Biotech Directive).

Firstly, we note that the Rothley Report, which provides an “Explanatory Statement” in connection with the (amendments to) the text of the 1995 proposal, states the following in connection with plant and animal varieties, at Point 6 of Section B of the Report.

“At the time when national patent legislation and also the EPC (1973) entered into force, it was possible to obtain plants and animals with new genetic characteristics only by means of ‘essentially biological procedures’, i.e. crossing and selection of the whole genome.

Such procedures do not meet the general conditions for patentability, as they are neither inventive nor reproducible. Breeding is a reiterative process, in which a genetically stable end-product with the required characteristics is attained only after much crossing and selection. This process is so strongly marked by the individuality of the initial and intermediate material that an identical result will not be obtained upon its repetition. Patent protection is not appropriate for such procedures and their products.

In the field of plant breeding, breeders’ need for protection was recognized by the law on protection of new varieties, which takes as its criteria distinctiveness, homogeneity, persistence and novelty.

There is no comparable protection of varieties for animal breeders.

Genetic engineering has completely altered the situation. Genetic engineering procedures and their products, which are new, may be inventive and be described in such a manner as to render them reproducible.

How does this patentability of genetic engineering procedures stand in relation to Article 53b of the EPC, which excludes plant and animal varieties from patentability?

The term ‘plant variety’ is defined by the law on the protection of new plant varieties. A plant variety is determined by its whole genome and possesses individuality (distinctiveness) thanks to this. A plant totality which is characterized only by a particular gene therefore cannot receive protection as a plant variety. Accordingly, it is not excluded from patentability pursuant to Article 53b of the EPC. This remains true even if the plant totality is a genus, for example the Solanaceae (nightshades), within which particular varieties are cultivated, e.g. the potato variety ‘Sieglinde’ or the tomato variety ‘beef tomato’. The protection of these varieties under the law on the protection of new plant varieties is unaffected by the right to patent genetically modified Solanaceae.

9 COM (95)0661 - C4-0063/96 - 95/0350(COD), June 25, 1997
Only if such a variety is modified in the same way as provided for by the invention is the patent breached.

A plant variety is still not patentable even if it is obtained by means of a genetic engineering procedure rather than by means of breeding.

If the invention lies in the fact that only a particular variety is genetically modified, the result is a new variety, which cannot be patented‘.

When this section of the Rothley Report is read as a whole, it is immediately evident that the first four paragraphs serve as a description of the historical status quo with regard to intellectual property protection for plant and animal varieties.

In this regard, it can be seen that the statement in the second paragraph that “Patent protection is not appropriate for such procedures and their products” merely provides historical context for the statements in the subsequent paragraph, in particular the reason why “In the field of plant breeding, breeders’ need for protection was recognized by the law on protection of new varieties”.

Thus, the first four paragraphs of Point 6 of Section B of the Rothley Report do nothing more than explain why plant and animal varieties are excluded from patent protection (by way of Article 53(b) EPC), and instead require different forms of protection (such as plant variety protection). In other words:
- the “products” mentioned at the end of the third paragraph are plant and animal varieties, and not plants and animals in general; and
- Point 6 of Section B of the Rothley Report makes no comment whatsoever upon plants and animals that are not varieties (and that meet the criteria for patentability set out in the EPC).

Moreover, because the purpose of the first four paragraphs of Point 6 of Section B of the Rothley Report is to provide background information on the status quo prior to the proposed legislation, they are inherently unlikely to contain any indicators on whether the EU legislators intended to depart from that status quo.

Secondly, there is nothing in the provisions of the Biotech Directive cited in the EC Notice (recital 32, and Articles 3(2), 4(1) and 4(3)) that points to a clear intention on the part of the EU legislators to depart from the historical status quo in connection with the patenting of plants and animals.

With regard to the meaning of recital 32, CIPA’s view is that this is best understood by considering the wording of all of the various recitals that touch upon the subject matter of the exclusions of Article 4(1)(b). This means considering the following wording of recitals 9 and 29 to 33.

“(9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty;

... 

(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions
which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;

(30) Whereas the concept ‘plant variety’ is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties;

(31) Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;

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

(33) Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological" (emphasis added).

Taking account of the wording of all of these recitals, it is immediately evident that:

- recital 32 is concerned solely with the exclusion from patentability of plant varieties; and
- any plant that is not a “variety” (according to the EU legislation protecting new varieties) is not excluded from patentability.

Indeed, the latter conclusion is directly supported by the wording of Article 4(2), which states that "Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety" (emphasis added).

With respect to Article 3(2), the EC Notice attempts to afford a special meaning to the phrase "isolated from its natural environment" (i.e. a meaning that excludes plants and animals that are the products of an essentially biological process). However, CIPA’s view is that the position in the EC Notice is untenable on the grounds that Article 3(2):

- is clearly intended to provide patentability for products that “previously occurred in nature”; and
- does not address the patentability of products that did not previously occur in nature (such as novel plants).

Further, with respect to Articles 4(1) and 4(3), we note that the final sub-clause of Article 53(b) EPC mirrors the wording of Article 4(3) of the Biotech Directive, with the exception that:

- it applies to both plant varieties and essentially biological processes (whereas Article 4(3) applies to only the essentially biological processes mentioned in Article 4(1)(b)); and
- it refers to “microbiological processes or the products thereof” (whereas Article 4(3) refers to "a microbiological or other technical process or a product obtained by means of such a process").

The first of these two differences raises the question of whether the “product” mentioned in Article 4(3) is to be understood as being other than a plant or animal variety. Whilst the answer to this question is not entirely clear from the wording of Article 4 alone, CIPA’s view is that a
clear answer is provided by way of recitals 29 to 32. That is, as discussed above, recitals 29 to 32 clearly indicate that any plant that is not a “variety” according to the EU legislation protecting new varieties is not excluded from patentability.

Furthermore, it is important to note that this interpretation of Article 4(3) of the Biotech Directive is confirmed by the manner in which the additional / different provisions of Article 4(3) (relative to Article 53(b) EPC) were translated into the EPC in 1999. In this respect, we refer to Rule 23c(c) EPC 1973 (now Rule 27(c) EPC 2000), which interpreted the additional / different provisions of Article 4(3) to mean that:

“Biotechnological inventions shall also be patentable if they concern:

... (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety” (emphasis added).

The date of the interpretation of Article 4(3) reflected in Rule 23c(c) EPC 1973 is 16 June 1999 (the date of the AC decision introducing Rules 23b, 23c, 23d and 23e EPC 1973). By way of contrast, the date of the (conflicting) interpretation of Article 4(3) set out in the EC Notice is 8 November 2016. In CIPA’s view, the near-contemporaneous interpretation from 1999 is far more likely to reflect the true intention of the EU legislator at the time of drafting the Biotech Directive than is a Commission Notice issued more than 17 years later.

Finally, because EPC 1973 did not contain a provision equivalent to Article 33(1)(b) EPC 2000, it is necessary to consider whether the manner in which Rule 23c(c) EPC was introduced in 1999 (i.e. without any attempt to exclude from patentability products other than plant or animal varieties) was constrained by the operation of Article 164(2) EPC.

In this respect, CIPA is not aware of any evidence on record which indicates that the AC in 1999 reached the conclusion that Article 164(2) EPC mandated only an incomplete translation of the provisions of Article 4(3) of the Biotech Directive into the EPC. Indeed, such a conclusion seems unlikely. This is because it would mean that, by electing to amend the Implementing Regulations (instead of enabling amendment of the Articles of the EPC by convening a Conference of the Contracting States), the AC would have consciously chosen not to fully align the provisions of the EPC with those of the Biotech Directive.

In any event, we note that when a Conference of the Contracting States was convened, the legislator changed neither the wording of Article 53(b) EPC nor the wording of any relevant exclusions defined in the Implementing Regulations. This decision by the legislator cannot be ignored.

In the light of the above, and contrary to the opinions expressed in the EC Notice, CIPA is of the view that the travaux préparatoires for the Biotech Directive:
- do not provide any support whatsoever for the contention that the EU legislators intended to exclude from patent protection plants and animals other than individual varieties; and
- do not give rise to reasons (let alone very clear reasons) for not following the interpretation of Article 53 EPC set out in G 2/12 and G 2/13.

2.5.13. Significance of certain provisions of EU law

Rule 26(1) EPC indicates that “Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation".
Recitals 3 and 9 of Directive 98/44/EC read as follows:

“(3) Whereas effective and **harmonised** protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

(9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas **harmonisation is necessary** to clarify the said uncertainty” (emphasis added).

In the light of the above, CIPA’s view is that Article 53 EPC should, as much as is possible, be interpreted in a manner that is harmonised with _judicial_ interpretations\(^ {10}\) of relevant provisions of Directive 98/44/EC (i.e. interpretations by national courts, or by the Court of Justice of the EU).

To our knowledge, the only (prevailing) _judicial_ interpretation of Article 4(1)(b) of the Biotech Directive by a court of an EU Member State is the 18 March 2015 decision of the Court of Appeal of The Hague in _Cresco v Taste of Nature_ (cases C/09/416501/HA ZA 12-452 and C/09/418860/HA ZA 12-577). That judicial interpretation aligns fully with the interpretation of Article 53 EPC as set out in G 2/12 and G 2/13.

Thus, at this time, only a decision to confirm the interpretation of Article 53 EPC as set out in G 2/12 and G 2/13 would be consistent with the harmonisation objective set out in Recitals 3 and 9 of Directive 98/44/EC (which Recitals are, via Rule 26(1) EPC, a supplementary means of interpretation of Article 53 EPC).

An additional provision of EU law that CIPA would like to bring to the attention of the EBA is Article 267 of the Treaty on the Functioning of the European Union (TFEU). That Article sets out the preliminary reference procedure, whose purpose that procedure is to provide “a fundamental mechanism of European Union law aimed at enabling the courts and tribunals of the Member States to ensure uniform interpretation and application of that law within the European Union”\(^ {11}\).

According to case law of the CJEU\(^ {12}\), any “court or tribunal against whose decisions there is no judicial remedy under national law” **must** use the preliminary reference procedure in circumstances where interpretation of a provision of EU law is relevant to national proceedings and the interpretation is neither:

- **acte éclairé** (that is, already the subject of a ruling from the CJEU); nor
- **acte clair** (that is, so obvious that no reasonable doubt is left).

This is precisely the situation for the interpretation of Article 4(1)(b) of the Biotech Directive as set out in the EC Notice, on the grounds that:

- the CJEU has not yet interpreted Article 4(1)(b) of the Biotech Directive (meaning that the interpretation in the EC Notice is not **acte éclairé**); and

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\(^{10}\) Indeed, alignment with such judicial interpretations would be consistent with the established practice of the EBA (as in, for example, G 5/83, G 2/12 and G 2/13) to give consideration to decisions of national courts of the EPC Contracting States.

\(^{11}\) See the CJEU’s “Recommendations to national courts and tribunals in relation to the initiation of preliminary ruling proceedings”, OJ EU 2012/C 338/01

\(^{12}\) See, for example, C-283/81 (Cilfit; OJ EC 82/C 296/03)
the prevailing, judicial interpretation of Article 4(1)(b) of the Biotech Directive (i.e. that provided in the decision of the Court of Appeal of The Hague in Cresco v Taste of Nature) is directly contradictory to that in the EC Notice, which latter interpretation is therefore self-evidently not acte clair.

Thus, without breaching the provisions of Article 267 TFEU, the interpretation of Article 4(1)(b) of the Biotech Directive as set out in the EC Notice cannot be applied (at this time) by a final instance court or tribunal of an EU Member State unless and until the CJEU has ruled that said interpretation is correct.

The EBA is clearly a “court or tribunal against whose decisions there is no judicial remedy under national law”. The EBA’s rulings also have effect in (or in respect of) EU Member States. However, according to G 2/06:

“Whereas EPO Boards of Appeal have been recognized as being courts or tribunals, they are not courts or tribunals of an EU member state but of an international organization whose contracting states are not all members of the EU” (emphasis added).

In the light of G 2/06, it is therefore clear that the EBA is incapable of making the reference to the CJEU that, at this time, would be mandatory under EU law for any court or tribunal of final instance contemplating applying the interpretation of Article 4(1)(b) of the Biotech Directive as set out in the EC Notice.

CIPA acknowledges that the EBA is bound only by the provisions of the EPC, and so is not obliged to ensure that the EPC is interpreted in a manner that honours EU law obligations of EPC Contracting States. Nonetheless, CIPA is of the view that it will be important for the EBA to take into consideration the facts that:

- applying (to Article 53 EPC) the interpretation of Article 4(1)(b) of the Biotech Directive as set out in the EC Notice would lead to rejection or invalidation of claims to plants or animals produced by essentially biological processes, and would thereby make it impossible for patent applicants or patent proprietors to secure the preliminary reference to which they are entitled under Article 267 TFEU; but
- maintaining the interpretation of Article 53 EPC as set out in G 2/12 and G 2/13 would, if it led to the grant of patents containing claims to plants or animals produced by essentially biological processes, enable courts of EU Member States to make a preliminary reference to the CJEU in connection with any disputes relating to the validity of such claims.

In other words, CIPA is of the view that it will be important for the EBA to take into account that only maintenance of the interpretation of Article 53 EPC as set out in G 2/12 and G 2/13 would lead to an outcome that honours the obligations of the EU Member States under Article 267 TFEU.

2.6. CIPA’s Proposed Answer to Questions 1 and 2

In the event that the EBA admits or comments on the Referral, CIPA proposes the following answers to Questions 1 and 2.

Firstly, for the reasons discussed in Sections 2.5.1 and 2.5.3 above, CIPA’s view is that Question 1 should be answered as follows.

In view of Article 164(2) EPC, the meaning and scope of an Article of the EPC, as established in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal, cannot be modified by way of an Implementing Regulation to
the EPC that is deemed applicable to patents and applications filed before the date of entry into force of that Implementing Regulation, and also cannot be modified by the Administrative Council other than by way of amendments (to Parts II to VIII and Part X of the EPC) that satisfy the requirements of both of Articles 33(1)(b) and 35(3) EPC.

Finally, CIPA’s view is that, for the reasons discussed at Sections 2.5.4 to 2.5.13 above, Question 2 should be answered as follows.

The exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC conflicts with Article 53(b) EPC. According to Article 164(2) EPC, the provisions of Article 53(b) EPC therefore prevail.