Registry of the Enlarged Board of Appeal

For the attention of Mr Wiek Crasborn (EBAamicuscuriae@epo.org).

Eindhoven, 23 September 2019,

Your reference: G 3/19 - "Article 164(2) EPC / Pepper"
Our reference: case number G 3/19 - written statements in accordance with Article 10(1) RPEBA

Dear Sirs,

In OJ 2019, A52 (Online publication date: 31.05.2019), “Communication from the Enlarged Board of Appeal concerning case G 3/19”, third parties were given the opportunity to file written statements in accordance with Article 10(1) of the Rules of Procedure of the Enlarged Board of Appeal.

Topic is the referral in accordance with Article 112(1)(b) EPC, whereby the President of the European Patent Office referred the following points of law to the Enlarged Board of Appeal:

1. Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said article given in an earlier decision of the boards of appeal or the Enlarged Board of Appeal?

2. If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?

In my opinion both questions must be answered in the negative.

I submit my observations and viewpoints on the next pages.

Yours faithfully,

Roel van Woudenberg
European Patent Attorney
Referred questions

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?

Introduction: the relevant provisions

1. Article 53(b) EPC (formatted) reads:

   European patents shall not be granted in respect of:
   
   – plant or animal varieties or
   
   – essentially biological processes for the production of plants or animals;
   
   – this provision shall not apply to microbiological processes or the products thereof.

2. Rule 28(2) EPC as introduced per 1/7/2017 reads:

   Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.

3. Thus, Rule 28(2) extends the exclusion provided by Article 53(b) to plants or animals exclusively obtained by means of an essentially biological process.

4. Further, Rule 28(2) indicates that this exclusion is “Under Article 53(b)”

5. W.r.t. conflicts between provisions, Article 164(2) EPC provides:

   In case of conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail.

6. W.r.t. amendments to the EPC, Article 33 EPC provides:

   The Administrative Council shall be competent to amend:

   (a) the time limits laid down in this Convention;

   (b) Parts II to VIII and Part X of this Convention, to bring them into line with an international treaty relating to patents or European Community legislation relating to patents;

   (c) the Implementing Regulations.
7. The referral was in reaction to T 1063/18 (written decision issued 5.2.2019\(^1\); not published in the OJ EPO\(^2\)):

“Case T 1063/18 concerns the appeal by the applicant against the decision of an examining division to refuse European patent application no. 12 756 468.0 (publication no. EP 2 753 168) for the sole reason that it considered the claimed subject-matter to be plants exclusively obtained by means of an essentially biological process which fell within the exception to patentability according to Article 53(b) and Rule 28(2) EPC.

Technical Board of Appeal 3.3.04, in an enlarged composition consisting of three technically and two legally qualified members, decided that Rule 28(2) EPC (see OJ 2017, A56) was in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13. In these decisions, the Enlarged Board of Appeal had concluded that the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC did not have a negative effect on the allowability of a product claim directed to plants or plant material.

In the reasons for its written decision in case T 1063/18 issued today, the technical board stated that Rule 28(2) EPC could not be interpreted in such a way that it was not in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal. The board also saw no reason to deviate from the interpretation of the Enlarged Board. The board concluded that, in view of Article 164(2) EPC, the provisions of the Convention prevailed.”

8. On 5 April 2019\(^3\), a News message was posted on the EPO website indicating:

“Pursuant to Article 112(1)(b) EPC, the President of the EPO has submitted questions to the Enlarged Board of Appeal which relate to the patentability of plants exclusively obtained by essentially biological processes and to decision T 1063/18 of a Technical Board of Appeal of December 2018. In the referral the President of the EPO seeks the Enlarged Board of Appeal to clarify the applicable legal framework.

The EPO reacts to the concerns expressed by the Contracting States, the user community and representatives of civil society who are worried about legal uncertainty resulting from decision T 1063/18.

The President of the EPO considers the referral to the Enlarged Board of Appeal as an important step on the way to restore legal certainty in the interest of the users of the European patent system and the general public.

\(^2\) This T-decision got internal distribution code B (To chairman and members) and is available on the case law website; it did not get internal distribution code A (Publication in OJ), also not after the associated stay was announced in OJ 2019, A34. It appears that T-decisions (except for interlocutory decisions to refer questions to the Enlarged Board) are no longer published in the OJ EPO. This decision is of such major impact that its publication in the OJ EPO could have been expected, unless the policy is to never publish T-decisions in the OJ EPO anymore.
The possibility of a referral to the Enlarged Board of Appeal was presented end of March at a meeting of the Administrative Council and met with broad support.”

Admissibility

9. The President of the European Patent Office referred the questions under Article 112(1)(b) EPC.

10. Article 112(1)(b) EPC only provides for allowing the President of the EPO\(^4\) to refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given different decisions on that question.

11. It does not provide for referring a point of law to the Enlarged Board of Appeal where a Board of Appeal has given a decision that conflicts with an Article of a Rule of the EPC, also not if the Board considers the Rule invalid and bases this decision on Article 164(2) EPC.

12. Neither does the Rules of Procedure of the Enlarged Board offer such terms for a referral.

13. So, in principle, the referral could be considered inadmissible.

14. An appropriate response to a decision from a Board allegedly not following the EPC may be to amend the EPC or the Rule, such that the same or another Board does no longer see the conflict.

15. However, that is not the route that the Administrative Council and the President have chosen. The Administrative Council and the President seem to be of the opinion that Rule 28(2) is, or at least could be, valid it, and ask the Enlarged Board to express its opinion.

16. As it may be considered very likely that another Board gives at some moment in time a conflicting decision (possibly because a party invoked it to have a referral to the Enlarged Board), it seems of all stakeholder’s interest to have clarify on the topic in the near future.

17. Legal certainty in this matter is urgently needed, as a large number of cases are stayed at this moment, and applicants also have no guidance on requirements imposed on new filings.

18. The Enlarged Board is therefore suggested to consider the referral admissible in view of the mutatis mutandis / by analogy argumentation given in the President’s referral.

19. If the Enlarged Board considers the referral inadmissible, it is suggested that the Enlarged Board explains in detail why and, as the Enlarged Board did in G 3/08, give an overview of the legal situation such that the legal situation is clear to all stakeholders (for applicants: to

\(^4\) Side-note: surprisingly, this option only exists for the President of the EPO. The possibility does not exist for the President of the Board of Appeal, nor can the Enlarged Board of own motion decide to pick up a point of law that needs clarification. The first could be obtained by the President delegating this option to the President of the Boards (main interest: clarity to all Boards) in parallel to his own possibility of referral (main interest: clarify to first instance examination and opposition). The latter could then be obtained by giving any Enlarged Board member the right to suggest to the President of the Boards a point of law for a referral.
proceed with currently stayed applications; to draft and file new applications; for third parties: to oppose), the Administrative Council (who can, if needed, on short notice cancel Rule 28(2) if the Rule is considered to violate Article 53(b) and, on longer notice, amend the Rule in an allowable manner or let the Article be amended by a Diplomatic Conference), as well as the Boards.

The first question

20. The first question reads:

*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?*

Purpose and “competence” of the EPC Rules

21. The EPC “Rules” are provisions from the “Implementing regulations”, and as such implement specific Articles of the EPC.

22. Two types of Rules may be considered:

i. Rules which are referred to in an Article to provide the requirements for fulfilling the Article’s provision. The Rule thus gets its competence from the reference in the Article;

ii. Rules which are not referred to in an Article. The Rule thus does not get its competence from a reference in the Article, but the Rule serves to provide details on specific situations within the scope of the Article.

23. Ad i): A Rule which is referred to in an Article to provide the requirements for fulfilling the Article’s provision gets its competence from the reference in the Article. The Article comprises a phrasing like “... if the requirements laid down in the Implementing Regulations are fulfilled”. An example of such a Rule is Rule 40, which gets its competence from the reference in Article 80 (filing date requirements).

24. Rules of type i) thus serve to define the details of the legal framework that is set in outline in the Article. Rule of type i) thus define the legal framework. A change in such a Rule results in a change in the legal framework. E.g., if Rule 40(1) would be amended to also require a fee, such an amendment would not violate any EPC provision but changes the requirements for a filing date considerably; similarly, if a new Rule would read “Under Article 53(a), European
patent shall not be granted for any CO$_2$-emitting products of methods” or “Under Article 53(c), European patent shall not be granted for any of such methods applied to animals”.

25. Ad ii): A Rule which is not referred to in an Article does not get its competence from a reference in the Article. Rather, but the Rule serves to provide details on specific situations within the scope of the Article. Examples of such rules are Rule 26 which provides for definitions and provisions for biotechnical inventions, Rule 27 which provides for patentable biotechnological inventions and former Rule 28 which defines some classes of excluded biotechnical inventions, which all relate to Art.53 but are not referred to in Art. 53. In principle, these rules are not needed to define the legal framework as such and do not change the existing legal framework, but only serve to clarify specific aspects of the existing framework. The latter is clear from e.g. T 315/01 (when Rules 26-29 were introduced, they also apply to cases pending at the date of their entry into force) as well as e.g. G 2/06 ("Rule 28(c) EPC (formerly Rule 23d(c) EPC) applies to all pending applications, including those filed before the entry into force of the rule.")

26. G 2/06 provides in reasons 12 and 13:

Q1. Does Rule 23d(c) [now 28(c)] EPC apply to an application filed before the entry into force of the rule?

12. By its decision of 16 June 1999, the Administrative Council of the EPO inserted a new Chapter VI (now V) entitled "Biotechnological inventions" into Part II of the EPC Implementing Regulations. These new provisions entered into force on 1 September 1999, thus transposing the Directive on the legal protection of biotechnological inventions into the European Patent law. Rule 26(1) (formerly 23b(1)) EPC expressly provides that the relevant provisions of the Convention shall be applied to European patent applications and patents concerning biotechnological inventions in accordance with the provision of this new chapter, and that the Directive shall be used as a supplementary means of interpretation. No transitional provisions for pending cases were adopted. Rule 28 (formerly 23d) EPC on "Exceptions to patentability" expressly refers to Article 53(a) EPC.

13. The introduction of this new chapter without any transitional provisions, can only be taken as meaning that this detailed guidance on what was patentable and unpatentable was to be applied as a whole to all then pending applications. It has not been argued that Rule 28 (formerly 23d) EPC took away the possibility to patent anything which had previously been regarded as patentable under Article 53(a) EPC, nor that the Directive did so (see in this respect the reference in Art. 6(1) to what is contained in Article 53(a) EPC as well as the reference to the TRIPS Agreement in Article 1(2)). Already by 1984 (see Dolder, Mitteilungen der Deutschen Patentanwälte, 1984, 1, "Barriers to patentability of biotechnological inventions under the EPC"), instrumentalization of the human body (as opposed to parts of it), thus degrading it to an object of technology, had been considered
as a barrier to patentability. There is no indication that the commercial exploitation of human embryos was ever regarded as patentable.

27. Rules of type ii) thus serve to clarify situations of the legal framework as set out in full by the Article. Rule of type ii) thus do not change the legal framework: the legal framework is defined by the Article alone. A change in such a Rule cannot result in a change in the legal framework as defined by the Article alone. If it does, such a change goes against the well-defined definition and boundaries set by the Article and would thus, in view of Article 164(2), not have effect: the Article would prevail. E.g., if a Rule (let’s call it Rule 25a) would be implemented that excludes all disclosures from the applicant and the inventor from the prior art, such an new Rule would change the meaning and definition of Art. 54(2) and 54(3), and would thus violate these articles, whereby it would not be allowable.

28. In its referral, under item 4, the President indicated: “Decision T 1063/18 differs from earlier case law with regard to the way in which an EPC Rule which clarifies the meaning and scope of Article 53 EPC is assessed under Article 164(2) EPC.” However, as argued above, Rule 28(2) does not clarify (=explains, makes understandable) the Article’s meaning and scope, but changes its meaning scope.

29. The President thus also considers, as was the intention of the Administrative Council, the Rule to effectively amend the Article – which is not appropriate, i.e., not in line with the competence of the Council under Article 33 EPC, as discussed in detail in T 1063/18 as well as in the CIPA submission to this referral.

30. In its referral, under item 46, under the heading “B.I.a) The Administrative Council is competent to implement Article 53 EPC”, the President indicated:

“This competence covers the possibility to implement the Articles of the Convention – including those related to substantive patentability requirements – by interpreting and clarifying their meaning and scope”, followed by a reference to G 2/07 in item 47

“[…] It is the function of the Implementing Regulations to determine in more detail how the Articles should be applied and there is nothing in the Convention allowing the conclusion that this would not also apply in the case of Articles governing issues of substantive patent law (emphasis added).” The Enlarged Board went on stating that “the legislator is entitled to provide for issues of substantive law in the Rules of the Implementing Regulations (scil.: as long as) such Rule (scil.: is) […] clear enough to indicate to those applying it in what way the legislator intended the Article to be interpreted by means of that Rule.”
and in item 49: “In decision G 2/06, too, the Enlarged Board of Appeal acknowledged the Administrative Council’s competence to introduce in the Implementing Regulations “detailed guidance on what was patentable and unpatentable” under the Articles of the Convention.”

31. Thus, the President herein indicated that the Council has the competence to interpret and clarify the scope of EPC Articles, also for substantive patent law, under the Articles of the Convention. This has indeed been done previously with, e.g., the introduction of Rules 26-29 to implement the provisions of the Biotech Directive and of morality, which implemented detailed guidance on the application of Article 53(a) and (b), but fully within the scope of the Article. However, none of the Rules introduced before the introduction of Rule 28(2) changed the scope of the Article. In other words, the meaning and scope of the Article was not changed by the various decisions that the President refers to in B.I.a); the Rules just provided clarification, by codifying specific situations, all under the Article. Rule 28(2) in contrast changes the meaning and scope of Article 53(b), as it excludes more than Article 53(b) does.

32. The president also comments, item 75, first dash that “Article 53(b) EPC itself does not explicitly allow the patentability of plants (or animals) exclusively obtained by essentially biological processes”.

However, Article 53(b) shall be read in the context of the system of Chapter I EPC, “Patentability”, as a whole. The dominant article therein is Article 52(1) EPC.

33. Article 52(1) provides that “European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application”.

34. The EPC only provides for a few exceptions and exclusions to Article 52(1): Art.52(2)&(3) provides for an exhaustive list of subject-matter or activities (as such) which are not an invention, and Art.53 provides an exhaustive list of inventions in respect of which no European patents shall be granted.

5 Article 52(1) may be read in conjunction with Article 4(3) “The task of the Organisation shall be to grant European patents.”, as well as Article 97(1) “If the Examining Division is of the opinion that the European patent application and the invention to which it relates meet the requirements of this Convention, it shall decide to grant a European patent, provided that the conditions laid down in the Implementing Regulations are fulfilled”, which provides that the system of the EPC is exhaustively defining (and, where needed, clarified/explained by case law) under which conditions a patent shall be granted (i.e., leaves no discretion to the EPO, the President or to the Administrative Council to define more non-patentability grounds), as well as with the case law on narrow interpretation of exclusions discussed later in this letter.

6 And there is of course the further requirements of Art.76, Art. 82-84, Art. 123, etc.
35. Thus, anything that is not within the definition of Article 52(2) & (3) or Article 53 is eligible to patent protection, “provided that they are new, involve an inventive step and are susceptible of industrial application”.

36. Thus, Article 53(b), when read together with Article 52(1), does allow the patentability of plants (or animals) exclusively obtained by essentially biological processes (provided that they are also novel, inventive and susceptible to industrial application).

37. Changing the scope of the exclusion of Article 53(b) can thus only be achieved by an amendment of Article 53(b) itself, not by a new or amended Rule (not even if all Contracting States in the Administrative Council would agree).

38. In the absence of any international treaty relating to patents or European Community legislation relating to patents which would allow the Council to amend the Article under Article 33(1)(b), and—as far as we are aware—no outlook to such a treaty or legislation (as also discussed in detail in T 1063/18), the only appropriate way seems to be a Diplomatic Conference (as discussed also in the CIPA submission).

39. It is noted that the Travaux Préparatoires\(^7\) also indicated the important difference between provisions being in the Articles and in the Rules, and that exclusions to patentability should be in the Articles. Reference may be made to, e.g., M/PR/I, page 28, item 33, where the Swiss delegation voiced that nobody wanted to afford the Administrative Council the possibility to amend the provisions of the exclusion\(^8\):

40. It is also noted that in item 108 of the referral, the President indicates that several Member States have introduced, or are in the process of introducing, a patentability exclusion for the products (plants and animals) of essentially biological processes in their national law. It is observed that each of these amendments to the national law are to the Articles of the law concerned, not to any implementing regulation (or not only to any implementing

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regulation). Item 108 thus rather gives string arguments for amending Article 53(b) than for Rule 28(2).

However, Article 33 does not allow the Administrative Council to amend the EPC to bring it into conformity with the national law of some or even all of the EPC Contracting States, nor of their practice, as suggested in item 111 of the referral.

Conclusions and suggested answer
41. Thus, it can concluded that:

i. Rules which are referred to in an Article to provide the requirements for fulfilling the Article’s provision co-define the legal framework together with the Article. The Rule thus fills in the legal framework within the competence given by the Article. A change in such Rule thus results in a change in the legal framework, but will as a rule not be in conflict with the Article that it implements;

ii. Rules which are not referred to in an Article do not get their competence from a reference in an Article, but the Rule serves to provide details on specific situations within the scope of the Article, without changing the meaning of the Article. If the Rule would change the meaning of the Article, the Rule is not allowed in view of Article 164(2). The Rule shall just clarify specific situations or requirements, without changing the legal framework defined by the Article.

42. The Article that a newly proposed Rule of type ii) relates to may have been subject to a clarification by the Enlarged Board. In such as case, the meaning and scope of the Article cannot be changed by the newly proposed Rule of type ii). The meaning and scope of the Article can only be clarified by the newly proposed Rule of type ii), while maintaining within the meaning and scope of the Article as interpreted by an earlier decision of the Enlarged Board of Appeal.

43. So, it is suggested to answer to the first question as follows:

No, having regard to Article 164(2) EPC, the meaning and scope of Article 53 EPC cannot 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, where the clarification is provided by an amendment to or an introduction of a Rule that does not get explicit competence from the related Article (type ii) – and Article 53(b) does not provide for that. The Implementing Regulations to the EPC can only clarify an Article of the EPC (within the scope and meaning of the Article), and only within the interpretation of said Article as given in the earlier decision of the Enlarged Board of Appeal.
44. The same applies for earlier decisions of the Board of Appeal, as far as those decisions have become established case law.

The second question

The link to the first question

45. As the proposed answer to the first question is “No”, the second question does not need to be answered.

46. However, the second question may be rephrased and answered specifically to leave no doubt as to the situation underlying the referral.

47. We suggest to reformulate the second question as:

*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?*

48. We refer to the argumentation given above for answering the first question, and we provide additional arguments below.

49. We suggest to answer the second question as:

*No, the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC is not in conformity with Article 53(b) EPC. The meaning and scope of Article 53(b) is unambiguously clear in itself and Art.53 and established case law leave no room for interpreting it differently, in particular to extend the scope of exclusions (to plants and animals exclusively obtained by means of an essentially biological process). Further, Article 53(b) allows said subject-matter (as is also acknowledged by the Commission Notice, T 1063/18 and the President’s Referral) and does not provide for the Implementing Regulations to exclude what is allowed by the Article itself.*

Specific argumentation w.r.t. new Rule 28(2) EPC

50. The argumentation in T 1063/18 is embraced. Repetition of the reasons provided therein does not seem necessary and appropriate. Its assessment of the recent developments, the status of the Commission Notice, and the lack of competence of the Administrative Council is shared by the undersigned.

51. The following considerations are added to the arguments given in T 1063/18.

*Article 53(b) EPC, its interpretation and established case law are stable*
52. Article 53(b) EPC was not amended since EPC2000 entered into force.

53. Article 53(b) EPC corresponds to earlier Article 52(4) EPC1973. The provision was not amended, only renumbered, in the transition from EPC1973 to EPC2000.

54. The wording of Article 53(b) EPC corresponds to the wording of Article 2 from the Strasbourg Convention (Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27.11.1963): 

*The Contracting States shall not be bound to provide for the grant of patents in respect of:

a) [...] 
b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to micro-biological processes and the products thereof.*

55. Article 53(b) is well- embraced via this treaty and unambiguously defines excluded subject-matter (essentially biological methods and plant varieties).

56. Amending the meaning and scope of the exclusion requires a revision of the EPC via Article 172 EPC. Article 33(1)(b) EPC does not apply: for that to apply, the interpretation given by the European Commission (deviating from the wording of the Biotech Directive) is not sufficient (reference is made to T 1063/18); an amendment to the BioTech Directive or other EU law would be needed (reference is made to the CIPA submission). Article 33(1)(c) EPC does not apply: for that to apply, the Article would need to give the competence to change the meaning of the Article to the Rule (see above).

57. G 2/12 (Tomatoes II) of 25.03.2015 provides:

1. **The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit. [editor’s note: also not if the claim is in the form of a product-by-process claim]**

2. In particular, the fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable.

3. **In the circumstances, it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an**

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essentially biological process for the production of plants excluded as such under Article 53(b) EPC

58. G 2/13 (Broccoli II) similarly provides:
   1. The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts.
   2. a) The fact that the process features of a product-by-process claim directed to plants or plant material other than a plant variety define an essentially biological process for the production of plants does not render the claim unallowable.
      b) The fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable.
   3. In the circumstances, it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC.

59. G 2/12 and G 2/13 may be seen as confirming earlier G 1/98 of 20.12.1999:
   I. A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties.
   II. When a claim to a process for the production of a plant variety is examined, Article 64(2) EPC is not to be taken into consideration.
   III. The exception to patentability in Article 53(b), first half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.

60. Thus, it is already confirmed in 1999 that the examination and validity of a product-by-process claim cannot be denied just due to the process being excluded.

61. Also, it is already confirmed in 1999 that the exclusion of plant varieties does not exclude a claim that protects plants varieties but does not claim them individually.

62. These two concepts were confirmed in G 2/07, G 1/08 and G 2/12 and G 2/13.

63. G 1/98, reason 5.3 also provided that the law is not restricted in their application to situations known to the legislator:
As already emphasised by the referring Board, it does not make any difference for the requirements under the UPOV Convention or under the Regulation on Plant Variety Rights, how a variety was obtained. Whether a plant variety is the result of traditional breeding techniques, or whether genetic engineering was used to obtain a distinct plant grouping, does not matter for the criteria of distinctness, homogeneity and stability and the examination thereof. This means that the term "plant variety" is appropriate for defining the borderline between patent protection and plant breeders’ rights protection irrespective of the origin of the variety. The argument that the legislator of the EPC did not envisage the possibility of genetically-modified plant varieties and for this reason could not have had the intention of excluding them from patentability cannot be accepted. Laws are not restricted in their application to situations known to the legislator. Since plant varieties are excluded, the only question is the conditions under which they are excluded. The Enlarged Board of Appeal supports the view of the referring Board (Reasons, point 92) that the mere fact of being obtained by means of genetic engineering does not give the producers of such plant varieties a privileged position relative to breeders of plant varieties resulting from traditional breeding only. Given the purpose of Article 53(b) EPC, question 4 has to be answered in the negative. Article 4(1)b and (3) of the Biotechnology Directive, using language corresponding to Article 53(b) EPC, is intended to be interpreted in the sense outlined above, since Recital 32 of the Directive postulates that a new plant variety bred as a result of genetically modifying a particular plant variety is still excluded from patent protection, even if the genetic modification is the result of a biotechnological process.

64. Thus, if the legislator wants to limit the application of the law, or extend the scope of exclusion, the legislator cannot try to give the law an interpretation that is different from the meaning of the law, but needs to amend the law, i.e., Article 53(b), itself.

Legislator’s intention

65. The President indicated in the referral that new Rule 28(2) provides for a codification of the legislator’s intended meaning of the Article. This argument does not hold. The original intention of Article 53(b) (Article 52(40 EPC1973) was exactly what the Article itself provides; excluding plants obtained from an excluded process was not the original intention.

66. Even when EPC2000 was drafted, well after the Biotech Directive was adopted, no changes were made to Article 53(b). Thus, the legislator may be considered to intentionally not have added the exclusion of current Rule 28(2) to Article 53(b).
67. The arguments given by the President are not convincing:

68. In item 47 of the referral, the President indicated that “The Enlarged Board went on stating that “the legislator is entitled to provide for issues of substantive law in the Rules of the Implementing Regulations (scil.: as long as) such Rule (scil.: is) [...] clear enough to indicate to those applying it in what way the legislator intended the Article to be interpreted by means of that Rule.””

Although the citation is correct, the conclusion that the President draws from this is incorrect. The citation just shows that, if an Article as originally implemented is open to ambiguous interpretation, a Rule may be introduced that clarifies the Article according to the original intention of the legislator, not to a change of mind (if any) at a (much) later moment.

69. In item 51, the President indicated that “In decision T 272/95 the Board concluded that the Administrative Council has the power to give a more detailed interpretation of the meaning of Article 53 EPC in the Implementing Regulations to the EPC”

Although the citation is correct, the conclusion that the President draws from this is incorrect. The citation just shows that more details on the meaning (as originally intended) may be given in a Rule, but the citation does not explicitly nor implicitly indicate that a Rule may change the meaning and scope of an Article, by excluding more subject-matter than the Article itself does.

70. In item 52, the President indicated that “In decision J 20/84 the Legal Board of Appeal not only recognised the Administrative Council’s power to implement Articles of the Convention, but even implied that a Rule may exclude a legal effect provided for in the Convention on the condition that it was “unambiguous both in its wording and as regards the recognisable intention of the legislator” (emphasis added). In decision T 991/04 the Board found that the Administrative Council can adopt EPC Rules to the effect that “the Implementing Regulations to the Convention stipulate an authentic interpretation within the framework set by the Convention”.

Although the citations are correct, the conclusion that the President draws from this is incorrect, for the reasons given at the previous two paragraphs. Further, Article 53(b) is fully unambiguous by itself (its meaning was confirmed by G2/07, G 1/08 as well as G2/12 and G 2/13) and expresses the clear recognizable (original) intention of the legislator.

Rule 28(2) goes beyond the framework of the Convention (esp., as set by Art.52(1) and Art.53(b)). The Council can thus not adopt such a Rule: the Rule would have to be within the framework set by the Convention.
**The Commission Notice and the (Intention of) Biotech Directive**

71. The Commission Notice\textsuperscript{10} provides, at the end of item 1.3, that

> The Commission takes the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.

72. The Commission Notice already indicated that, in EU context, it is not the Commission, but rather the Court of Justice of the European Union (CJeU), that is competent to interpret the BioTech Directive:

> In view of the above, this Notice sets out the Commission's views on the patentability of products emanating from essentially biological processes (addressed in Article 4 of the Directive). [...] The Notice is intended to assist in the application of the Directive, and does not prejudge any future position of the Commission on the matter. Only the Court of Justice of the European Union is competent to interpret Union law.

73. Thus, the Commission expressly indicated that the interpretation given by the Commission may not be valid, and that an interpretation by the CJeU may deviate from the interpretation by the Commission. The Commission expressly indicated also that any future position of the Commission on the matter. It seems thus at least premature, if not incorrect, to base an amendment of the EPC on the preliminary position taken by the Commission in the Notice. That many states expressed the same interpretation as the Commission, and even changed their national law accordingly, does not change the conclusion: the legal value and authority of the interpretation as expressed by the Commission and the states can only be considered premature and preliminary in view of the lack of any interpretation by the Court of Justice of the European Union w.r.t. (the aspects under discussion of) Article 4 of the Biotech Directive.

74. Further, w.r.t. the interpretation of EPC provisions, it is not the Commission nor the Court of Justice of the European Union, but the Enlarged Board of Appeal that is competent to interpret the EPC provisions and to give decisions and opinions of point of law.

75. Rule 26(1) EPC provides 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.". It does not provides that any (preliminary or final) position of the EU Commission is to be used as a supplementary means of interpretation, and not even that any opinion or decision of the Court of Justice of the European Union would need to be taken into account (even though the latter may be considered, as it will an opinion or decision of the Court of Justice of the

\textsuperscript{10} Citations: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC1108%2801%29
European Union will be binding in all EU states, and hence on the national interpretation of the EPC provisions; in the context of the EPC as applied by the EPO at any instance, it is however the Enlarged Board which is the highest authority, not the CJEU).

76. It is further noted that Consideration (29) of the Biotech Directive provides:

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;

77. Consideration (33) of the Biotech Directive provides:

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

78. Article 2(2) of the Biotech Directive provides this definition:

A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection

79. With Rule 26(5) EPC, this definition was incorporated in the Implementing Regulations of the EPC. As said above, the case law of the Enlarged Board has given a specific interpretation of this definition in the context of the EPC, in particular G 2/07, reason 6.4.2.3 and headnote 1-4, and in particular headnote 1-2.

80. The Commission does not seem to have taken the specific interpretation of “essentially biological” as being “any non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants”, even if “it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.” Into account when drafting the Notice. It is not excluded that the Commission has a more narrow interpretation in mind when drafting the Notice, i.e. one where the inclusion of a technical step results in the process not being essentially biological and for that reason not excluded from patentability. The Commission’s interpretation may thus have resulted in a wider exclusion that (implicitly) intended. (See also below)

81. Article 4 of the Biotech Directive provides:

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.

82. Thus, Article 4(2) of the the Biotech Directive itself explicitly provides that Article 4(1)(b) of the Directive shall be without prejudice to the patentability of 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. This is in line with Consideration (29).

83. There is no reference in Article 4(2) to Article 4(1), so it is not appropriate to consider the exception of Art. 4(1) to have any impact on the positive patentability of Art.4(2).

84. Thus, any plant obtained from an essentially biological processes for the production of plants or animals must be patentable under Art. 4(2).

Exclusions should be interpreted narrowly

85. Article 53 provides for an exhaustive and limited set of inventions which are excluded from patentability.

86. The Case Law Book (2019), I.B.1.2 “Basic principle” indicates that any exceptions to patentability must be narrowly construed (emphasis added):

The case law indicates that any exceptions to patentability must be narrowly construed. In respect of Art. 53(a) EPC, see T 356/93 (OJ 1995, 545) and T 866/01, but also T 1374/04 (OJ 2007, 313); in respect of Art. 53(b) EPC, see T 320/87 (OJ 1990, 71), T 19/90 (OJ 1990, 476) and T 315/03 (OJ 2006, 15); regarding Art. 53(c) EPC (Art. 52(4) EPC 1973) see T 144/83 (OJ 1986, 301), T 385/86 (OJ 1988, 308) and G 1/04 (OJ 2006, 334).

Given the ratio legis of the individual provisions, however, this narrow interpretation produces different results: a claim which embraces plant/animal varieties, but does not claim them individually, is not excluded from patentability under Art. 53(b) EPC (G 1/98, OJ 2000, 111; T 19/90, OJ 1990, 476; T 315/03, OJ 2006, 15). According to the established case law of the boards of appeal, a method claim falls under the prohibition of Art. 53(c) EPC if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy (see in this chapter I.B.4.2.). By contrast, several method steps are required to define a diagnostic method within the meaning of Art. 53(c) EPC owing to the inherent and inescapable multi-step nature of such a method (G 1/04, OJ 2006, 334).

87. The Enlarged Board addressed this basic principle already in G 5/83 (EPC1973 provisions) (emphasis added) when addressing Article 52(4) EPC1973 = Article 53(c) EPC2000:
22. The intention of Article 52(4) EPC, again as recognised by the Federal Court of Justice, is only to free from restraint non-commercial and non-industrial medical and veterinary activities. To prevent the exclusion from going beyond its proper limits, it seems appropriate to take a special view of the concept of the “state of the art” defined in Article 54(2) EPC. Article 54(5) EPC alone provides only a partial compensation for the restriction on patent rights in the industrial and commercial field resulting from Article 52(4) EPC, first sentence. It should be added that the Enlarged Board does not deduce from the special provision of Article 54(5) EPC that there was any intention to exclude second (and further) medical indications from patent protection other than by a purpose-limited product claim. The rule of interpretation that if one thing is expressed the alternative is excluded (expressio unius (est) exclusio alterius), is a rule to be applied with very great caution as it can lead to injustice. No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention: not can it be deduced from the legislative history of the articles in question. On this last point, after conducting its own independent studies of the preparatory documents, the Enlarged Board finds itself also in accord with the conclusion of the Federal Court of Justice.

88. So, the exclusions of Article 53 have “proper” limits and need to be narrowly interpreted. Further, if one thing (applied to Article 53(b): an essentially biological process) is excluded, it may lead to injustice if the rule is not applied with great caution so as to not exclude more than what is excluded (applied to Article 53(b): products obtained from essentially biological processes).

89. The Enlarged Board also addressed this basic principle in G 1/04 (EPC1973 provisions) (emphasis added):

6. When it comes to determining the scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods which, in order to comply with Article 52(1) EPC, include preceding steps (cf. point 5.3 above), the following is to be considered.

A narrow interpretation of the scope of the exclusion presupposes that Article 52(4) EPC excludes diagnostic methods practised on the human or animal body only if all of the preceding steps which are constitutive for making a diagnosis as an intellectual exercise (cf. point 5.2 above) are performed on a living human or animal body (cf. T 385/86, point 4.1 of the Reasons), whereas a broad interpretation of said scope implies that this provision excludes all methods practised on the human or animal body which relate to diagnosis or which are of value for the purpose of diagnosis (cf. T 964/99, point 4.4 of the Reasons).

According to Article 4(3) EPC, it is the general task of the EPO to grant European patents. Moreover, Article 52(1) EPC lays down the fundamental maxim of a general entitlement to patent protection to the effect that, as a matter of principle, a European patent is to be granted for an invention which meets the requirements of that provision. It is true that there are exclusion clauses from patentability provided for in the EPC. It is also true that the frequently cited principle, according to which exclusion
clauses from patentability laid down in the EPC are to be construed in a restrictive manner, does not apply without exception. However, the Enlarged Board of Appeal considers that the principle of a narrow interpretation of such exclusion clauses is to apply in respect of the scope of the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods.

[...]

6.4.4 From the very wording of Article 52(4) EPC in respect of diagnostic methods it already follows that the various method steps of a technical nature (cf. point 6.4.1 above) relating to such a method are basically meant to be performed on the human or animal body, implying an interaction with the latter, rather than in vitro. Since a narrow interpretation of the scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods is equitable (cf. point 6.1 above), it is thus justified to require that all method steps of a technical nature of such a method should satisfy the criterion "practised on the human or animal body", i.e. the performance of each and every one of these steps should imply an interaction with the human or animal body, necessitating the presence of the latter (cf. point 6.4.2 above). This is true all the more as a broad interpretation of that criterion, to the effect that only one single method step of the diagnostic method needs to be performed on the human or animal body, which may or may not be the step that constitutes an essential diagnostic activity (cf. paragraphs II.(xi) and II.(xii) above), would contravene the overriding principle of legal certainty for the reasons already indicated under points 6.1, 6.2.3 and 6.3 above.

[...]

8. The scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods is to be interpreted in a narrow manner (cf. point 6 above). Thus, in order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include (in view of Article 84 EPC) the feature pertaining to the diagnosis for curative purposes as a purely intellectual exercise representing the deductive medical or veterinary decision phase (cf. point 6.2.3 above), as well as the features relating to (i) the preceding steps which are constitutive for making the diagnosis (cf. point 6.2.3 above), and (ii) the specific interactions with the human or animal body which occur when carrying those out among said preceding steps which are of a technical nature (cf. point 6.4.4 above).

90. There is no reason to consider that the same reasoning does not apply mutatis mutandis to the other exclusions in Article 53 EPC, in particular the part cited in boldface. On the contrary, this narrow interpretation is followed by decisions T 320/87, T 19/90 and T 315/03, which are also listed in the cited paragraph of the Case Law Book.

91. T 320/87, reason 6, provides:

6. Like any exception to a general rule of this kind the exclusion of "essentially biological" processes for the production of plants (or animals) has to be narrowly construed. This is underscored by the fact that this exclusion does not apply to
microbiological processes or the products thereof, as also stated in Article 53(b) EPC. The Board takes the view that whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being "essentially biological". Human interference may only mean that the process is not a "purely biological" process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of a quantitative or qualitative character.

92. T 19/90, reason 4.5 provides:

4.5 Firstly, the Examining Division did not take duly into account that Article 53(b) EPC is an exception, for certain kinds of inventions, to the general rule under Article 52(1) EPC that European patents "shall be" granted for all inventions which are susceptible of industrial application, which are new and which involve an inventive step. Any such exception must, as repeatedly pointed out by the Boards of Appeal, be narrowly construed (cf. in particular T 320/87, point 6, OJ EPO 1990, 76). The Examining Division has given no convincing reasons for deviating in this particular case from this principle of interpretation, nor are any such reasons apparent to the Board.

93. Thus, the exclusions provided for by Article 53(b) shall be interpreted narrowly.

94. Only if an invention is within the definition of Article 53(b) EPC when interpreted narrowly, shall the invention be exceptionally denied and shall be deviated from “the fundamental maxim of a general entitlement to patent protection to the effect that, as a matter of principle, a European patent is to be granted for an invention which meets the requirements of that provision.”

95. When introducing or amending a Rule, the Rule shall thus be consistent with the narrow interpretation of the Article given by established case law.

96. If the legislator wants to exclude more than what is provided for in current Article 53(b), the legislator shall thus amend the Article itself. Introducing or amending a Rule, such as introducing Rule 28(2) EPC, is not compatible with the narrow interpretation of the provisions of Article 53.

97. Rule 28(2) indicates that the exclusion to plants or animals exclusively obtained by means of an essentially biological process “Under Article 53(b)”.

Link to Article 53(b) in Rule 28(2) EPC
98. However, as argued above, the exclusion of Rule 28(2) is not under the provision (i.e., within meaning and scope) of Article 53(b), but rather extends the excluded subject-matter with plants or animals exclusively obtained by means of an essentially biological process.

99. The opening words “Under Article 53(b)” thus seem to indicate that the Rule implements the Article, while Rule 28(2) rather contradicts Art. 53(b) as it excludes subject-matter which is allowed by the Article itself and as interpreted established case law of the Boards as well as of the Enlarged Board.

If nevertheless Rule 28(2) EPC is considered valid – good faith & transitional provision

100. If the Enlarged Board would consider new Rule 28(2) EPC to be valid, the undersigned also want to submit the following and request the Enlarged Board to comment on these observations.

101. New Rule 28(2) was introduced without any transitional provision, even though it had a major effect on the range of patentable subject-matter.

102. This goes against the principle of legitimate expectations (applicants and third party may rely on EPO practice being predictable): such a significant change would need to have a transitional provision and could only need to apply for applications having a priority date or, of no priority is claimed, filing date of a certain date after the entry into force of the new rule.

103. Reference may be made to not accepting the Swiss-type form anymore for second medial indication by G 2/08, answer to question 3 (reason 7.1.4) and OJ 2010, 514, item 2-4:

2. In order to ensure legal certainty and to protect the legitimate interests of applicants, the Board makes provision for transitional arrangements for the abolition of such claims. It sets a period of three months after the publication of decision G 2/08 in the Official Journal for future applications to comply with the new situation. Pending applications are not affected by this ruling. The relevant date for future applications is their date of filing or, if priority has been claimed, their priority date (see point 7.1.4).

3. Decision G 2/08 has been published in this issue of the Official Journal. Its publication date is therefore 28 October 2010, which means that the three-month period set by the board will expire on 28 January 2011.

4. Consequently, for inventions relating to second or further medical uses, European patents may not be granted in respect of European or international patent applications having a filing date or earliest priority date of 29 January 2011 or later if they contain Swiss-type claims. If any such application contains Swiss-type claims, the applicant will be invited to correct this deficiency.
104. If the Enlarged Board would consider new Rule 28(2) EPC to be valid, it is suggested that similar transitional provision is imposed.

*If nevertheless Rule 28(2) EPC is considered valid – is the scope correct?*

105. In G 2/07, the questions of law referred to the Enlarged Board were answered as follows:

1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.

2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

4. In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

106. It is not clear from the Commission Notice whether their interpretation has the same interpretation of “essentially biological processes” and Rule 26(5)’s “[A] process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection”, in particular of the meaning of the word “entirely” in combination with “natural phenomena”, as given in the G 2/07.

107. It may well be that the Commission considers “European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process” to relate to only “traditional UPOV” crossing and selection.

108. However, in view of G 2/07, headnote 2 and related reasons, this provision would include much more, i.e. also if the method includes “a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants”
109. In this context, it is observed that earlier cited T 320/87, reason 6, provides (emphasis added):

6. Like any exception to a general rule of this kind the exclusion of "essentially biological" processes for the production of plants (or animals) has to be narrowly construed. This is underscored by the fact that this exclusion does not apply to microbiological processes or the products thereof, as also stated in Article 53(b) EPC. The Board takes the view that whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being "essentially biological". Human interference may only mean that the process is not a "purely biological" process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of a quantitative or qualitative character.

110. Thus, the Board had -in this decision issued far before the G 2/07 and G 1/08- a different interpretation than G 2/08 and G 1/08. In fact, the interpretation given by the Board seems to be closer to what a person that is not a European patent attorney would consider “not essentially biological: “the totality of human intervention and its impact on the result achieved” rather than “[a] non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants”, even if the process has “as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plant”.

111. It is also observed the Commission seems to accept that there is overlap between plant breeders’ rights and patent rights, as the Commission nowhere indicates that here should not be any patents which have plants or plants varieties in their scope of protection.

112. By excluding plants or animals exclusively obtained by means of an essentially biological process from patentability, there may be a risk that current Rule 28(2) EPC excludes more than is considered necessary by the Commission.

Conclusions

113. As Article 53(b) EPC is a self-contained provision, and does not provide competence to a Rule to change its meaning and scope (not “according to the Implementing Regulations”), in
particular not by extending the meaning and scope of exceptions to patentability, current Rule 28(2) EPC is not allowable.

114. Further exclusions from patentability than those provides in Article 53 require an amendment to the Article itself.

115. It is suggested to answer both questions with “No”.

Looking forward to your considerations and your decision/opinion,

Kind regards,

Roel van Woudenberg
European Patent Attorney
DeltaPatents
23 September 2019