

**Enlarged Board of Appeal EPO, 14 May 2020,
Pepper
(G 3/19)**



PATENT LAW

Patentability of essentially biological process for the production of plants or animals

Negative effect on allowability if claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process

- Taking into account developments after decisions [G 2/12 and G 2/13](#) of the Enlarged Board of Appeal, the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC has a negative effect on the allowability of product claims and product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process.

This negative effect does not apply to European patents granted before 1 July 2017 and European patent applications which were filed before that date and are still pending.

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Enlarged Board of Appeal EPO, 14 May 2020

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[Case Number: G 0003/19]

Opinion of the Enlarged Board of Appeal of 14 May 2020 in relation to a point of law referred by the President of the European Patent Office pursuant to Article 112(1)(b) EPC

Composition of the Board:

Chairman: C. Josefsson

Members: F. Blumer

G. Eliasson

A. Aslan

I. Bechedorf

T. Bokor

A. Ritzka

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SUMMARY OF THE PROCEEDINGS

The referred questions

I. By letter dated 4 April and received on 8 April 2019, the President of the European Patent Office hereinafter the EPO President) referred the following questions to the Enlarged Board of Appeal (hereinafter the Enlarged Board) under Article 112(1)(b) EPC:

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?

Summary of the referral

II. The EPO President's arguments on the admissibility and on the substance of his referral are summarised in the following.

II.1 On the admissibility of the referral

II.1.1 The referral relates to decision T 1063/18 of 5 December 2018 of Technical Board of Appeal 3.3.04 (not published in the OJ EPO), which concluded that amended Rule 28(2) EPC was in conflict with Article

53(b) EPC as earlier interpreted by the Enlarged Board in decisions G 2/12 (OJ EPO 2016, A27) and G 2/13 (OJ EPO 2016, A28), which are referred to hereinafter as decision G 2/12. The Board did not consider Rule 28(2) EPC to be relevant for the interpretation of Article 53(b) EPC, and disregarded it pursuant to Article 164(2) EPC. The Board thus adhered to the interpretation of the exception to patentability of Article 53(b) EPC given in decision G 2/12 and allowed the applicant's appeal against the decision of the examining division, which had refused European patent application No. 12756468.0 because the claimed subject-matter fell within the exception to patentability of Article 53(b) EPC and Rule 28(2) EPC.

II.1.2 The EPO President considers that the approach taken in decision T 1063/18 (supra) diverges from the case law relating to the implementation in the EPC of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter EU Biotech Directive; OJ EU 1998 L 213/13; OJ EPO 1999, 101). The EPO President refers in particular to decisions G 2/07 (OJ EPO 2012, 130; see also G 1/08, OJ EPO 2012, 206), T 315/03 (OJ EPO 2006, 15, Reasons, points 7.3 and 7.6), T 272/95 (of 23 October 2002, not published in the OJ EPO, Reasons, point 4), T 666/05 (not published in the OJ EPO, Reasons, point 75), and T 1213/05 (not published in the OJ EPO, Reasons, point 44). The approach taken in decision T 39/93 (OJ EPO 1997, 134), referred to in decision T 1063/18 (supra), was neither followed nor endorsed in any of the aforementioned decisions, and none of said decisions considered it decisive under Article 164(2) EPC whether a Rule of the Implementing Regulations to the EPC (hereinafter the Implementing Regulations) was in conflict with an Article of the EPC as interpreted by the Enlarged Board of Appeal in an earlier decision. Therefore decision T 1063/18 (supra) deviated from the case law of the Boards of Appeal and of the Enlarged Board. Rather, those decisions at least implicitly acknowledged the competence of the Administrative Council of the European Patent Organisation (hereinafter, respectively, the Administrative Council and the EPOrg) to interpret the exceptions to patentability laid down in Article 53 EPC by amending the Implementing Regulations under Article 33(1)(c) EPC. The Administrative Council's competence to interpret an Article of the EPC by means of a provision of the Implementing Regulations is independent of the interpretation of that Article given by the Enlarged Board and unrestricted by Article 164(2) EPC.

II.1.3 In conclusion, the EPO President submits that there is different case law relevant to the question whether, for the purposes of Article 164(2) EPC, a potential conflict exists between Article 53 EPC and Rule 28(2) EPC, the latter having been adopted to clarify the former's meaning and scope. The conflict of Rule 28(2) EPC with Article 53(b) EPC found by the Board in decision T 1063/18 (supra) was the direct consequence of a different approach which it took to the

examination under Article 164(2) EPC in that case. Thus, question 1 is clearly admissible, and the admissibility of question 2 should follow from the admissibility of question 1. The questions are directly related because compliance of Rule 28(2) EPC with Article 53(b) EPC depends on whether the earlier interpretation of said Article in decision G 2/12 is seen as precluding the Administrative Council's clarification of Article 53(b) EPC.

II.1.4 In the event that the admissibility of question 2 is not already acknowledged as a consequence of the admissibility of question 1, it should be considered admissible under Article 112(1)(b) EPC by analogy. In this regard, the EPO President refers to G 1/97 (OJ EPO 2000, 322), G 2/02 (OJ EPO 2004, 483), G 3/08 (OJ EPO 2011, 10), and in particular G 4/98 (OJ EPO 2001, 131, Reasons, point 1.2).

II.1.5 The aim of a referral under Article 112(1)(b) EPC is to establish uniformity of law and legal certainty within the European patent system. In this context, the criterion of "different decisions" in Article 112(1)(b) EPC serves to prevent abstract points of law being referred. However, the current referral does not concern an abstract legal question, but a concrete one which has arisen or could arise in a significant number of pending cases, i.e. in the context of eighteen appeals pending against decisions based on Rule 28(2) EPC, as well as about 250 examination and about seven opposition cases in which the application of Rule 28(2) EPC has or could become decisive. Hence, the present situation is closely comparable to that in which the legislator had provided for a right of referral under Article 112(1)(b) EPC in the case of different decisions of Boards of Appeal.

II.1.6 If a right of referral by the EPO President exists in the case of divergent interpretations of the EPC in two Board of Appeal decisions with *inter partes* effect, it must exist all the more in the case of a divergence between the interpretation of an Article of the EPC (i.e. Article 53(b) EPC) in a single Board of Appeal decision and the Article's implementation (i.e. interpretation) with *erga omnes* effect set forth in a Rule of the EPC (i.e. Rule 28(2) EPC).

It follows from Enlarged Board's function as the highest judicial authority of the EPO (G 2301/16, not published in the OJ EPO, Reasons, point 42) that it is responsible for deciding and giving opinions on points of law of fundamental importance in order to ensure the uniform application of the law. Such a point of law of fundamental importance arose in decision T 1063/18 (supra) and thus requires clarification by the Enlarged Board. A new referral to the Enlarged Board is necessary and appropriate in view of the legal developments which have occurred since it issued its earlier decision G 2/12 (supra) (see T 297/88, not published in the OJ EPO, Reasons, point 2.4). The legal developments and administrative practices following decision G 2/12 which the EPO President relies upon are dealt with in the Reasons below.

II.2 On the substance of the referral

II.2.1 Question 1 should be answered in the affirmative.

The correct approach to follow under Article 164(2) EPC when examining the conformity of a Rule of the EPC which implements Article 53 EPC should be that taken in decisions J 20/84 (OJ EPO 1987, 95, Reasons, point 5), J 16/96 (OJ EPO 1998, 347, Reasons, point 2.3), T 272/95 (supra, Reasons, point 4), T 315/03 (supra, Reasons, points 5.1 and 7.7), T 991/04 (not published in the OJ EPO, Reasons, point 6), T 666/05 (supra, Reasons, point 75), T 1213/05 (supra, Reasons, point 44), G 9/93 (OJ EPO 1994, 891, Reasons, point 6), G 2/06 (OJ EPO 2009, 306, Reasons, point 13), G 2/07 (supra, Reasons, point 2.2), and G 2/08 (OJ EPO 2010, 456, Reasons, point 7.1.4). According to the approach followed in those decisions, a Rule clarifying the meaning and scope of Article 53 EPC is not a priori limited by earlier case law of the Boards of Appeal or the Enlarged Board. From this, the EPO President concludes the following:

(a) The Administrative Council is competent under Article 33(1)(c) EPC to implement Article 53 EPC by interpreting and clarifying its meaning.

(b) Article 164(2) EPC does not provide a basis for excluding or limiting a priori the Administrative Council's interpretation and implementation of Article 53 EPC on the ground that it deviates from an earlier interpretation given to that Article by the Enlarged Board.

(c) The decisions of the Enlarged Board have a de facto binding effect based on Article 21 RPBA 2020 but do not per se preclude a development in the law or its interpretation.

(d) In interpreting an Article of the EPC, the Boards of Appeal have to consider all elements relevant to its interpretation, including an amendment of the Implementing Regulations by the Administrative Council.

II.2.2 Question 2 should also be answered in the affirmative on the basis of the following:

(a) It can be concluded from G 2/12 (supra) that

i. Article 53(b) EPC does not explicitly allow the patentability of plants or animals exclusively obtained by essentially biological processes;

ii. Article 53(b) EPC is in principle open to different interpretations as to the scope of the exceptions to patentability;

iii. Article 53(b) EPC leaves room for further clarification by means of the Implementing Regulations.

(b) In the light of these conclusions, it is within the Administrative Council's powers under Article 33(1)(c) EPC to provide an interpretation of Article 53(b) EPC in line with the EU Biotech Directive as interpreted by the European Commission's Notice on the interpretation of certain articles of the EU Biotech Directive (OJ EU 2016 C 411/3, hereinafter the EU Commission's Notice of interpretation).

(c) By introducing Rule 28(2) EPC, the Administrative Council applied an interpretation of Article 53(b) EPC that is in line with the legislative intent derivable from the "incorporation" of the EU Biotech Directive into the EPC.

(d) Both Rule 28(2) EPC itself and the legislative developments and administrative practices which have emerged in the Contracting States since decision G 2/12 (supra) lead to the conclusion that, for the purposes of Article 164(2) EPC, Rule 28(2) EPC is to be considered as being in conformity with Article 53(b) EPC, in the sense that Article 53(b) EPC is to be interpreted in the light of Rule 28(2) EPC to mean that it also excludes from patentability the products of essentially biological processes.

Statements by third parties (amicus curiae briefs)

III. In a communication published in the Official Journal of the EPO (OJ EPO 2019, A52), the Enlarged Board gave third parties the opportunity to file written statements in accordance with Article 10 RPEBA. It received the following amicus curiae briefs, which were published on the internet website of the Enlarged Board (www.epo.org/law-practice/case-law-appeals/eba.html):

(1) G. König, König Szynka Tilmann, von Renesse Patentanwälte Partnerschaft mbH, Düsseldorf/München (KSVR), Patentanwälte – 24 May 2019;

(2) Portuguese Institute of Industrial Property (PT) - 22 May 2019;

(3) Dirk Peter - 17 August 2019;

(4) Elisabeth Albrecht - 4 September 2019;

(5) Written statements filed in standardised form by 23 052 natural persons via "Umweltinstitut München e.V." (UIM);

(6) Spanish Patent and Trademark Office (ES) – 16 September 2019;

(7) Bundesregierung der Bundesrepublik Deutschland (DE) - 10 September 2019;

(8) German Plant Breeders' Association (BDP) - dated 17 September 2019;

(9) Eric Alasdair Kennington - 18 September 2019;

(10) Euroseeds - 20 September 2019;

(11) Maximilian Haedicke - 23 September 2019;

(12) DeltaPatents - dated 23 September 2019;

(13) Industrial Property Office of the Czech Republic (CZ) - 20 September 2019;

(14) L.J. Steenbeek - 24 September 2019;

(15) Julian Cockbain - 24 September 2019 and 2 November 2019, referring to Sigrid Stercks / Julian Cockbain, Exclusions from Patentability, Cambridge University Press 2012 (ISBN 978-1-107-54262-4), pages 5 to 8, 17 and 18 of chapter 7 and chapter 9;

(16) König, Szynka, Tilmann, von Renesse (KSVR), Patentanwälte - 24 September 2019;

(17) Office belge de la Propriété Intellectuelle (BE) - 24 September 2019;

(18) Fédération Internationale des Conseils en Propriété Intellectuelle (FICPI) - 25 September 2019;

(19) Austrian Patent Office (AT) - 26 September 2019;

(20) European Federation of Agents of Industry in Industrial Property (FEMIP) - 26 September 2019;

(21) Patent Office of the Republic of Poland (PL) – 26 September 2019;

(22) The Kingdom of the Netherlands (NL) - 26 September 2019;

(23) IP Federation (IPF) - 27 September 2019;

- (24) Association of Intellectual Property Experts (VPP) - 27 September 2019;
- (25) Institut National de la Propriété Industrielle (FR) - 27 September 2019;
- (26) No patents on seeds! (NPS) - 30 September 2019;
- (27) Statement signed by 49 organisations and 2 725 individuals (collective statement) - 30 September 2019;
- (28) Peter de Lange - 30 September 2019;
- (29) The Danish Government (DK) - 30 September 2019;
- (30) Axel Metzger, Herbert Zech and Charlotte Vollenberg (Metzger/Zech/Vollenberg) – 30 September 2019;
- (31) Fritz Dolder - 30 September 2019;
- (32) Institute of Professional Representatives before the European Patent Office (epi) - 30 September 2019;
- (33) Plantum - 30 September 2019;
- (34) CropLife International and the European Crop Protection Association (ECPA) - 30 September 2019;
- (35) Intellectual Property Owners Association (IPO) – 30 September 2019;
- (36) Chartered Institute of Patent Attorneys (CIPA) – 30 September 2019;
- (37) Thomas Leconte - 1 October 2019;
- (38) International Association of Horticultural Producers (AIPH) - 1 October 2019;
- (39) Compagnie Nationale des Conseils en Propriété Industrielle (CNCPI) - 1 October 2019;
- (40) European Commission (EU Commission) – 1 October 2019;
- (41) Olaf Malek, Vossius & Partner (VP) – 21 October 2019.

III.1 Statements concerning the admissibility of the referral

III.1.1 Some third parties, either explicitly or, by submitting arguments on the merits of the referral, implicitly, considered the referral to be admissible. This group included public and governmental institutions (AT, BE, CZ, DE, DK, ES, FR, NL, PL, PT), the EU Commission, plant breeders' associations (BDP, Euroseeds, Plantum), non-governmental organisations (NPS), legal experts and individuals (Dolder, Metzger/Zech/Vollenberg).

First, within the field of biotechnological inventions, decisions in the field of plants had always been taken by the same Technical Board. As a consequence, the condition of “two Boards of Appeal” could never be fulfilled. However, it could not have been the legislator's intention to prevent the EPO President from referring to the Enlarged Board a point of law which concerned the field of biotechnological inventions. That would deprive the provision of its “effet utile” and also unjustifiably discriminate against one field of technology.

Secondly, there were “different decisions” within the meaning of Article 112(1)(b) EPC because decision T 1063/18 (supra) was contrary to the earlier decision of the same Board of Appeal in case T 1208/12 (not published in the OJ EPO), which relied on some key principles set out in Enlarged Board decision G 1/98 (OJ EPO 2000, 111). The fact that this reasoning was not even mentioned in decision T 1063/18 (supra) had led to

there being different decisions from that Board of Appeal in a different composition which touched upon the same fundamental point of law, i.e. the scope of the exceptions to patentability under Article 53(b) EPC.

Thirdly, the purpose of Article 112(1)(b) EPC was to ensure the uniform application of the EPC and to clarify legal matters of fundamental importance. Underlying the present referral was the need to obtain clarification of the potential impact that legal developments subsequent to decision G 2/12 (supra) had on the interpretation of Article 53(b) EPC.

III.1.2 Other third parties, either explicitly or at least implicitly, considered the referral to be inadmissible. These included patent attorneys, patent attorneys' associations and firms (O. Malek, CIPA, CNCPI, DeltaPatents, FEMIP, FICPI, KSVR), interest groups and trade associations (ECPA, IPF, VPP), legal experts and individuals (M. Haedicke, L.J. Steenbeek).

(a) In general terms

The referral was not warranted by different, let alone contradictory, decisions of the Boards of Appeal. It did not concern a point of law of fundamental importance within the meaning of Article 112(1) EPC, but was rather a political initiative of the EPO President and the Administrative Council, and contravened the binding effect of decisions of the Boards of Appeal in general and of the Enlarged Board in particular. In fact, none of the decisions cited in the referral actually involved the point of law specifically dealt with in decision T 1063/18 (supra), i.e. the validity of Rule 28(2) EPC under Article 53(b) EPC. Thus, there was no conflict between decision T 1063/18 (supra) and earlier case law.

(b) In respect of question 1

It was argued that the inadmissibility of question 1 did not result from there being case law which contradicted decision T 1063/18 (supra). Question 1 related to this decision only formally but not in substance. To reflect what had actually been decided upon, the question needed to be redrafted to ask whether Rule 28(2) EPC was in compliance with Article 164(2) EPC. However, there were no diverging decisions of the Boards of Appeal on this point, as Article 112(1)(b) EPC required. Furthermore, question 1 de facto referred to an abstract point of law, which as such could not justify a referral under Article 112(1)(b) EPC.

(c) In respect of question 2

Since question 1 was inadmissible it could not serve as a basis for the alleged admissibility of question 2; rather, question 2 was likewise inadmissible. As the second question was specific to Article 53(b) EPC and Rule 28(2) EPC, and given the absence of any case on this point besides decision T 1063/18 (supra), there was no conflict with any other decision that could justify the referral. Question 2 had already been exhaustively answered by the Enlarged Board in decision G 2/12 (supra), and this left no room for a different interpretation of Article 53(b) EPC. Article 112(1)(b) EPC could not be applied by analogy to render question 2 admissible. Article 112(1) EPC explicitly distinguished between referrals by a Board of Appeal (sub-paragraph (a)) and by the EPO President (sub-

paragraph (b)). They were subject to different requirements, which were more restrictive for the EPO President than for a referring Board of Appeal. Their distinct types and legal nature excluded relaxing any of the specific requirements of a presidential referral by analogy.

III.2 Statements concerning the substance of the referred questions

III.2.1 Statements in favour of an interpretation of Article 53(b) EPC different from [decision G 2/12](#)

A number of third parties, in particular public and governmental institutions (AT, BE, CZ, DE, DK, ES, FR, NL, PL, PT), the EU Commission, plant breeders' associations (AIPH, BDP, Euroseeds, Plantum), nongovernmental organisations (NPS), legal experts and individuals (Dolder, Metzger/Zech/Vollenberg), argued that the two questions referred to the Enlarged Board should be answered in the affirmative.

(a) In general terms

Decision G 2/12 (supra) had interpreted Article 53(b) EPC incorrectly. It followed from the legislator's intention to exclude from patentability processes for the breeding of plants and animals that no patent could be granted for a product derived from such a process and that such products therefore also fell within the exception to patentability according to Article 53(b) EPC.

(b) In respect of question 1

It was submitted that the conclusions reached by the Enlarged Board in decision G 2/12 (supra) did not prevent the Administrative Council from arriving at an alternative interpretation of Article 53(b) EPC at a later point in time. Given the lack of clarity in Article 53(b) EPC, it was a matter for the legislator to decide how this provision was to be interpreted. The Administrative Council was competent to clarify details of the EPC by amending the Implementing Regulations pursuant to Article 33(1)(c) EPC in order to bring them in line with EU legislation. In amending Rule 28 EPC, the Administrative Council had remained within the scope of the EPC and had issued a binding interpretation of Article 53(b) EPC. Although Article 53(b) EPC could be amended by the Administrative Council under Article 33(1)(b) EPC, this solution was less desirable than interpreting Article 53(b) EPC in line with Rule 28(2) EPC. On Article 164(2) EPC, two main lines of argument were advanced:

First, since Article 164(2) EPC was silent on decisions by the Boards of Appeal, and in view of the fact that different Boards of Appeal and different national courts might come to different interpretations of the same EPC provision, a clarification of EPC provisions in the Implementing Regulations could and should not be limited by the interpretation of one Board of Appeal.

Secondly, even if there was an apparent conflict between, on the one hand, an amended provision of the Implementing Regulations and, on the other, an interpretation of an Article of the EPC given by case law before the entry into force of the amended Rule, this should not be considered a conflict within the meaning of Article 164(2) EPC.

(c) In respect of question 2

Both Rule 28(2) EPC and the various legislative and other initiatives in a number of the Contracting States and in the EU since 2015 qualified as "any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" within the meaning of Article 31(3)(a) Vienna Convention. For the purpose of interpreting Article 53(b) EPC, the EU Commission's Notice of interpretation should be taken into account both to determine the actual intention of the legislator of the EU Biotech Directive and to acknowledge the subsequent adaptation of national laws to said Notice. To do so would not mean that there was a conflict between Rule 28(2) EPC and Article 53(b) EPC. Underlying the amendment of Rule 28 EPC was the Contracting States' intention that the interpretation which it expressed should be used as a supplementary means of interpretation pursuant to Rule 26(1) EPC with regard to Article 53(b) EPC. The clarification introduced by new Rule 28(2) EPC was also in accord with the basic principle that the patent laws of the Contracting States were to be interpreted and applied in harmony. Hence, any product, be it a plant or an animal or parts thereof, that was obtained by means of an essentially biological process was excluded from patentability.

(d) Other comments

One third party (J. Cockbain) "urged" the Enlarged Board to revisit its decision G 1/98 (supra), and conclude that Article 53(b) EPC was to be understood as excluding from patentability true-breeding plants and that, accordingly, Rule 28(2) EPC was valid.

III.2.2 Statements rejecting an interpretation of Article 53(b)

EPC different from [decision G 2/12](#)

A number of third parties, including patent attorneys, patent attorneys' associations and firms (E.A. Kennington, T. Leconte, O. Malek, CIPA, CNCPI, DeltaPatents, FEMIP, FICPI, KSVR), interest groups and trade associations (ECPA, IPF, VPP), legal experts and individuals (M. Haedicke, L.J. Steenbeek), argued that the two questions referred to the Enlarged Board should be answered in the negative.

(a) In general terms

Article 53(b) EPC was phrased in clear terms in that it provided for the exception to patentability of only three distinct items: plant varieties, animal varieties, and essentially biological processes for the production of plants or animals. Anything not listed, such as plants and animals obtained by essentially biological processes, was in principle patent-eligible. Hence, the relevant law was not open to interpretation. Since the EU Commission's Notice of interpretation was meant merely to assist the application of the EU Biotech Directive, this Notice could not empower the Administrative Council to amend the EPC. The EU Commission's Notice of interpretation did not have the force of law even within the jurisdiction of the EU, and certainly lacked it under the EPC. The mere fact that EU institutions and the Administrative Council believed it to be politically desirable to exclude from patentability

plants or animals exclusively obtained by means of an essentially biological process did not result in the law having changed. Even without decision G 2/12 (supra), it would not have been legally possible to adopt Rule 28(2) EPC.

(b) In respect of question 1

Rule 28(2) EPC attempted to change, not clarify, the meaning of Article 53(b) EPC. According to a well established principle of law, legal hierarchies could not be inverted in such a way that primary legislation could be amended by secondary legislation, unless an express statutory provision granted the power to amend it. The Implementing Regulations could only clarify the meaning and scope of an Article of the EPC, and only in line with the interpretation of the Article given in an earlier decision of the Enlarged Board.

The EPC empowered both the Boards of Appeal and the Administrative Council to interpret the Articles of the EPC. However, Articles 33 and 164(2) EPC limited the competence of the Administrative Council in this respect. The Administrative Council, being an executive organ with certain “regulatory”, rather than legislative, powers (M. Haedicke), was not competent to provide an interpretation of the Convention by introducing or amending implementing Rules which contradicted the Articles of the EPC. Logically, in the event of conflict between a Rule and an Article of the EPC, the limits on the Administrative Council’s competence prevented it from reversing the interpretation of the Article given previously by the Enlarged Board, the judicial branch of the EPC. If it were otherwise, Article 164(2) EPC would be rendered otiose, because the effect of a new or amended Rule would always be to modify the Article to the extent required to eliminate any conflict. This would alter the distribution of powers within the EPO to the detriment of the judiciary. Rather, the doctrine of separation of powers and the duty of loyalty, or loyal cooperation, among the different authorities under the EPC had to be respected. This meant that, in the matter of interpreting the EPC, the jurisprudence should prevail.

Hence, an affirmative answer to question 1 would be in contradiction to the limited competence of the Administrative Council under Article 33(1)(c) EPC to interpret Articles of the EPC only within the boundaries of Article 164(2) EPC. It would even lead to the Administrative Council being provided with powers reserved to a Diplomatic Conference pursuant to Article 172 EPC.

The developments in the EU and the Contracting States on which the referral relied did not change the legal framework after decision G 2/12 (supra), either because they were only non-legislative and thus non-binding (EU), or because they did not concern all the Contracting States.

(c) In respect of question 2

Article 53(b) EPC was a self-contained provision, which did not enable a Rule of the Implementing Regulations to change its meaning and scope, and in particular did not allow extending the meaning and scope of exceptions to patentability. Since Article 52(1) EPC

provided for the patentability of inventions in all fields of technology as a general principle, and because any limitation of that general rule required a clear legal basis in the EPC, the introduction of Rule 28(2) EPC could not and did not change the interpretation of Article 53(b) EPC given in decision G 2/12 (supra). The outcome of decision T 1063/18 (supra) required either that the Administrative Council delete Rule 28(2) EPC or that the Contracting States amend Article 53(b) EPC. However, there was currently no need for such amendment which would constrict future developments in breeding processes. Without an amendment of the EPC, Rule 28(2) EPC had to be disregarded by virtue of Article 164(2) EPC.

III.3 Statements of a more general nature

A number of third parties (E. Albrecht, collective statement, D. Peter, UIM) raised general concerns over the patentability of biotechnological inventions and criticised the institutional structure and legal status of the EPOrg. One third party (P. de Lange) commented only on some institutional issues in the context of the first question, and did not directly address the matter of the referral’s admissibility or discuss how the referred questions should be answered. Another third party (epi), while refraining from suggesting any particular answer to the referred questions or their admissibility, pointed to the differences between the narrow interpretation of “essentially biological processes” in Article 2(2) EU Biotech Directive and the broader definition formulated in decisions G 2/07 and G 1/08 (supra). Furthermore, the Enlarged Board was asked to consider transitional measures to protect legitimate expectations established by its earlier decisions.

The course of the proceedings before the Enlarged Board

IV. Since the present proceedings are based on a referral by the EPO President under Article 112(1)(b) EPC, there are no parties to the proceedings before the Enlarged Board. After considering the reasoning of the EPO President for his referral as well as the various statements put forward by third parties under Article 10(1) RPEBA, the Enlarged Board now issues its opinion on the point of law referred to it in written proceedings without prior oral proceedings.

REASONS FOR THE OPINION

The relevant legal provisions

I. Specific reference will be made to the following: Article 112(1)(b) EPC Decision or opinion of the Enlarged Board of Appeal; Article 53(b) EPC Exceptions to patentability; Rule 26(1) and (5) EPC General and definitions, corresponding to Rule 23b(1) and (5) EPC 1973, which was inserted in the Implementing Regulations by decision of the Administrative Council of 16 June 1999 and entered into force on 1 September 1999 (OJ EPO 1999, 437); Rule 27(b) EPC Patentable biotechnological inventions, as amended by decision of the Administrative Council CA/D 6/17 of 29 June 2017 (OJ EPO 2017, A56) and in force from 1 July 2017; Rule 28(2) EPC – Exceptions to patentability, introduced by decision of the Administrative Council CA/D 6/17 of 29 June 2017 (OJ

EPO 2017, A56) and in force from 1 July 2017; Articles 31 and 32 Vienna Convention on the Law of Treaties of 23 May 1969 (Vienna Convention); Articles 1 to 4 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (EU Biotech Directive, OJ EU 1998 L 213/13; OJ EPO 1999, 101).

Scope and focus of the referral

II. As an initial matter, before the admissibility and substantive issues of the referral are addressed, it is necessary to analyse the scope and focus of the referred questions and the supporting reasoning. Formally speaking, the present referral addresses two issues: first, the scope of the Administrative Council's power to adopt or amend Rules of the Implementing Regulations to give effect to an interpretation of an Article of the EPC which differs from that given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal (question 1); secondly, the proper interpretation of Article 53(b) EPC following the adoption of Rule 28(2) EPC, which excludes from patentability plants and animals exclusively obtained by means of an essentially biological process (question 2).

II.1 Question 1 is drafted in somewhat general terms and is directed to the abstract legal concept of the relationship between the EPC and its Implementing Regulations. It also focuses on the matter of the interpretation of the EPC, on the one hand by the Enlarged Board in fulfilment of its judicial function under Articles 22(1)(a) and (b) and 112(1) EPC (judicial interpretation), or on the other hand by a decision of the Administrative Council acting as the rule-making body competent to adopt Implementing Regulations under Article 33(1)(c) EPC (regulatory interpretation). Hence, the first question relates to the rule of the hierarchy of norms, the Articles of the EPC being the primary legislation and the Implementing Regulations the secondary legislation. It further addresses the allocation of competences according to the EPC in so far as this concerns the body which is empowered to interpret the EPC in a binding manner; also relevant to this latter aspect is the doctrine of separation of powers known to all the Contracting States, which governs the EPC as well.

II.2 Question 2, which has been framed to be dependent on an affirmative answer to question 1, concerns Rule 28(2) EPC's conformity with Article 53(b) EPC. Thus, the second question asks whether there is a conflict between a later implementing provision, i.e. Rule 28(2) EPC, and the earlier higher-ranking provision of the Convention to which it is connected, i.e. Article 53(b) EPC.

II.3 In the EPO President's submission, decision T 1063/18 (*supra*) was wrong in finding that Rule 28(2) EPC was in conflict with Article 53(b) EPC as interpreted in decision G 2/12 (*supra*) and that, in view of Article 164(2) EPC, the provisions of the Convention prevailed (Reasons, point 46). Contrary to that, the EPO President suggests

i. that the wording of Article 53(b) EPC allows for different interpretations and that in decision G 2/12 the

Enlarged Board found that this Article did not explicitly acknowledge the patentability of plants or plant materials exclusively generated by an essentially biological process (points 71 to 75 of the referral);

ii. that Article 53(b) EPC is to be interpreted in the light of, and with the same result as expressly stipulated in, Rule 28(2) EPC, which provides a permissible clarification of the meaning and scope of Article 53(b) EPC (points 76 and 77 of the referral);

iii. that the EU legislator's intention is not barred by decision G 2/12 (point 93 of the referral);

iv. that, in view of the intention of the EU legislator (points 85 to 92 of the referral) and the intention of the EPC legislator, which is demonstrated by the "incorporation" of the EU Biotech Directive into the EPC (points 78 to 84 of the referral), Article 53(b) EPC is to be interpreted as excluding from patentability the products of essentially biological processes (points 94 to 98 of the referral);

v. that, based on said interpretation of Article 53(b) EPC and in view of the subsequent agreement between and practice of the Contracting States, Rule 28(2) EPC is fully in line with Article 53(b) EPC (points 99 to 111 of the referral);

vi. that, having regard to Article 164(2) EPC, Rule 28(2) EPC is in conformity with Article 53(b) EPC (point 112 of the referral).

II.4 While, at a formal level, the first question addresses two aspects, these being the allocation of competence under the EPC to determine the legal content of an Article of the Convention and the question of the hierarchy of norms, the second question leaves no doubt as to the real purpose of the EPO President's referral. This is to request the Enlarged Board to review and, in the end, abandon its interpretation of Article 53(b) EPC in decision G 2/12 (*supra*), and to re-interpret the exception to patentability to the effect that Rule 28(2) EPC gives a conclusive interpretation of the legal scope of that Article.

II.5 The wording of question 1 is too general and unspecific in that it broaches an institutional topic which reaches well beyond the ultimate object of the referral. As it is framed, this question calls for a "yes" or "no" answer to cover every conceivable scenario that could arise from any regulatory attempt to shape the legal content of a provision of primary legislation, i.e. an Article of the EPC, by means of secondary legislation, i.e. a Rule of the Implementing Regulations. In fact, the scenario presented in the first question would, if followed to its logical conclusion, effectively give the Administrative Council, as the authority empowered by the EPC to adopt the Implementing Regulations, a "carte blanche" to deviate from established case law and give a particular meaning to any Article of the EPC by means of the Rules of the Implementing Regulations. This would open the door to the possibility of circumventing the statutory procedures for amending the Convention itself, namely by way of a diplomatic conference pursuant to Article 172 EPC or by unanimous vote in the Administrative Council pursuant to Articles 33(1)(b) and 35(3) EPC.

Hence, the first question needs to be re-phrased to reflect the referral's true object.

II.6 Question 2 already contains, in thinly disguised form, the answer that it seeks, by stating that Article 53(b) EPC "neither explicitly excludes nor explicitly allows" the patentability of plants and animals exclusively obtained by an essentially biological process. Therefore, the second question likewise needs to be rephrased to ensure that it is unencumbered by the opinion of the EPO President as the originator of the referral.

Re-phrasing of the referred questions

III. For the aforementioned considerations, the Enlarged Board concludes that the referred questions need to be re-phrased in a way that takes the following two points into account.

III.1 First, the two issues underlying the referral are interlinked. The matter of the Administrative Council's competence to adopt secondary legislation is a preliminary question which must necessarily be examined before the substantive issue of the legal scope of Article 53(b) EPC is dealt with. Hence, both issues can be combined in a single question.

III.2 Secondly, from its reading of the referral as a whole, i.e. the questions and the supporting reasoning, the Enlarged Board takes the view that the referral's true object can be paraphrased as follows:

i. With regard to the exception to patentability of "essentially biological processes for the production of plants and animals", does Article 53(b) EPC permit only a single interpretation or could it bear a wider scope of interpretation?

ii. Does Article 53(b) EPC allow a dynamic interpretation in the sense that its meaning may change over time?

iii. And if so, can an amendment to the Implementing Regulations give effect to a change of meaning resulting from a dynamic interpretation of Article 53(b) EPC?

III.3 The Enlarged Board thus considers that the open and abstract wording of the following single question articulates the real issues at stake in the EPO President's referral:

Taking into account developments that occurred after a decision by the Enlarged Board of Appeal giving an interpretation of the scope of the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC, could this exception have a negative effect on the allowability of product claims or product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature define an essentially biological process?

Admissibility of the referral

IV. To be admissible under Article 112(1)(b) EPC, the referral must meet the following requirements:

i. an answer by the Enlarged Board is needed in order to ensure uniform application of the law, or a point of law of fundamental importance has arisen and

ii. two Boards of Appeal have given different decisions on that question.

V. As regards the first admissibility requirement, the President submits that the point of law raised in decision T 1063/18 (supra) is of fundamental importance and requires clarification from the Enlarged Board as the highest judicial authority of the EPO (point 31 of the referral).

V.1 For the EPO President, the fundamental importance of the point of law stems from three considerations in particular. First, the validity of Rule 28(2) EPC in view of Article 164(2) EPC and Article 53(b) EPC is not only a point of law of fundamental importance. It is also a question which cannot be conclusively resolved by reference to the EPC. The non-applicability of a provision of the Implementing Regulations due to a perceived conflict with an Article of the EPC is a legal question of fundamental importance. In the specific case at issue, it raises fundamental questions of legal interpretation, i.e. the impact of subsequent legal developments on the interpretation of Article 53(b) EPC and the significance of an earlier decision of the Enlarged Board of Appeal on the operation of Article 164(2) EPC (point 37 of the referral). Secondly, the issue at stake concerns fundamental questions of legal uniformity. Rule 28(2) EPC was adopted by the Administrative Council in order to align the EPC with the EU Biotech Directive. The importance of a uniform interpretation and application of harmonised European patent law is generally recognised and confirmed by Rule 26(1), second sentence, EPC (point 38 of the referral). Thirdly, the point of law is relevant for more than 250 similar cases before the examining and opposition divisions. This calls for the point of law to be settled by a de facto binding decision of the Enlarged Board (point 39 of the referral).

V.2 The Enlarged Board acknowledges the institutional implications of the various issues underlying the referral, namely, the legislator's intention to harmonise the EPO's approach to the patentability requirements for biotechnological inventions with the respective developments in the Contracting States and in the EU, the legal principles relating to conflicts of legal norms (e.g. "lex superior derogat legi inferiori" and "lex posterior derogat legi priori"), and the relevance of the referral for numerous other pending and future cases before the administrative (i.e. examining and opposition) divisions and the Boards of Appeal.

V.3 Taking all these aspects into account, the Enlarged Board considers that the issues underlying the referral concern a point of law of fundamental importance within the meaning of Article 112(1) EPC which requires a uniform application of the law.

VI. Concerning the second admissibility requirement, which applies specifically to a referral by the EPO President, it is essential that it is clear what is meant by "different decisions" of "two Boards of Appeal", and in what respects those decisions must be different.

VI.1 Regarding "different decisions", the Enlarged Board held in its opinion G 3/08 (supra, Reasons, points 7 et seq.; see also G 3/95, OJ EPO 1996, 169, Reasons, point 8) that the terms "different/abweichende/divergentes" in Article

112(1)(b) EPC had to be interpreted in the light of the provision's object and purpose according to Article 31 Vienna Convention. The purpose of the EPO President's power to refer points of law to the Enlarged Board is to establish uniformity of law within the European patent system. Having regard to this purpose, the term "different decisions" has to be understood restrictively in the sense of "conflicting decisions". Legal development is an additional factor which must be carefully considered. Development of the law is an essential aspect of its application and is inherent in all judicial activity. As a consequence, legal development cannot on its own form the basis for a referral, because case law does not always develop in a linear fashion, and earlier approaches may be abandoned or modified.

VI.2 On the requirement "two Boards of Appeal", the case law of the Enlarged Board does not provide clear guidance. In its opinion G 4/98 (supra, Reasons, point 1.1), the Enlarged Board held that a discrepancy between the Office's practice on the one hand and the case law of the Boards of Appeal on the other is not in itself sufficient to justify a referral by the EPO President, if the administrative practice of the EPO is not warranted by the case law. However, the Enlarged Board also found that if the EPO President's power of referral was to be defined by a restrictive reading of "two Boards of Appeal" based on organisational structure of the Boards of Appeal, no referrals would be possible with respect to the sole Legal Board of Appeal. This would unduly restrict the effect of Article 112(1)(b) EPC, since conflicting decisions could also occur within that Board (supra, Reasons, point 1.2). Likewise, different decisions by a single Technical Board of Appeal in differing compositions may be the basis of an admissible referral by the EPO President (G 3/08, supra, Reasons, point 6; see also G 1/04, OJ 2006, 334, Reasons, point 1).

VI.3 Whether the present referral complies with the requirement of different decisions by the Boards of Appeal, as defined in cases G 4/98, G 1/04 and G 3/08 (supra), is not immediately apparent. However, what is evident is a conflict between, on the one hand, decision T 1063/18 (supra), which held that for claims directed to a plant product obtained by an essentially biological process the interpretation of Article 53(b) EPC given in decision G 2/12 (supra) must prevail over Rule 28(2) EPC, and, on the other hand, the regulatory intention underlying Rule 28(2) EPC, which is to exclude such claims from patentability.

VI.4 The EPO President presents the following two lines of argument in support of the referral's admissibility.

VI.4.1 First, he argues that decision T 1063/18 (supra) differed from earlier case law with regard to the way in which a Rule of the Implementing Regulations is assessed under Article 164(2) EPC (points 4 to 18 of the referral). The approach adopted in that decision, according to which the interpretation of Article 53(b) EPC given in decision G 2/12 (supra) would exclude any subsequent clarification in the Implementing Regulations which deviated from that interpretation, differed from other decisions relating to the EU Biotech

Directive (e.g. T 272/95, T 315/03, T 666/05 and T 1213/05 (supra)).

VI.4.2 Secondly, the EPO President suggests applying Article 112(1)(b) EPC by analogy because the effect of decision T 1063/18 (supra) is comparable to the situation in which two Boards have given different decisions and because the EPC legislator cannot be presumed to have advertently left out the possibility of a presidential referral in the present scenario (points 19 to 30 and 43 of the referral). If a right of referral by the EPO President exists in the case of divergent interpretations of the EPC in two Board of Appeal decisions with inter partes effect, it must all the more exist in the case of a divergence between the interpretation of an EPC Article in a single Board of Appeal decision and the implementation (i.e. interpretation) of the Article with erga omnes effect set forth in a Rule of the Implementing Regulations adopted by the Administrative Council.

VI.5 As regards the first line of argument, for decisions of two Boards of Appeal within the meaning of Article 21 EPC to be different for the purposes of Article 112(1)(b) EPC, they must differ on a particular point of law. The decisions should differ in the legal assessment on which they are based (ratio decidendi). However, in its opinion G 3/93 (OJ EPO 1995, 18, Reasons, point 2; see also opinion G 2/92, OJ EPO 1993, 591) the Enlarged Board found the referral to be admissible even though the decisions cited by the EPO President conflicted only insofar as one decision contained an "obiter dictum", because it is the function of the Enlarged Board to ensure uniform application of the law. "Even an 'obiter dictum' may give rise to legal uncertainty."

VI.5.1 From its assessment of the decisions cited by the EPO President in relation to this aspect, and taking note of inter alia the opinion of Mr. C. Rennie-Smith on decision T 315/03 (supra) filed by KSVR Patentanwälte along with their amicus curiae brief, the Enlarged Board notes the following: In decision T 315/03 (Reasons, point 7.3), Board of Appeal 3.3.08 stated that Article 53(a) EPC contains nothing which precludes or limits its own subsequent interpretation whether by case law or by (secondary) legislation (Rule 23d EPC 1973). This notion was relevant to the case (see headnotes 1 to 3). The Board also held that a subsequent rule deviating from a particular interpretation given to a legal provision by a court is not per se ultra vires (Reasons, point 7.3):

"The respondent appears to have argued that the law in question is not simply Article 53(a) EPC but that Article as interpreted in T 19/90. Not only is this a legal impossibility - one cannot combine a legislative provision with case-law interpretation to construct an artificial vires by which to judge an action or rule as ultra vires - but even if possible it would make no difference since that notional 'law' would still contain nothing to preclude or limit subsequent interpretation." In decision T 272/95 (supra, Reasons, points 4 and 5), Board of Appeal 3.3.04 acknowledged that the Administrative Council had amended the Implementing Regulations in the light of the EU Biotech Directive by adopting Rules 23b to 23e EPC 1973, for the purpose of

applying and interpreting the provisions of the Convention relevant to European patent applications and patents concerning biotechnological inventions. Having regard to Article 164(2) EPC, the Board examined the conformity of the new Rules with Article 53(a) EPC. For this purpose, it referred to Enlarged Board decision G 1/98 (supra, Reasons, point 5.3) dealing with the interpretation of Article 53(b) EPC and found Rule 23c EPC 1973, which was related to Article 53(b) EPC, to be interpretative only. The Board considered that the same held true for the new Rules as far as they related to the interpretation of Article 53(a) EPC, and applied Rules 23d and 23e to the case before it. This approach was followed by the same Board in different compositions in decisions T 666/05 (supra, Reasons, point 75) and T 1213/05 (supra, Reasons, point 44).

VI.5.2 The aforementioned decisions can be read as acknowledging that a subordinate but later provision of the Implementing Regulations can have an impact on the interpretation of a higher-ranking and previously enacted provision of the Convention, irrespective of a particular interpretation given to the latter in an earlier decision by a Board of Appeal.

VI.5.3 This notion is consistent with Article 31(3)(a) Vienna Convention, which provides for any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions to be taken into account. It is also supported by the Enlarged Board's decision G 2/12 (supra, Reasons, point VII.4 and VII.6).

VI.5.4 In decision T 1063/18 (supra), however, the Board of Appeal did not take up that notion by examining whether the interpretation of Article 53(b) EPC could be affected by Rule 28(2) EPC on the basis of Article 31(3) Vienna Convention. Rather, it established that Rule 28(2) EPC was in contradiction to the particular interpretation of Article 53(b) EPC given in decision G 2/12 (supra) before the Rule was adopted (Reasons, points 24 to 26 and 46) and that the Administrative Council was not competent to amend Article 53(b) EPC by means of Rule 28(2) EPC (Reasons, points 31 to 36). As a consequence, the Board disregarded Rule 28(2) EPC pursuant to Article 164(2) EPC because it considered the Rule to deviate from the interpretation given in an earlier decision of the Enlarged Board.

It is this aspect that constitutes the difference from other aforementioned Board of Appeal decisions, which evaluated the impact of a later-adopted provision of the Implementing Regulations on the construction of a provision of the Convention.

VI.5.5 Hence, the Enlarged Board considers that there are different decisions of two Boards of Appeal on the question whether an amendment to the Implementing Regulations can have an impact on the interpretation of an Article of the EPC.

VI.6 Concerning the EPO President's suggestion that Article 112(1)(b) EPC could be applied by analogy, the Enlarged Board has the following observations, which are independent of its conclusion in point VI.5.5 above.

VI.6.1 The proposed application by analogy appears neither plausible nor appropriate. The wording of Article 112(1)(b) EPC, in particular when compared with that of Article 112(1)(a) EPC concerning referrals by a Board of Appeal, is quite clear as to the specific requirement of "different decisions" by "two Boards of Appeal" for referrals by the EPO President. The Enlarged Board cannot identify any unintended legal gap in Article 112(1) EPC which might have arisen as a result of the distinct conditions stipulated for referrals by Boards of Appeal on the one hand and referrals by the EPO President on the other.

Thus, there is neither room nor need for an application of Article 112(1)(b) EPC by analogy in order to admit a referral on points of law by the EPO President in the absence of different decisions of Boards of Appeal, regardless of their fundamental importance or of the need to ensure uniformity in the application of the law.

VI.6.2 These considerations are in line with the case law of the Enlarged Board on the admissibility of referrals by the EPO President.

The Enlarged Board endorses its previous case law, according to which the EPO President's power of referral is to be understood in a restrictive sense. This view was expressed in opinion G 3/08 (supra, Reasons, points 7.2.4 et seq.) as follows:

"7.2.4 ... Article 112 EPC - like corresponding provisions in the legal orders of the Contracting States - defines the conditions in which legal uniformity within the European patent system may be established by means of a referral to the Enlarged Board of Appeal. ... Hence the Enlarged Board does not rule on abstract points of law, but only ever on real issues arising from the cited differing decisions, as well as on specific legal questions adduced in the referral ... It is to be noticed that the President is not a party in a referral procedure because she or he cannot be adversely affected by answers given by the Enlarged Board. 7.2.5 Thus it is clear that the interpretation of the EPC is primarily the responsibility of the Boards of Appeal. As a rule they have interpretative supremacy with regard to the EPC because their decisions are subject to review only under the narrowly defined conditions of Articles 112(1) and 112a(2) EPC. It is only when these apply that the Enlarged Board has the last word. The fact that the Enlarged Board takes action only on a referral from the Boards of Appeal or the President (with the exception of petitions for review under Article 112a EPC, which however concern procedural matters and have a very narrow scope) and thus does not constitute a further instance ranking above the Boards of Appeal within the EPC judicial system is a clear indication of the extent of its significance for legal uniformity. The exhaustive list of admissibility criteria for a referral under Articles 112(1)(a) and (b) EPC implies that the Enlarged Board takes decisions on specific legal questions and that neither the Boards of Appeal nor the President are authorised to consult it whenever they so wish in order to clarify abstract points of law. For that purpose the President can call upon a separate Legal Department within the Office.

7.2.6 On the same restrictive grounds, Article 112(1)(b) EPC as an additional constraint for a referral by the President as opposed to one by a Board of Appeal requires there to be differences in the rulings of two Boards of Appeal (in the sense already discussed) on a point of law. 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. It is of course immaterial whether the initiative behind the referral comes from a third party, as long as there is objective evidence of divergent applications of the law.

7.2.7 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 ..."

VI.7 Hence, the Enlarged Board considers that the referral of the EPO President concerns a point of law on which two Boards of Appeal have given different decisions within the meaning of Article 112(1)(b) EPC.

VII. As a consequence, the EPO President's referral complies with the requirements of Article 112(1)(b) EPC and is admissible within the terms of the question as rephrased by the Enlarged Board under point III.3 above.

Background to the present referral

VIII. The present referral is the sixth referral in respect of the interpretation of Article 53(b) EPC of which four were dealt with in consolidated proceedings. It is thus appropriate to recapitulate the preceding referrals briefly at this point.

G 1/98 – plant varieties

VIII.1 In decision [G 1/98](#) (supra, headnotes I and II), the Enlarged Board was concerned with points of law relating to claims comprising but not identifying plant varieties and plant varieties as products of recombinant gene technology. The referred questions were answered as follows (headnotes):

"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."

G 2/07 and G 1/08 – essentially biological processes (process claims)

VIII.2 In consolidated cases [G 2/07 and G 1/08](#) (supra), also referred to as "Broccoli" and "Tomatoes", the points of law referred to the Enlarged Board concerned the interpretation of Article 53(b) EPC. Since the

wording of Rule 26(5) EPC (formerly Rule 23b(5) EPC 1973), which is identical to Article 2(2) of the EU Biotech Directive, could not be of assistance in interpreting Article 53(b) EPC, the exception to patentability of "essentially biological processes for the production of plants" had to be interpreted on the basis of Article 53(b) EPC alone. The term "plants" could not be interpreted, contrary to the word itself, as meaning "plant varieties". There was no indication in the legislative history that "plants" was meant to signify only "plant varieties". The exception of "essentially biological processes for the production of plants" could thus not be read as being limited to processes for the production of plant varieties. The referred questions were answered as follows (G 2/07 and G 1/08, supra, headnotes):

"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."

G 2/12 and G 2/13 – essentially biological processes (product and product-by-process claims)

VIII.3 The present referral is a follow-up to consolidated cases [G 2/12 and G 2/13](#) (supra), also referred to as "Tomatoes II" and "Broccoli II". As in the present case, the Enlarged Board was concerned with the question whether the exception to patentability of essentially biological processes for the production of plants in Article 53(b) EPC had a negative effect on the allowability of product claims or product-by-process claims directed to plants or plant material (such as a fruit or plant parts) which are directly obtained and/or defined by an essentially biological process. It concluded that it did not. The Enlarged Board analysed the meaning and scope of Article 53(b) EPC in the light of Articles 31 and

32 Vienna Convention, of the various established methods of interpretation (grammatical, systematic, teleological and historical interpretations), and of the EU Biotech Directive. None of these led the Enlarged Board to conclude that the term “essentially biological processes for the production of plants” extended beyond the processes to products defined or obtained by such processes. The Enlarged Board went on to examine whether considerations had arisen since the Convention was signed which might give reason to believe that a grammatical interpretation of the relevant provision would conflict with the legislator's aim. It found that the developments in the field of plant breeding techniques had not prompted the EPC legislator to amend Article 53(b) EPC and saw no indication why the original intention of the legislator in drafting Article 53(b) EPC was no longer justified, just because there were new techniques available in this sector. It also held that the clear wording of Article 53(b) EPC ruled out that the patenting of a product claim or a product-by-process claim for a plant or plant material obtained by means of an essentially biological process was to be regarded as a circumvention of the process exclusion. To the contrary, broadening the scope of the process exclusion to the extent that it included products obtained by essentially biological processes for the production of plants would introduce an inconsistency in the system of the EPC, as plants and plant material other than plant varieties were generally eligible for patent protection.

However, the Enlarged Board also emphasised that its judicial decision-making powers did not extend to the ethical, social and economic aspects raised in the general debate, as it had no mandate to engage in legislative policy.

The Enlarged Board thus held (combined reading of the headnotes of G 2/12 and G 2/13) that the exception to patentability 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 such as a fruit or plant parts. The fact that the process features of a product-by-process claim directed to plants or plant material other than a plant variety defined an essentially biological process for the production of plants did not render the claim unallowable. The fact that the only method available at the filing date for generating the claimed subjectmatter was an essentially biological process for the production of plants disclosed in the patent application did not render a claim directed to plants or plant material other than a plant variety unallowable. In the circumstances, it was of no relevance that the protection conferred by the product claim encompassed 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.

Case law implementing G 2/12 and G 2/13

IX. In its final decision T 83/05 of 10 September 2015 (not published in the OJ EPO), the Board of Appeal applied decision G 2/13 (supra) stemming from its earlier interlocutory decision of 8 July 2013 (OJ EPO 2014, 39). The Board set aside the decision under appeal

and remitted the case to the opposition division with an order to maintain the patent on the basis of claims 1 to 5 of the main request and a description to be adapted thereto. Claim 1 was directed to an edible Brassica plant produced according to a method of crossing and selecting. Claims 2 and 3 were directed to an edible portion and to the seed of a broccoli plant produced by a method defined in the same manner as in claim 1. Claims 4 and 5 were directed to a broccoli plant and a broccoli inflorescence.

X. In its final decision T 1242/06 of 8 December 2015 (not published in the OJ EPO), the Board of Appeal applied decision G 2/12 (supra) stemming from its earlier interlocutory decision of 31 May 2012 (OJ EPO 2013, 42). The newly submitted claims were restricted to claims for products and related to a (naturally) dehydrated tomato fruit. The Board held that the subject-matter of the claims of auxiliary request I was not excluded from patentability pursuant to Article 53(b) EPC. The Board set the decision under appeal aside and remitted the case to the opposition division with the order to maintain the patent on the basis of these claims and a description to be adapted thereto.

XI. And finally, in decision T 1063/18 (supra), which led the EPO President to make the present referral, the Board of Appeal applied decision G 2/12 (supra).

Interpretation of Article 53(b) EPC

XII. The re-phrased question focusses on the interpretation of Article 53(b) EPC and on whether and to what extent the understanding of the scope of the exception to patentability may have changed in the light of developments since decision G 2/12 (supra), and in particular the introduction of Rule 28(2) EPC.

XIII. Considering Article 53(b) EPC on its own, i.e. without reference to Rule 28(2) EPC, the Enlarged Board confirms its earlier decisions in case G 1/98 (supra), in consolidated cases G 2/07 and G 1/08 (supra) and in consolidated cases G 2/12 and G 2/13 (supra).

Grammatical, systematic and teleological interpretations of Article 53(b) EPC

XIV. The decisive question of the present referral is whether Article 53(b) EPC excludes from patentability a product claim or a product-by-process claim directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature define an essentially biological process. In its analysis of Article 53(b) EPC in decision G 2/12 (supra), the Enlarged Board applied the grammatical, systematic and teleological methods of interpretation. The Enlarged Board endorses the conclusions which were reached in decision G 2/12 on the basis of each of these methods.

XIV.1 It is well established in the jurisprudence of the Enlarged Board and of the Boards of Appeal that the principles of interpretation provided for in Articles 31 and 32 Vienna Convention are to be applied when interpreting the EPC. Decisions and opinions given by national courts in interpreting the law may also be taken into consideration (G 2/12, supra, Reasons, points V.(2), (3) and (5), with further references to the case law; Case law of the Boards of Appeal, 9th edition 2019, III.H.).

XIV.2 In accordance with Article 31(1) Vienna Convention, the objective method of interpretation is directed to establishing the "authentic" meaning of the relevant provision and its legal terms. The starting point of interpretation is thus the wording, i.e. the "objective" meaning, regardless of the original "subjective" intention of the contracting parties. To this end, the provisions are to be read in their context so that they comply with the object and purpose of the EPC. The preparatory work ("travaux préparatoires") and the circumstances of the conclusion of the EPC serve only as supplementary sources of evidence to confirm the result of the interpretation or if no reasonable meaning can be determined by applying the general rule of interpretation (Article 32 Vienna Convention) (G 2/12, supra, Reasons, point V.(4)).

XIV.3 The grammatical interpretation of the wording of Article 53(b) EPC leads to the conclusion that, since more than one meaning could in principle be attributed to it, the true and intended meaning of the term "essentially biological processes for the production of plants and animals" requires further analysis (G 2/12, supra, Reasons, point VII.1, with reference to G 1/88, OJ EPO 1989, 189, Reasons, point 2.2).

XIV.4 The systematic interpretation of Article 53(b) EPC is directed to establishing its meaning in the context of the provision itself and, in addition, by taking into account its position and function within a coherent group of related legal provisions. The Enlarged Board reaffirms the conclusion which it came to in decision G 2/12 (supra, Reasons, point VII.2, with reference to G 1/88, supra, Reasons, point 3; G 9/92, OJ EPO 1994, 875, Reasons, point 1; G 4/95, OJ EPO 1996, 412, Reasons, points 4 and 5; G 1/98, supra, Reasons, point 2; G 3/98, OJ EPO 2001, 62, Reasons, point 2.2; and G 4/98, supra, Reasons, point 4) that the systematic interpretation of Article 53(b) EPC does not support giving the process exclusion a broad meaning to the effect that it also excludes product claims or product-by-process claims from patentability.

XIV.5 Turning to the teleological interpretation of Article 53(b) EPC in the light of its purpose, values, and the legal, social and economic goals that it aims to achieve, the Enlarged Board also confirms its finding in decision G 2/12 (supra, Reasons, point VII.3, with references to G 1/88, supra, Reasons, point 5; G 1/03, OJ EPO 2004, 413, Reasons, point 2.1.1; and G 6/91, OJ EPO 1992, 491, Reasons, point 8) that the object and purpose of the exception to patentability under Article 53(b) EPC is not sufficiently obvious to answer the question whether or not the clause is to be construed in a narrow or broad way.

XIV.6 It follows that none of the various methods of interpretation provided for in Article 31(1) Vienna Convention leads to the conclusion that the term "essentially biological processes for the production of plants" clearly extends beyond processes to products defined or obtained by such processes.

Subsequent agreement or practice

XV. Under Article 31(3)(a) and (b) Vienna Convention, any subsequent agreement or practice between the

parties regarding the interpretation of the treaty or its application, and any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation is to be taken into account.

For this purpose, the EPO President relies on

- i. Rule 26 EPC (points 80 to 84 of the referral);
- ii. the EU Commission's Notice of interpretation relating to the European Union (hereinafter the EU) legislator's intent when adopting the EU Biotech Directive (points 85 to 99 of the referral);
- iii. legislative and administrative developments in Contracting States after decision G 2/12 (supra) (points 100 to 111 of the referral).

XV.1 Regarding Rule 26 EPC (formerly Rule 23b EPC 1973), the Enlarged Board stated in decision G 2/12 (supra, Reasons, point VII.4(1)) that Rule 26(5) EPC could be regarded as such a subsequent agreement and practice. Rule 26(1) EPC lays down that the EU Biotech Directive is to be used as a supplementary means of interpretation for the relevant EPC provisions (see G 2/06, supra, Reasons, point 16), but it does not have the effect of formally incorporating the Directive into the legal system of the EPC.

XV.1.1 The Enlarged Board takes note of the EPO President's submission that the EPC legislator's intention was to bring the EPC into full alignment with the EU Biotechnology Directive (point 94 of the referral). He also points out that, of the 19 Contracting States that existed at the time Rule 26(1) EPC was adopted, 15 were the same EU Member States that had shortly before adopted the EU Biotech Directive. The EPO President concludes from this that the EPC legislator had the same intention as the EU legislator. He further concludes that, for the question at issue, this should mean that the EPC legislator agreed that, based on Rule 26(1) EPC, Article 53(b) EPC is to be interpreted in the light of this legislative intent and that products (plants and animals) exclusively obtained by essentially biological processes shall not be patentable.

XV.1.2 However, in the view of the Enlarged Board, even if, by adopting Rule 26(1) EPC, the EPC legislator intended to align the EPC with the EU Biotech Directive, the Directive itself does not directly lead to the conclusion, drawn by the EPO President, that the EPC legislator intended Article 53(b) EPC to be interpreted as excluding from patentability products (plants and animals) exclusively obtained by essentially biological processes.

As already explained in decision G 2/12 (supra, Reasons, points VII.4.(2) and (3)), the exception to patentability according to Article 53(b) EPC is worded identically to Article 4(1)(b) EU Biotech Directive. Article 4(2) EU Biotech stipulates that "inventions which concerns plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety". Article 3 Biotech Directive allows the patenting of "inventions which are new, which involve an inventive step and which are susceptible of industrial application ... even if they concern a product consisting of or containing biological

material or a process by means of which biological material is produced, processed or used".

XV.1.3 Thus, neither Rule 26 EPC as such nor the very wording of the EU Biotech Directive, to which Rule 26(1) EPC refers, lead directly to an interpretation of Article 53(b) EPC which would expand the process exclusion to the products of such processes.

XV.2 In 2016 the EU Commission issued a Notice of interpretation of the EU Biotech Directive (supra) in reaction to decision G 2/12 (supra), in which it took the view that the EU legislator's intention in adopting the EU Biotech Directive was to exclude from patentability products (plants/animals and plant/animal parts) obtained by means of essentially biological processes.

XV.2.1 The Enlarged Board is familiar with the travaux préparatoires to the EU Commission's Notice of interpretation, mentioned in the introduction of said Notice, in particular the European Parliament resolution of 17 December 2015 on patents and plant breeders' rights (2015/2981(RSP), P8_TA(2015)0473) calling on the EU Commission to clarify the scope and interpretation of the EU Biotech Directive regarding the prohibition of the patentability of products obtained from essentially biological processes. Likewise, the Enlarged Board takes note of the European Parliament's resolutions of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP), T7-0202/2012) and of 19 September 2019 on the patentability of plants and essentially biological processes (2019/2800(RSP), P9_TA(2019)0020). Equally, the Enlarged Board takes note of the report of the EU expert group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973) dated 17 May 2016 (Ref. Ares(2016)5165507 - 12/09/2016), and of the conclusions of the Council of the EU on the EU Commission's Notice of interpretation and on the legal protection of biotechnological inventions (OJ EU 2017 C 65/2), endorsing said Notice and urging the EU member states, in their capacity as members of the EPOrg, to advocate that the practice of the EPO be aligned with these conclusions.

XV.2.2 As to the legal nature of the EU Commission's Notice of interpretation, the Notice itself explains:

"[...]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 prejudice any future position of the Commission on the matter. Only the Court of Justice of the European Union is competent to interpret Union law."

It follows clearly from this proviso that the EU Commission's Notice of interpretation is not legally binding but is intended as an internal document aimed at reducing the risk of divergent legal interpretations and promoting the harmonised application and implementation of the law of the EU (hereinafter Union law) by EU institutions and EU member states. Notices of the EU Commission do not figure on the list of EU legal instruments which are the secondary sources of Union law (Article 288 of the Treaty on the Functioning

of the European Union (TFEU), consolidated version 2016). The list mentions as legally binding acts only regulations, directives and decisions, whereas recommendations and opinions are described as non-binding. "Notices" are not mentioned at all. They, like resolutions, declarations and action programmes, constitute other forms of action for forming and shaping the EU legal order, but do not qualify as legal acts.

XV.2.3 At any rate, the EU Commission's Notice of interpretation does not prejudice the interpretation of the EU Biotech Directive by the competent EU organ. The legally effective and binding interpretation of Union law, whether provisions of primary law, e.g. the treaties, or of secondary law, e.g. regulations and directives, lies within the exclusive competence of the Court of Justice of the European Union (CJEU), which has the interpretative supremacy with respect to Union law (Article 19(3)(b) of the Treaty on EU (TEU), consolidated version 2016, in combination with Article 267 TFEU). To date, no decision concerning the exception to patentability in respect of animals, plants or plant materials obtained by an essentially biological process and the interpretation of Article 4 EU Biotech Directive has been handed down by the CJEU.

XV.2.4 Irrespective of this, as an independent international organisation with its own autonomous legal order, the EPOrg is not directly bound by Union law. It is therefore all the more true that a legally non-binding Notice on the interpretation of the EU Biotech Directive issued by the EU Commission in reaction to decisions of the Enlarged Board on the interpretation of a provision of the EPC, i.e. Article 53(b) EPC, does not form part of EPC law.

XV.3 The EPO President refers to legislative and administrative developments in the EPC Contracting States which should be taken into account in the interpretation of Article 53(b) EPC.

XV.3.1 In the national legislation of 10 of the 38 Contracting states, plant or animal products obtained by essentially biological processes are excluded from patentability. This exception to patentability was already law in three Contracting States before decision G 2/12 (supra) was issued:

- Germany, § 2a(1) No. 1 German Patent Act 1936 (Patentgesetz), as published on 16 December 1980, § 2a(1) No. 1 introduced in October 2013;

- The Netherlands, Article 3(1), lit. c. and d., Dutch Patent Act 1995 (Rijkssoctrooiwet 1995), valid from 5 June 2008; and

- Italy, subject to additional conditions, Article 45.4.b of the Italian Industrial Property Code (IIPC, Decreto Legislativo 10 febbraio 2005, n. 30 Codice della proprietà industriale) as amended in 2010.

Seven Contracting States amended their law after that decision:

- Austria, § 2(2) of the Austrian Patent Law 1970 (Patentgesetz) in the version published in the Official Journal on 1 August 2016;

- Belgium, Article XI.5 § 1er, 3°, of the Belgian Code of Economic Law (Code de droit économique -

Dispositions relatives au droit d'obtenteur) 2013 was amended with effect from 1 June 2019;

- France, Article L611-19, I 3^obis, of the French Patent Act (Code de la propriété intellectuelle), as modified by Article 9 of the Law n° 2016-1087 of 8 August 2016 for the recovery of biodiversity, nature and landscapes;

- Norway, Section C - chapter IV - 2a.3.2 of the examination guidelines of the Norwegian Intellectual Property Office, although Section 1(4) of the Norwegian patent law (Lov om patenter (patentloven) av 15. desember 1967 nr 9), last amended in 2013, does not deal with products obtained by essentially biological processes;

- Poland, Article 29(1)(ii) of the Polish Act of 30 June 2000 on Industrial Property Law (IPL), as amended by Article 1(4) of the Act of 16 October 2019 (Journal of Laws of 2019. Pos. 2309);

- Portugal, Article 52(3)c) of the Portuguese Industrial Property Code 2018 (Código da Propriedade Industrial - IPC), Decree-Law 110/2018 of 10 December 2018, which entered into force on 1 July 2019; and - Serbia, Article 9(3) of the Patent Law 2011, in the version of 16 December 2018.

XV.3.2 The Enlarged Board takes note of these legislative and administrative developments in roughly a quarter of the Contracting States, which have resulted in national patent protection no longer being granted for animals, plants or plant materials exclusively obtained by means of an essentially biological process. The EPO President also submits that similar developments were planned in two other Contracting States (Croatia and Finland) and that all Contracting States which are EU Member States have declared vis-à-vis the EU that their national law and practice is in line with the EU Commission's Notice of interpretation (point 104 of the referral). However, such developments do not amount to a subsequent agreement between "the" - to be understood as "all" - contracting parties regarding the interpretation or the application of Article 53(b) EPC, as required by Article 31(3)(a) Vienna Convention. Nor do they constitute subsequent practice in the application of the EPC which establishes the agreement of "the" - again to be understood as "all" - contracting parties regarding the interpretation of Article 53(b) EPC, as required by Article 31(3)(b) Vienna Convention.

Further considerations

Historical interpretation

XVI. Under Article 32 Vienna Convention, recourse may be had to supplementary means of interpretation, particularly the preparatory work for a treaty and the circumstances in which it was concluded, in order to confirm the meaning arrived at by the application of Article 31 or to determine the meaning when the application of Article 31 either (a) leaves the meaning ambiguous or obscure, or (b) produces a meaning which is obviously nonsensical or unreasonable (see J 8/82, OJ EPO 1984, 155, Reasons, point 13; J 4/91, OJ EPO 1992, 402, Reasons, point 2.4.2; T 128/82, OJ EPO 1984, 164, Reasons, point 9; G 1/98, supra, Reasons, points 3.4 et seq.; G 2/07 and G 1/08, supra, Reasons, point 4.3; G 2/12, supra, Reasons, point VII.5.(1)).

XVII. The Enlarged Board has dealt with the legislative history of Article 53(b) EPC on several occasions and, in line with the generally recognised principle of international law recognised in Article 32 Vienna Convention, has made use of material relating to the genesis of the EPC as a supplementary means of interpreting this provision.

In this regard, the Enlarged Board confirms its conclusions in decisions G 1/98 (supra, Reasons, points 3.4 et seq., in particular points 3.6 and 3.7), G 2/07 and G 1/08 (supra, Reasons, point 6.4.2.2) and G 2/12 (supra, Reasons, points VII.5.(2) to (5)) that in the context of the historical discussion about what kind of inventive processes, if any, should be excluded from patentability, there is no evidence in the travaux préparatoires of the EPC that a product that is characterised by the method of its manufacture but claims protection regardless of that (or any other) method was meant to be excluded.

Dynamic interpretation in the light of Rule 28(2) EPC

XVIII. As set out above, the Enlarged Board in its current composition endorses both the conclusions and the reasoning of decision G 2/12 (supra). However, this is not to say that, with decision G 2/12, the meaning of the exception to patentability under Article 53(b) EPC has been settled once and for all, for it may emerge at a later point that there are aspects or developments which were unknown at the time the decision was issued or irrelevant to the case, or were otherwise not taken into consideration.

XIX. The Board of Appeal in decision T 1063/18 (supra, Reasons, points 31 to 36) concluded that the adoption of Rule 28(2) EPC was not a new development which was to be taken into account in interpreting Article 53(b) EPC, in particular because the Administrative Council lacked competence to "amend" that Article by means of the Implementing Regulations. The Board's conclusion seems to have been based on the notion that in decision G 2/12 (supra) the Enlarged Board gave a definitive interpretation of the scope of the exception to patentability, which could only be overturned by a formal amendment of Article 53(b) EPC itself.

XX. However, this notion, which is not supported by the EPC itself or by any general legal principle, is too strict, bearing in mind that Article 53(b) EPC has been acknowledged to be open to interpretation and, furthermore, that a subsequently made Rule which diverges from a particular interpretation of an EPC Article by a Board of Appeal is not per se ultra vires (see T 315/03, supra, Reasons, point 7.3).

A particular interpretation which has been given to a legal provision can never be taken as carved in stone, because the meaning of the provision may change or evolve over time. This aspect is intrinsic to the ongoing development of the law by way of judicial decision-making, and, in the context of the jurisprudence of the Boards of Appeal, is reflected in Article 21 RPBA 2020, which requires a Board of Appeal to make a referral to the Enlarged Board if it intends to deviate from an earlier decision or opinion of the Enlarged Board. Such a new referral would be pointless if there was no possibility,

not even a theoretical one, that the Enlarged Board would revise its previous ruling on the point of law in question.

Whether a change of interpretation effected by a Rule complies with the rule of law, in the sense that it remains within the legal limits set by the relevant Article, is a separate consideration.

XXI. As a consequence, the understanding of the scope of the exception to patentability under Article 53(b) EPC which the Enlarged Board came to in decision G 2/12 (supra) may still be subject to later developments, be they legal, or even practical or factual.

XXII. In cases G 3/98 (supra, 76 et seq., Reasons, point 2.5 et seq.) and G 2/12 (supra, Reasons, point VIII.1.(1)), the Enlarged Board referred to a further approach to construing a legal term or provision of the EPC, namely, the “dynamic interpretation”. This method of interpretation could come into play where considerations have arisen since the Convention was signed which might give reason to believe that a literal interpretation of the provision’s wording would conflict with the legislator’s aims. It might thus lead to a result which diverges from the wording of the law.

XXIII. Article 53(b) EPC has remained unamended since the drafting of the EPC, in spite of the significant changes made in the context of the EPC 2000 revision. Its legislative purpose is still applicable (see in this regard G 2/07 and G 1/08, supra, Reasons, point 6.4.2.2, also referred to in G 2/12, supra, Reasons, point VIII.1.(2)).

XXIV. However, although neither the Contracting States, in accordance with Article 172 EPC, nor the Administrative Council, in accordance with Article 33(1)(b) EPC, has formally amended Article 53(b) EPC to extend the scope of the process exclusion to animals, plants and plant material obtained by essentially biological processes, when now interpreting Article 53(b) EPC, the Enlarged Board cannot ignore the Administrative Council’s decision to introduce a new paragraph 2 in Rule 28 EPC.

XXV. In this regard, the Enlarged Board is aware of the argument put forward in some amicus curiae briefs, in particular by Professor M. Haedicke, that, in adopting Rule 28(2) EPC, the Administrative Council, being the body competent to adopt secondary law, i.e. the Implementing Regulations, breached its duty of loyalty to, or of loyal cooperation with, the judiciary, i.e. the Boards of Appeal and in particular the Enlarged Board of Appeal. It was further argued that any attempt to establish a certain interpretation of an Article of the EPC by regulatory means requires a formal amendment of the Article itself.

These concepts are part of the established rule-of-law principles which underpin the doctrine of the separation of powers. Another aspect according to German constitutional law is the “essentiality” theory (“Wesentlichkeitsprinzip”), according to which legislative decisions on matters of fundamental or essential importance are reserved to the legislature (Parliament). Decisions of this nature must not be left to

administrative bodies to make by means of administrative regulations.

XXV.1 The EPOrg is an intergovernmental organisation founded under international law by nation states, i.e. the Contracting States, in accordance with their respective constitutional structures, and it too is governed by the rule of law (see G 3/08, supra, point 7.2.1, with further references to the case law of the Enlarged Board of Appeal and the Boards of Appeal). The principles underpinning the rule of law have been subscribed to in substance at national level by all the Contracting States, despite their differing constitutional traditions.

XXV.2 However, the precise scope of these principles and their implementation need to reflect the specific nature and organisational structure of the EPOrg. The structure of the EPOrg is established in Article 4(2) EPC, which provides for two organs, i.e. the EPO and the Administrative Council, with the task of granting European patents to be carried out by the EPO under the supervision of the Administrative Council (Article 4(3) EPC). In this respect, both the EPO and the Administrative Council have an executive function. In addition, the Administrative Council is the body competent to adopt secondary legislation in accordance with Article 33 EPC. The Boards of Appeal are assigned the role of an independent judiciary in the European patent system (Articles 21 to 23 EPC; G 6/95, OJ EPO 1996, 649, Reasons, points 2 et seq.), even if a separate organisational unit with increased organisational and managerial autonomy (CA/43/16 Rev.1), they are still, pursuant to Article 4(2) EPC, not an organ of the EPOrg but structurally integrated into the EPO under Article 15 EPC.

Notably, however, the EPOrg has no parliament equivalent to the legislature which forms part of the constitutional arrangements of the Contracting States.

XXV.3 In view of the particular structural organisation and constitution of the EPOrg, there is no foundation for the amicus curiae opinion that the Administrative Council’s adoption of Rule 28(2) EPC violated the doctrine of separation of powers and the “essentiality” theory.

XXV.3.1 First, regardless of a general duty of loyalty among all organs and bodies, the Enlarged Board cannot deduce from the doctrine of separation of powers that there is a general prohibition on adopting secondary legislation, here Rule 28(2) EPC, which concerns the interpretation of a provision of primary legislation, here Article 53(b) EPC, given by a court, here the Enlarged Board. This argument does not even address the actual point of law underlying the re-phrased question, which is not directed to Rule 28(2) EPC but to the issue of a potentially new interpretation of Article 53(b) EPC itself by the Enlarged Board as the competent independent judicial body according to Article 112(1) EPC.

XXV.3.2 Secondly, since the EPOrg has no parliament, the “essentiality” theory cannot be directly applied. Even if this principle were to be understood as meaning that it would be for the Contracting States alone to amend Article 53(b) EPC in the context of a revision of the EPC pursuant to Article 172 EPC, this would be too

restrictive as it would ignore the possibility that the Administrative Council has to amend Article 53(b) EPC using its powers under Articles 33(1)(b) and 35(3) EPC. Furthermore, this argument does not relate either to the point of law underlying the re-phrased question, as explained in the preceding paragraph.

XXV.3.3 Hence, neither the doctrine of separation of powers nor the “essentiality” theory per se call for the fact of Rule 28(2) EPC’s adoption to be disregarded for the purpose of interpreting Article 53(b) EPC.

XXVI. The amendment of the Implementing Rules by the introduction of Rule 28(2) EPC was proposed and adopted after decision G 2/12 (supra) was issued. Therefore it is necessary to examine whether and, if so, to what extent this new development justifies a dynamic interpretation of Article 53(b) EPC.

XXVI.1 In this context, the Enlarged Board takes note of the travaux préparatoires for Rule 28(2) EPC:

- CA/PL PV 45, Minutes of the 45th meeting of the Committee on Patent Law (Munich, 15 September 2015), points 58 – 72, 80;

- CA/PL 12/15, Presentation given at the 45th meeting of the Committee on Patent Law – Update on the EPO practice with regard to Tomatoes II / Broccoli II, dated 6 November 2015;

- CA/PL 3/16, EPO legal framework and practice with regard to the patentability of plant-related inventions, dated 25 April 2016;

- CA/PL 4/16, Patentability of biotechnological inventions – practice in EPC contracting and observer states, dated 6 April 2016;

- CA/PL 4/16 Add. 1, Patentability of biotechnological inventions – practice in EPC contracting and observer states, dated 22 April 2016;

- CA/PL 4/16 Add. 2, Patentability of biotechnological inventions – practice in EPC contracting and observer states, dated 6 May 2016;

- CA/PL 4/16 Add. 3, Patentability of biotechnological inventions – practice in EPC contracting and observer states, dated 9 May 2016;

- CA/PL 4/16 Add. 4, Patentability of biotechnological inventions – practice in EPC contracting and observer states, dated 22 November 2016;

- CA/PL PV 46, Minutes of the 46th meeting of the Committee on Patent Law (Munich, 12 May 2016), points 21 – 41; - CA/PL PV 47, Minutes of the 47th meeting of the Committee on Patent Law (Munich, 21 and 22 November 2016), points 4 – 42;

- CA/PL 18/16, Presentation given at the 47th meeting of the Committee on Patent Law – Commission Notice of 3 November 2016 on certain articles of Directive 98/44/EC (pub. OJ EU C 411 of 8.11.2016, p. 3), dated 30 November 2016;

- CA/PL 4/17, Patentability under the EPC of plants and animals produced by essentially biological processes following the EU Commission Notice of 3 November 2016 on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, dated 27 March 2017;

- CA/PL 4/17 Add. 1, Presentation given at the 48th meeting of the Committee on Patent Law – Patentability under the EPC of plants and animals produced by essentially biological processes following the EU Commission Notice of 3 November 2016 on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, document dated 16 May 2017;

- CA/PL 6/17, EPO stay of proceedings for inventions concerning plants or animals obtained by means of essentially biological processes – CIPA position paper, dated 13 March 2017;

- CA/PL 8/17, Patentability under the EPC of plants and animals produced by essentially biological processes following the EU Commission Notice of 3 November 2016 on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions – Comments by BUSINESSSEUROPE, dated 24 April 2017;

- CA/PL 9/17, Patentability under the EPC of plants and animals produced by essentially biological processes following the EU Commission Notice of 3 November 2016 on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions – Comments by epi, dated 25 April 2017;

- CA/PL PV 48, Minutes of the 48th meeting of the Committee on Patent Law (Munich, 27 and 28 April 2017), points 8 – 92;

- CA/56/17, Exclusion from patentability under Article 53(b) EPC of plants and animals produced by essentially biological processes – amendment of Rules 27(b) and 28 EPC, dated 6 June 2017;

- CA/PV 152, Minutes of the 152nd meeting of the Administrative Council (The Hague, 28 and 29 June 2017), points 128 – 144;

- CA/72/17, Summary of decisions of the 152nd meeting of the Administrative Council (The Hague, 28 and 29 June 2017), points 14, 37 – 39.

XXVI.2 The Enlarged Board is also aware of the follow-up documents on the patentability of inventions concerning plants and animals under the EPC: - CA/PL 3/18, Update on the patentability of inventions concerning plants and animals under the EPC, dated 30 January 2018, and - CA/PL PV 49, Minutes of the 49th meeting of the Committee on Patent Law (Munich, 20 February 2018), 19 – 26 (discussing the previous document).

XXVI.3 Having regard to the wording of Rule 28(2) EPC and the travaux préparatoires for that Rule, the Enlarged Board accepts that it was the EPC legislator’s intention to establish, by this means, a particular interpretation of Article 53(b) EPC, which is that plants or animals exclusively obtained by means of an essentially biological process are excluded from patentability.

As set out above, the application of the various methods of interpretation provided for in Articles 31 and 32 Vienna Convention, which also takes into account the

subsequent developments in the Contracting States, does not lead to the finding that the term "essentially biological processes for the production of plants" in Article 53(b) EPC is to be read clearly and unambiguously as extending to products defined or obtained by such processes. The Enlarged Board therefore endorses the respective conclusions that it came to in G 2/12 (supra, Reasons, point VII.6.(2) and (3)).

XXVI.4 At the same time, however, the Enlarged Board acknowledges that Article 53(b) EPC does not prohibit this broader understanding of the process exclusion either. Furthermore, the Enlarged Board recognises that, with the introduction of Rule 28(2) EPC, the legal and factual situation underlying decision G 2/12 (supra) has substantially changed. This amendment constitutes a new aspect or consideration which has arisen since the EPC was signed which may give reason to believe that a grammatical, and restrictive, interpretation of the wording of Article 53(b) EPC conflicts with the legislator's aims, whereas a dynamic interpretation may bring a result that diverges from the wording of the law. XXVI.5 The vast majority of the Contracting States represented in the Administrative Council voted in favour of introducing Rule 28(2) EPC (for: 35; against: 1; abstentions: 1; not present: 1; see: minutes of the 152nd meeting of the Administrative Council of 28 and 29 June 2017, CA/PV 152). This demonstrates how far the Contracting States' intention and aims with regard to Article 53(b) EPC have evolved since decision G 2/12 was issued. In addition, a significant number of them have aligned their national provisions to the content of Rule 28(2) EPC.

XXVI.6 It must therefore be concluded that, in introducing Rule 28(2) EPC, the Contracting States intended that plants, plant material or animals are to be excluded from patentability, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature define an essentially biological process. The Enlarged Board takes the view that this exclusion is not incompatible with the wording of Article 53(b) EPC, which, as discussed, does not rule out this broader construction of the term "essentially biological processes for the production of plants or animals". Bearing in mind the rather exceptional circumstances which marked the various approaches for determining the scope of the process exclusion in Article 53(b) EPC up to now, Rule 28(2) EPC could be considered to reflect the Contracting States' intention to give a special meaning to that term.

XXVI.7 Finally, the Enlarged Board concludes that, in view of the clear legislative intent of the Contracting States as represented in the Administrative Council and having regard to Article 31(4) Vienna Convention, the introduction of Rule 28(2) EPC allows and indeed calls for a dynamic interpretation of Article 53(b) EPC.

XXVI.8 The Enlarged Board accordingly abandons the interpretation of Article 53(b) EPC given in decision G 2/12 (supra) and, in the light of Rule 28(2) EPC, holds that the term "essentially biological processes for the

production of plants or animals" in Article 53(b) EPC is to be understood and applied as extending to products exclusively obtained by means of an essentially biological process or if the claimed process feature defines an essentially biological process.

Additional matters

Compliance with Article 164(2) EPC

XXVII. As the content of Rule 28(2) EPC does not stand in contradiction to the new interpretation of Article 53(b) EPC given in this opinion, there is no conflict between these provisions. Hence, Article 164(2) EPC, which provides that an Article of the EPC prevails over a conflicting Rule of the Implementing Regulations, and which was applied by the Board of Appeal in decision T 1063/18 (supra) in view of the previous interpretation of Article 53(b) EPC given in decision G 2/12 (supra), is not relevant. Consequences of the new interpretation of Article 53(b) EPC for granted European patents and pending European patent applications

XXVIII. The new understanding of Article 53(b) EPC which has resulted from the Enlarged Board's dynamic interpretation of this provision has a negative effect on the allowability of product claims or product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature define an essentially biological process.

XXIX. In order to ensure legal certainty and to protect the legitimate interests of patent proprietors and applicants, the Enlarged Board considers it appropriate that the new interpretation of Article 53(b) EPC given in this opinion has no retroactive effect on European patents containing such claims which were granted before 1 July 2017, when Rule 28(2) EPC entered into force, or on pending European patent applications seeking protection for such claims which were filed before that date. For applications, the relevant date is their date of filing or, if priority has been claimed, their priority date.

CONCLUSION

Based on its understanding of the true object of the point of law referred to it by the President of the European Patent Office and on its findings above, the Enlarged Board of Appeal answers this point as follows:

Taking into account developments after decisions G 2/12 and G 2/13 of the Enlarged Board of Appeal, the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC has a negative effect on the allowability of product claims and product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process.

This negative effect does not apply to European patents granted before 1 July 2017 and European patent applications which were filed before that date and are still pending.
