G 3/19 'PEPPER' – PATENTABILITY OF PLANTS OBTAINED BY BREEDING PROCESSES. IS THIS THE END?

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On 14 May 2020, the Enlarged Board of Appeal (EBA) in decision G 3/19 'Pepper'[1] at first sight put an end to the debate about the patentability of breeding methods and plants obtained therefrom, which split the seed industry into an 'anti-patent' fraction consisting of seed and farmers associations, NGOs, and the majority of the EU Member States, and a pro-patent fraction consisting of multinational seed and crop protection companies and IP professional organisations. The debate was fuelled by a concern that patents on plants obtained by breeding processes could negatively affect the 'freedom-to-breed'[2] for European breeders and eventually hamper the improvement of plant varieties. The decision came more than 20 years after the filing of the Tomato and Broccoli patents,[3] which started the debate, and almost ten years after the first out of six decisions of the EBA in that matter in the meantime.

This article discusses what has been decided, the practical and judicial implications and the issues left open, and attempts a look into the crystal ball to see what may come next.

1. A Short Review of the Case History

In G 2/07–G 1/8 (Broccoli/Tomato I)[4] the EBA decided that a process for the production of plants is excluded from patentability if it contains steps of sexually crossing and subsequent selection,[5] irrespective of additional steps of a technical nature[6] even if those are new, fundamental, or the essence of the invention.[7] A narrow exception is provided if a step of a technical nature introduces or modifies a trait in the plant genome, provided that the trait is not the result of a sexual crossing,[8] and provided that 'such additional step is performed *within* the steps of sexually crossing and selection'.[9] The decision has been reviewed in detail elsewhere.[10] In G 2/12–G 2/13 (Broccoli/Tomato II)[11] the EBA found that Article 53(b) EPC did not exclude plant and animal products produced by essentially biological processes from patentability. The decision has been reviewed in detail elsewhere.[12]

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1) Available at: http://documents.epo.org/projects/babylon/eponet.nsf/0/44CCAF7944B9BF42C12585680031505A/$File/G_3-19_opinion_EBoA_20200514_en.pdf.

2) The majority of plant varieties in the EU today are solely covered by plant breeders' rights (PBR). The PBR breeders' exemption enables breeders to use any protected material to breed and develop new varieties. With the avoidable, narrow exception for essentially derived varieties breeders can always commercialise the resulting new varieties. Thus, freedom-to-operate is easy to manage and to obtain. The opposite is true for the use of varieties covered by a patent: while the use for breeding is allowed, commercialisation requires a licence if the resulting plant is still covered by the patent because, for example, it still includes the trait protected by the patent.

3) EP 1 069 819 (Broccoli), priority: 9 April 1998, filed: 21 October 1999.

4) G 2/07–G 1/08 (Broccoli and Tomato I), decision of 9 December 2010; OJ EPO 2012, 130, 206.

5) Ibid., Hn.1.

6) Ibid., Hn.2.

7) Ibid., Hn.4.

8) Ibid., Hn.3.

9) Ibid., 6.4.2.3 (pp. 69–70). This exception from the exception seems to have no practical value.

10) Reviewed in SJR Bostyn, (2007) *BioScience Law Review* 9(4),146–155; SJR Bostyn, (2013) *Journal of World Intellectual Property* 16 (3-4), 105–149; M Blakeney, (2012) J. Exp. Bot. 63 (3), 1069–1074; S Sterckx, (2009) *Journal of World Intellectual Property*, 13(1),1–23; MA Kock, (2007) *Journal of Intellectual Property Law & Practice* 2(5) 286–297.

11) G 2/12– G 2/13 (Broccoli & Tomato II), decision of March 25, OJ EPO 2016,22.

12) Kock M (2015) Bio-Science Law Review, 14(4), 167–176; Kock MA (2017) Bio-Science Law Review, 15(6), 231; Kock MA, Patenting non-transgenic plants in the EU. In Research Handbook on Intellectual Property and the Life Sciences (Ed. Matthews D, and Zech H). 2017: 132–159; Kock MA, Zech H (2017) GRUR 10:1004-1016; Snodin M, CIPA Journal (1997) Volume 46, number 7-8, p. 11–14; Kock MA, Morgan G (2017) Bio-Science Law Review 16(3):123-128; Kock MA (2018) Life Science Recht 1:54–58.

The G 2/12–G 2/13 decision led the EU Commission to issue a notice in November 2016 ('Com Notice')[13] expressing the view that the EU Biotech Directive[14] intends to exclude products produced by natural processes from patentability. Following the Com Notice and a proposal by the Patent Law Committee under Administrative Council (AC) of European Patent Office (EPO) ('AC Proposal')[15] the AC decided to amend the Implementing Regulations of the European Patent Convention (EPC) to include a new Rule 28(2) EPC. The new Rule stated that products produced exclusively by an essentially biological process are excluded from patentability. In T 1063/18 (Pepper)[16] the Board of Appeal found that Rule 28(2) EPC was in conflict with the prior interpretation of Article 53(b) EPC in G 2/12–G 2/13 (Broccoli/Tomato II) and therefore void. The Board in Pepper saw no need to refer the issue to the EBA as the EBA had already decided on the question in G 2/12–G 2/13 (Broccoli/Tomato II).

2. The G 3/19 Referral and Decision

The decision T 1063/18 (Pepper) prompted the EPO President to refer two questions to the EBA in April 2019. The first question[17] asked whether the AC is permitted to amend the Rules of the EPC to conflict with or overrule a previous interpretation of the Articles by the EBA. Provided the EBA confirms the power of the AC, the second question[18] asked the EBA to confirm the validity of Rule 28(2) EPC. As the referral came from the President, the patent applicant in the Pepper case was not a party before the EBA and there were no oral proceedings. However, the EBA took into account 41 amicus curiae briefs from companies, law firms, NGOs, breeders, industry and IP organisations.[19]

2.1 Admissibility

Before addressing the questions, the EBA had to assess the admissibility of the referral. According to Article 112(1) EPC to be admissible a referral must relate (i) to a point of law of fundamental importance and (ii) to a question on which there are conflicting decisions by the Board of Appeal.

With respect to the first requirement the EBA acknowledged that '*the legislator's intention to harmonise the EPO's approach to the patentability requirements for biotechnological inventions […], the legal principles relating to conflicts of legal norms […], and the relevance of the referral for numerous other pending and future cases*' provide arguments for a point of law of fundamental importance.[20]

For the second requirement, the EBA stated that '*[w]hether the present referral complies with the requirement of different decisions […] is not immediately apparent. However, what is evident is a conflict between, on the one hand, decision T 1063/18 […] and, on the other hand, the regulatory intention underlying Rule 28(2) EPC […].*'[21] However, the EBA rejected the EPO President's suggestion that such conflict should be sufficient and that Article 112(1)(b) EPC could be applied by analogy as '*neither plausible nor appropriate*'.[22]

Nevertheless the EBA assisted the President to overcome the hurdle of admissibility. The EBA saw T 272/95[23] in conflict with T 1063/18 (Pepper). In T 272/95 the Board considered the AC's amendment of Rules 23b and 23a EPC in view of the Biotech Directive. This amendment changed the previous practice applied by the office and the Boards of Appeal. In T 272/95 the Board found that the new Rules are a binding

13) Commission Notice of 3 November 2016 on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (OJ 2016/C 411/03 – 14). While the Com Notice has officially no binding character, the Com Notice was the product of a request from the EU legislator and in that respect may have a quasi-law status.

14) Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions OJ L 213, 30.7.1998, p. 13–21.

15) Proposal submitted by the President of the European Patent Office to the Administrative Council relating to '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.' Document CA/56/17 (06.06.2017).

16) Available under http://documents.epo.org/projects/babylon/eponet.nsf/0/426B74FD32463ACEC1258398003EA3F4/$File/T_1063-18_en.pdf.

17) Question 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?

18) Question 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?

19) Available under https://www.epo.org/law-practice/case-law-appeals/eba/pending/g3-19.html.

20) G 3/19 (Fn. 1), V.2, p.29–30.

21) G 3/19 (Fn. 1), VI.3, p.31–32.

22) G 3/19 (Fn. 1), VI.6.1, p.36.

23) T 0272/95 (Relaxin/HOWARD FLOREY INSTITUTE), decision of 23.10.2002.

interpretation of Article 53(b) EPC, which – in view of the EBA in G 3/19 – provides an example that a new Rule can change a previous interpretation of the Articles. According to the EBA this decision is therefore in conflict with T 1063/18 which found otherwise. The President's referral was therefore found admissible.

However, these arguments are not persuasive. For the Rules assessed in T 272/95 there has been a prior deviating practice by the examination division and the Boards of Appeal, which are both bound by the Rules unless there is a deviating decision by the EBA. This practice was effectively changed and overruled by the implementation of the new Rules. However, there has not been a decision of the EBA, which had to be changed and overruled, and which is NOT bound by the Rules but by the Articles of the EPC alone. To the contrary: with respect to the patentability of plants, the EBA in G 1/98[24] confirmed the conformity of the interpretation provided by the new Rules with the EPC. The opposite is the case in the present situation: the EBA in G 2/12 decided that the exception for essentially biological process has no impact on the patentability of resulting plants. Thus, the Board of Appeal in T 1063/18 ('Pepper') did not decide that a Rule cannot change a previous interpretation of the EPC *per se*. The Board decided that a Rule, which has the function to interpret the EPC, cannot change a previous interpretation of the EPC provided by the EBA as the highest authority for the interpretation of the EPC.

Thus, to enable admissibility the EBA 'designed' a conflict, which in fact does not exist. In doing so, the EBA achieved what it – according to its own words in G 3/19 – did not want to do: render a decision on the hierarchy of norms, blur the separation of powers, and grant the AC 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*.'[25] The EBA thereby opened '*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*.'[26]

With respect to the 'essentiality' theory, according to which legislative decisions on matters of fundamental or essential importance are reserved to the legislature, the EBA argued that '*since the EPOrg has no parliament, the "essentiality" theory cannot be directly applied*.' A narrow application '*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*.'[27] Based on these statements it seems that the EBA finds the legal basis for the AC to overrule an interpretation of the EBA in Articles 33(1)(b) and 35(3) EPC. While indeed these Articles could provide such a basis, the EBA in the present case conveniently ignored two points:

(i) In adapting Rule 28(2), the AC has specifically NOT brought the EPC '*into line with […] European Community legislation relating to patents*'. To the contrary: As the EBA acknowledged, Rule 28(2) has been motivated by the Com Notice[28], which has no legally binding character[29]. In addition, the AC failed to correct the lack of alignment in the definition of 'essentially biological processes' between G 2/07–G 2/08 (Broccoli and Tomato I) and the Biotech Directive, despite a clear guidance in the Com Notice for narrow definition (see under 3.4.3(ii)).

(ii) More importantly, the vote for Rule 28(2) EPC was not unanimous and not taken with all the Contracting States represented as required by Article 35(3) EPC for any change under Article 35(1)(b) EPC. There was one vote against, one abstention, and one absence, as the EBA was clearly aware of.[30]

If the EBA saw the legal basis for an empowerment of the AC to overrule a prior decision of the EBA by a new Rule in Articles 33(1)(b) and 35(3) EPC, then in the case of Rule 28(2) EPC the legal requirements have not been fulfilled. However,

24) G 1/98 (Transgenic Plant/Novartis II), decision of 20.12.1999, OJ 1991,155; GRUR Int 2000, 431.

25) G 3/19 (Fn. 1); II-5; p.25–26.

26) G 3/19 (Fn. 1); II-5; p.25–26.

27) G 3/19 (Fn. 1); XXV.3.2, p.60.

28) Fn. 13.

29) G 3/19 (Fn. 1); XV.2.2-XV.2.3, p.50–51. While the Com Notice has officially no binding character, it should be noted that the Com Notice was the product of a request from the EU legislator and in that respect may have a quasi-law status.

30) G 3/19 (Fn. 1), XXVI.5, p.63.

the EBA did not further investigate or elaborate on this point as for the EBA the issue was moot in view of the rephrased question: the rephrased questions no longer related to the introduction of Rule 28(2) EPC, but merely to the question whether Rule 28(2) EPC changed how the EBA could or should interpret Article 53(b) EPC.

By assuming that the process towards Rule 28(2) EPC has been valid, the EBA caused a substantial shift in power from the EBA to the AC and de facto abandoned the principle of separation of powers. It also substantially strengthened the dual function of the AC. While the EBA recognised that the AC has primarily an executive function it now also recognised its competence '*to adopt secondary legislation in accordance with Article 33 EPC*'.[31] The use of the term '*secondary legislation*' is telling. It is a common term to describe EU secondary legislation made by the EU institutions[32], but has almost never been used in relation to the EPO Implementing Regulations.[33] So far the AC's legislative power has been seen as quite limited and rather by a 'delegation of authority' from the Diplomatic Conference. Now G 3/19 by both terminology and essence seems to endorse a stronger legislative function of the AC than ever before. While the EBA explicitly confirmed its previous decisions in G 1/98, G 2/07–G 1/08, and G 2/12–13, it de facto abandoned – or at least amended – its decision in G 2/95, G 6/95, and G 1/02, where it found that '*the Administrative Council may not amend the Implementing Regulations in such a way that the effect of an amended Rule would be in conflict with the EPC itself.*'[34] A conflict with the EPC itself cannot be limited to a mere literal contradiction but needs to include also binding interpretations provided by the EBA. According to Article 22 and Article 112 EPC the Enlarged Board has the responsibility to decide on points of law i.e., to interpret the EPC. The Boards of Appeal, in particular the EBA, have jurisdiction to review the compliance of Rules with the Articles of the Convention.[35] The previous view that the EBA's authority to interpret the EPC is sole and undivided is now challenged.

It has become questionable whether the EBA can still be seen as the highest authority for the interpretation of the EPO. G 3/19 enables any amendment to the Articles 'by the backdoor' through a change of the Rules with a mere majority (sic!) of the AC, as long as the wording is not in an obvious contradiction with the Articles. This allows the AC to change essentially any interpretation of the EPC, as interpretations are only required where the wording is not sufficiently explicit. This empowers the AC to overrule the EBA by a new Rule whenever the AC feels fit, even without unanimous agreement by the contracting states or a diplomatic conference. As the EBA astutely notes '*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*'.[36] Unfortunately the EBA avoided such consideration. The resulting 'self-castration' of the EBA will raise questions as to its functioning as an independent body, free from the political influence of the President and the AC. As the AC unlikely would have acted without the Com Notice, G 3/19 also shows the influencing power of the EU and the EU Commission, which should be a concern for the non-EU contracting parties of the EPC.

2.2 Rephrasing the Questions

The EBA refused to accept the questions as referred. A positive answer to question 1 would '*give the Administrative Council […] 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.*'[37] Nevertheless, by deeming the case accessible and the Rule 28(2) EPC valid the EBA answered question 1 in the positive (see under 2.1).

31) G 3/19 (Fn. 1), XXV.2, p.59.

32) The five EU legal instruments specifically provided for in the Treaties are: Regulations, Directives, Decisions, Recommendations and Opinions.

33) A rare use of the term 'secondary legislation' with respect to the Rules is found in the EPO Strategic Plan 2023 (p.57); available under http://documents.epo.org/projects/babylon/eponet.nsf/o/2217F5B7CC07D47CC125841C00610386/$File/EPO_Strategic_Plan_2023_en.pdf.

34) G 6/95 (Interpretation of Rule 71a(1) EPC), decision of 24.7.1996, OJ EPO 1996, 649 – Reasons under 4.

35) Art 164(2) EPC; T 315/03, point 5.8 of the Reasons; T 39/93, point 3.2 of the Reasons.

36) G 3/19 (Fn. 1); XX., p.56.

37) G 3/19 (Fn. 1), II-5, p.26.

Also question 2 requires rephrasing as it '*already contains, in thinly disguised form, the answer that it seeks*'.[38] As the EBA deemed the two questions intrinsically interlinked it decided to merge and rephrase the '*referral's true object*' as follows:

> '*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?*' [39]

According to the EBA, the rephrased question addresses three points:[40]

(i) With regard to the exception to patentability of 'essentially biological processes', does Article 53(b) EPC permit only a single interpretation or could it bear a wider scope?

(ii) Does Article 53(b) EPC allow a dynamic interpretation i.e., that its meaning may change over time?

(iii) And if so, can an amendment to the Implementing Regulations give effect to such change of meaning?

2.3 The Decision

Most experts – this author included – believed that the EBA could not decide the question without amending either one (or all) of its earlier decisions related to the subject matter or confronting the AC in invalidating the new Rule 28(2) EPC. However, at least on first sight, the EBA seems to have found a 'diplomatic' answer to the dilemma.

As emphasised in multiple *Amicus curiae*, the EBA conceded that the grammatical, systematic and teleological interpretations of Article 53(b) EPC do not provide a basis for the AC's introduction of Rule 28(2) EPC. The EBA specifically confirmed that the Com Notice was not legally binding on the EPO and that '*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*'. Even if, the EBA emphasised that the EPO is independent of the EU and not bound by Union law. The EBA further stressed that the Rule 28(2)-like amendments in several EPC member states[41] are irrelevant and did not amount to an 'agreement' between the contracting states on the interpretation of Article 53(b) EPC. In consequence, the EBA confirmed all earlier decisions.

However, the EBA found rescue in the sole remaining resort: 'dynamic interpretation'. The EPO press release[42] explains: '*On the merits of the referral, the Enlarged Board endorsed its earlier findings on the scope of Article 53(b) EPC, which were based on the classical (i.e. the grammatical, systematic, teleological and historical) methods of interpretation. However, the Enlarged Board found that 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 meant that decisions G 2/12 and G 2/13 did not settle the meaning of Article 53(b) EPC once and for all. Taking account of the Administrative Council's decision to introduce Rule 28(2) EPC, the preparatory work on this provision and the circumstances of its adoption, as well as legislative developments in the EPC contracting states, the Enlarged Board concluded that new Rule 28(2) EPC allowed and indeed called for a dynamic interpretation of Article 53(b) EPC*.'

According to the EBA particular interpretation of the Articles are not 'carved in stone', but can be subject to later developments, 'be they legal, or even practical or factual'. Therefore, EBA found that '*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*

38) G 3/19 (Fn. 1), II-6, p.26.

39) G 3/19 (Fn. 1), III.3, p.27–28.

40) G 3/19 (Fn. 1), III.2, p.27.

41) Plant or animal products obtained by essentially biological processes are excluded from patentability in 10 of the 38 EPO Contracting States, and similar exclusions are planned in some other states.

42) Press Communiqué of 14 May 2020 concerning opinion G 3/19 of the Enlarged Board of Appeal. Available under: https://www.epo.org/law-practice/case-law-appeals/communications/2020/20200514.html.

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'.[43]

Leaving aside the question whether the AC in introducing Rule 28(2) over-reaches its powers, the EBA saw in Rule 28(2) EPC a clear intention of the contracting states to exclude plant and animal products produced by natural process from patentability: '*[T]he 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*'.[44]

While the EBA confirmed its previous interpretation of Article 53(b) EPC, it also found that the wording does not prohibit a 'broader understanding' i.e., the wording of Article 53(b) EPC was not incompatible with Rule 28(2) EPC. The EBA concluded: '*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*.'[45]

3. The Impact of the Decision

The EPO President alleges that the G 3/19 decision '*will bring greater legal certainty for patent applicants, and the general public, on what is a sensitive and complex issue that has legal, societal and economic implications*.'[46] This author believes that the President's view might be overly optimistic and that the first impression of many stakeholders may prove to be incorrect.

3.1 The Lack of Retroactivity

To '*ensure legal certainty and to protect the legitimate interests of patent proprietors and applicants*', the EBA decided that the opinion and thereby the effect of Rule 28 (2) EPC has no retroactive effect on European patents granted before the Rule came into effect (1 July 2017) or applications filed – or claiming a priority – before that date.[47] To limit the impact of a new regulation to patents filed after its date of entry into force is normally reserved for a change of articles. This shows that the introduction of Rule 28(2) EPC is a new legislation and more akin to a change of the EPC Articles than a change of the Implementing Regulations.

While the denial of retroactivity overcomes some fundamental issues related to Rule 28(2) EPC[48], it deviates from the usual practice that new Rules are applied to all pending cases based on the rational that rules – normally – are a mere interpretation of the law. In the present case the deviation from this practice is justifiable if not unavoidable. As a consequence of the 'dynamic interpretation' the new Rule is more than a mere interpretation of the existing law. It is linked to a newly expressed legislative intent, a new 'secondary' legislation and therefore has a clear date of entry into force. This is in line with the EBA decision in G 9/93[49], the first – and until G 3/19 only – decision where the EBA modified an earlier decision. In G 9/93 the EBA not only put the bar high for such changes[50], it also emphasised that '*there may be reasons of equity for not applying to pending cases the law as thus interpreted*' as '*obviously patent proprietors had every*

43) G 3/19 (Fn. 1); XXIV; p.57.

44) G 3/19 (Fn. 1), XXVI.4; p.63.

45) G 3/19 (Fn. 1); XXVI.8; p.64–65.

46) Statement by EPO President António Campinos available under https://www.epo.org/news-events/news/2020/20200514a.html.

47) G 3/19 (Fn. 1); XXIX; p.66.

48) See e.g., third party observation in the Pepper case submitted by Prof. Kirchberg: Rule 28(2) '...infringes the legitimate expectations based on the existing legal and judicial practice as a generally accepted procedural principle in the EPC contracting states (Art. 125 EPC). This is because of the retrospective application of the amended Rules which has been ordered. Finally, it also unjustifiably intervenes with the proprietary right to the European patent under Art. 60 EPC guaranteed by Art. 1 of the Additional Protocol I of the ECHR.'

49) G 9/93 (opposition by patent proprietor) of 6.7.1994 changed the EBA position in G 1/84. G 9/93 was confirmed in G 3/97.

50) G 9/93 under 6: *This is the first time the Enlarged Board has found it necessary to modify the interpretation of the EPC it gave in an earlier decision. Obviously, so as not to jeopardise the continuity and predictability of application of the EPC, any such departure must be restricted to situations like the present where there are very clear reasons for not following the earlier interpretation.*

reason to expect that self-opposition would be considered admissible'. Therefore *'it would be inequitable now to prevent them from continuing proceedings they embarked on in good faith and which cannot adversely affect the rights of any third party*.'[51]

The lack of retroactivity is a disappointment for some stakeholders and there are already voices questioning whether the decision of the EBA to deny retroactivity is really 'cast in stone' – to use the EBA's words in G 3/19 – or can also be overruled by a majority decision of the AC. Some even see the EBA's soft wording in this context as an invitation to challenge this part of the decision: The EBA only 'considers it appropriate' that the new interpretation has no retroactive effect but not a mandatory consequence of a dynamic interpretation.

It seems odd that the EBA empowers the AC to act as a legislator and coin a new interpretation of Article 53(b) when it introduced Rule 28(2), but then ignore the explicit intent of the AC to make the change retroactive and remove all pending native trait patents. One would assume that either you implement the whole of the AC proposal when relying on 'dynamic interpretation' or none of it. However, it could be the EBA's way to submit by appearances to the substantial political pressure, but then to 'win' the battle by reducing the consequences of the decision to almost zero, thereby undermining the political intent and making it a Pyrrhic victory for the AC. While such Machiavellian approach is not out of scope, the decision not to grant retroactivity could also be based on mere legal considerations (see above) or a concern that, in view of the fact that the principles of the division of power have already been (over)stretched with the present decision, a retroactive effect could get the barrel overflowing with an even higher risk for far reaching unintended consequences (see under 4.1).

Nevertheless, the apparent frustration may induce the AC to take another bite at the apple, especially as the Rule 28(2) EPC approach was deliberately chosen to enable a retroactive effect on pending applications.[52] Such approach may not be without risk as the rationales provided in G 9/93 do not necessarily apply in the present case: First, patent proprietors could hardly argue to have '*had every reason to expect*' a continuation of the previous practice as there was a clearly expressed intent of the legislator to change that practice, at least after the issuance of the Com Notice. In addition, and in contrast to G 9/93, the lack of retroactivity does '*adversely affect the rights of any third party*.'[53]

3.2 A Disappointment for Breeders Associations and NGOs?

Breeders associations[54] and NGOs like 'No Patents on Seed'[55] celebrate the G 3/19 decision as a land mark decision and victory. Some early comments see the opinion as a 'blow to the European Agritech industry and the owners of the many patent applications'.[56] However, these views ignore the lack of retroactivity. According to G 3/19, there are 18 appeals pending against decisions based on Rule 28(2) at the EPO, as well as about 250 examination and 7 opposition cases in which its application could be decisive.[57] While the EPO indicated that '*[t]he Office will act in accordance with the clarifications provided in the Enlarged Board's opinion and implement them in its examination practice in close consultation with stakeholders*', G 3/19 confirmed that

51) G 3/93 under 6.1: *In principle, any interpretation of the EPC by the Enlarged Board implies that the law has always been in conformity with that interpretation. However, on purely procedural issues there may be reasons of equity for not applying to pending cases the law as thus interpreted. In cases currently pending before the EPO and relying on decision G 1/84, which has now been followed for many years, obviously patent proprietors had every reason to expect that self-opposition would be considered admissible. In the present Board's opinion, it would be inequitable now to prevent them from continuing proceedings they embarked on in good faith and which cannot adversely affect the rights of any third party. Its ruling that, contrary to the earlier interpretation of the EPC, self-opposition is inadmissible, should therefore not be applied to notices of opposition filed before publication of the present decision*.

52) AC Proposal (Fn. 15), No.68.

53) Fn. 51.

54) See press release of the European seed Association available under https://www.euroseeds.eu/news/euroseeds-welcomes-limitation-of-patentability-by-european-patent-office/; German Breeders association (BDP) available under https://www.bdp-online.de/de/Presse/Aktuelle_Mitteilungen/Patentierungsverbot_von_Pflanzen/2020-05-15_Patentierungsverbot_von_Pflanzen.pdf.

55) See press release available under https://www.no-patents-on-seeds.org/en/node/638.

56) Rose Hughes in 'BREAKING: EBA finds plants produced by essentially biological processes are NOT patentable (G 3/19)', May 14, 2020. Available under http://ipkitten.blogspot.com/2020/05/breaking-eba-finds-plants-produced-by.html.

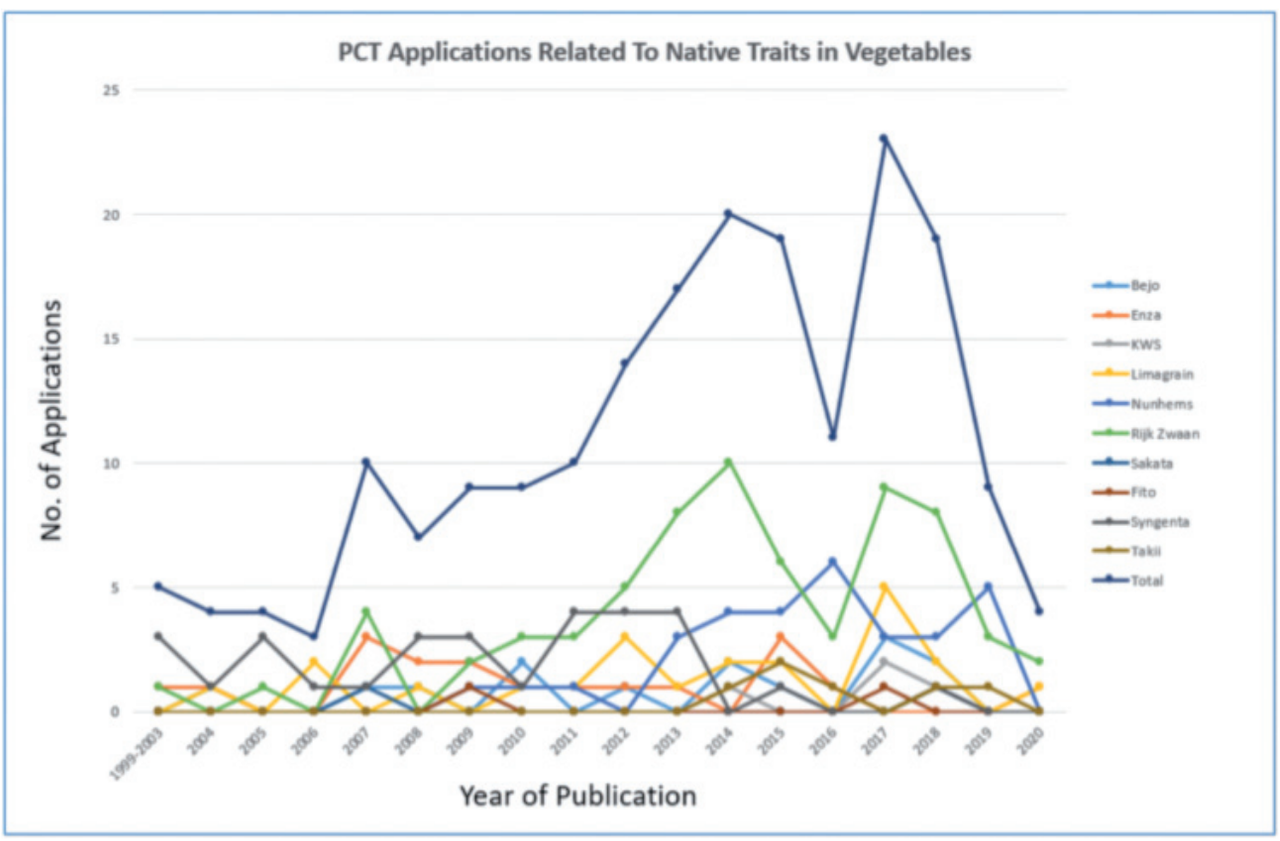
57) G 3/19 (Fn. 1); II.1.5; p.6.

Rule 28(2) EPC has no impact on any of these pending cases, which all have been filed prior to July 1, 2017. As most applicants use the PCT approach, cases with a priority after July 1, 2017 will often reach the EPO only 30 months later i.e., not earlier than January 1, 2020. None of them will have reached the stadium of substantive examination, opposition, or appeal.

The issue of 'essentially biological processes' is intrinsically linked with conventional breeding technologies, which are rapidly replaced with 'new breeding technologies' based on CRISPR/Cas and other technologies. Thus, G 3/19 can be compared with a decision to ban trains fuelled with coal at a time when railways become electric. The trend can be seen in the statistics for patents committed to the International Licensing Platform for Vegetables (ILP)[58]. The publication of PCT applications[59] on 'native traits'[60] dropped substantially from a maximum in 2017.[61] Out of the 197 PCT patent families not more than 13 (e.g., less than 8 per cent) will be affected by the change due to a priority date after July 1 2017.

The lack of retroactivity leaves the impact on breeders largely unchanged for the next few decades until the patents expire. The breeders associations see this as a 'bitter pill' and may challenge this provision by lobbying the AC.[62] Others may

Figure 1: PCT applications related to native traits in vegetables submitted to the International Licensing Platform according to its patent register. Available under https://www.ilp-vegetable.org



58) Fn. 115.

59) PCT applications are potentially a better indicator for innovations trends in that field as the number of EP applications is potentially distorted due to the long-lasting legal uncertainty.

60) The term 'native trait' means traits obtained by crossing of whole genomes e.g., introgression of a disease resistance from a wildtype plant into a commercial variety. While the term may include natural mutations, it normally does not include mutations obtained by man-induced, random mutagenesis.

61) Representing a priority year from 6/2015 to 6/2016.

62) Lack of retroactivity is a 'Bitter Pill' (Wermutstropfen) Press Release German Breeders Association BDP dated May 15, 2020: https://www.bdp-online.de/de/Presse/Aktuelle_Mitteilungen/Patentierungsverbot_von_Pflanzen/2020-05-15_Patentierungsverbot_von_Pflanzen.pdf.

hope that these patents get invalidated in national proceedings.[63] And the NGOs have already defined their next target: Mutations made by methods of random mutagenesis, a thinly veiled attempt to limit patentability to regulated (GM) technologies.[64] Due to the regulatory uncertainty around new breeding technologies for targeted mutagenesis as a consequence of the CJEU judgment in C528/16[65] many researchers use targeted mutagenesis for trait and target validation but then for product development move to the use of libraries of obtained by random mutagenesis to select the equivalent mutation resulting from a method exempted from the GM regulation.[66]

3.3 A False Hope for Patent Applicants?

The hope of patent applicants that all patent applications with a priority date prior to July 1, 2017 will now smoothly move to grant might be false. Without much attention the Boards of Appeal have found an approach to reject virtually all pending patent applications related to native traits in Article 84 EPO, which requires that '*[t]he claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description*.' Board 3.3.04 established a smaller series of decisions and denied clarity based on the fact that the claimed properties have only been 'disclosed' in the form of a deposit of the material, sometimes further described by molecular markers linked with the property, but not by any structural information for the underlying genetics as such.

The Board developed a 'standard' language and argued in T 967/10 and T 1988/12: *It is undisputed that the skilled person cannot derive from the claim per se the explicit structural or informational nature of this genetic information, in terms of, e.g. its sequence or genetic markers for its identification. Neither the description, the skilled person's common general knowledge nor the deposit numbers, convey such information*.[67] Similarly the Board argued in T 1957/14: *In the board's view, the skilled person may well understand the terms used in the claim and how to use the technology related to these terms in practice. Yet this understanding and these practical skills do not, in the present case, convey to the skilled person the structural features necessary to unambiguously characterise the alleles referred to in the claim*.[68]

The Board has a point: A deposit is often sufficient to enable the disclosure requirement of Article 83 to ensure that the invention can '*be carried out by a person skilled in the art*'. However, this does not mean that also the clarity requirements are met. Rule 43(1) EPC requires that '*[t]he claims shall define the matter for which protection is sought in terms of the technical features of the invention*.' And the established case law of the Board of Appeal has clarified that '*the technical features essential to the invention should be clear for the person skilled in the art from the wording of the claim alone*'.[69] Thus, the critical question is 'can a skilled person without undue burden understand whether a certain material is covered by the claim? Does the claim provide sufficient information on structure and function?'

The majority of the pending patent applications related to 'native traits' has a typical language such as '*A X plant showing a property Y, which plant is obtainable by crossing a susceptible X plant with a X plant grown from the seed as deposited with NCIMB/ATCC on DATE and having the accession number 123456 and selecting for a plant that*

63) 'We will however need to wait and see how national jurisdictions will now view the validity of those patents granted or applied for before the entry into force of Rule 28(2).' Press release available under https://www.euroseeds.eu/news/euroseeds-welcomes-limitation-of-patentability-by-european-patent-office/.

64) 'Clear definitions are needed to distinguish patentable technical inventions from the random processes used in conventional breeding in order for existing prohibitions to be effective.' Press release available under https://www.no-patents-on-seeds.org/en/node/638.

65) The CJEU decided that organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive. Only organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the directive or to other obligations. While there is debate whether this ruling affects all products obtained by targeted mutagenesis, it has at least raised legal uncertainty about the use of these techniques. Press release available under: https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf.Judgement available under: http://curia.europa.eu/juris/document/document.jsf?text=&docid=207002&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=5492257.

66) For example TILLING libraries. Kurowska M et al., TILLING – a shortcut in functional genomics. J Appl Genet. 2011 Nov; 52(4): 371–390.

67) So in T 967/10 (Bremia resistant lettuce, Rijk Zwaan); T 1988/12 (Sclerotinia resistant Brassica; Pioneer).

68) T 1957/ 14 (Quantitative trait loci, SYNGENTA).

69) G 1/04, OJ EPO 2006, 334, Reasons 6.2.

shows property Y [wherein in the deposited plant the property Y is linked to marker Z].' To understand whether a certain material infringes this claim would require (i) to sequence deposited material and identify the trait[70] and (ii) to sequence the potentially infringing material and identify the trait and (iii) compare the traits from both materials. This is unlikely possible without undue burden.

The Institute of Professional Representatives before the European Patent Office (EPI) also suggests a higher clarity threshold as an alternative to Rule 28(2): '*Another option would be to ensure that claims to plants carrying a novel characteristic could only be granted when the genetic basis for such characteristic is clearly and unambiguously and reproducibly described in the specification. This would allow breeders to unequivocally determine whether any material in their possession would be infringing any such claim. Further, it would give legal certainty to all involved parties what is patentable subject matter or not. […] Raising the clarity requirements for plant based inventions is actually already an ongoing process as is shown by developing case law (T 0967/10, T 1988/12)*.'[71]

While the Board's approach is not without merit, it would introduce a substantial change of practice with impact beyond the area of plants. Many patents related to microorganism define the microorganism not by full sequence information but by deposit. Even some transformation events for genetically modified plants are 'only' defined by a combination of molecular markers (e.g., 'junction sequences'[72]) and a deposit.

It also needs to be noted that the sequence information would solely be required to fulfil the patentability requirement of clarity. Although the costs for sequencing have dropped significantly[73], in the case of native traits such sequence information is not a routine 'side product' of the R&D process leading to the invention. It needs to be established solely for patenting purpose and may require more than 'just' obtaining sequence data i.e., substantial bioinformatics and often experimental work to identify the causative gene in what likely is a larger gene cluster. While this will raise the bar for 'native trait' patent applications it may have unintended consequences. In contrast to small and medium breeders, large breeding cooperations have both the technical capability and the financial resources to provide the sequence information to meet a higher clarity standard. This would make the patent system an even more exclusive tool for large cooperations than it is already. Nevertheless, in pending applications this 'deficiency' will be challenging to fix.[74]

Due to the impact it is therefore likely that the issue of clarity will trigger a referral to the EBA to clarify a question as follows: '*Does Art. 84 EPC always require complete structural information (i.e., full sequence information), or can 'clarity' also be satisfied by alternative means (molecular marker associated with a trait) if they enable the person skilled in the art to determine whether a subject matter falls within the claims or not*.'

3.4 Greater Legal Certainty?

The EPO President may be disappointed in his hope that the decision creates legal certainty as important points of law are left uncovered.

3.4.1 The Validity of Rule 28(2) EPC

3.4.1.1 Formal Invalidity of Rule 28(2) EPC

The EBA in G 3/19 avoided any statement on the validity of the process of how Rule 28(2) EPC was introduced. However, the principle of dynamic interpretation, the cited changed aim of the legislator, and the EBA's reference to Articles 33(1)(b) and 35(3) EPC suggest that the implementation of Rule 28 (2) EPC would have required an unanimous decision of the Member States with all Member States present. This, however, was not the case. Does this open a route to challenge the validity of Rule 28(2) EPC again, either by an affected patentee or by

70) Even with a molecular marker this is not a trivial task as markers often span several hundred thousand nucleotides and several genes.

71) EPI Comments on the 'Rule 28(2) disclaimer'. Available under https://information.patentepi.org/issue-4-2018/report-of-the-committee-on-biotechnological-inventions.html.

72) Junction sequences describe the site where the transgene inserted into the plant genome. The junction sequence consists part of plant and part of transgene DNA and is a unique identifier for a specific event.

73) A full genome sequence can often be obtained for less than 1000 €.

74) T 1228/01 (Zona pellucida antigens/ZONAGEN INC.) of 23.4.2003 under 15: 'Thus, the disclosure in the application as originally filed of the deposition of the recombinant bacteriophage Lambdagt11-P3, is not considered to be a basis within the requirements of Article 123(2) EPC for the disclosure of a DNA sequence designated as 'the P3 coding sequence' which allegedly is contained in said bacteriophage, but which as such is not disclosed in the application as originally filed.'

the Member State which voted against the Rule? Or can this 'weakness' be fixed by a unanimous confirmation of the Rule by the AC in one of their next meetings?

3.4.1.2 Invalidity of Rule 28(2) EPC Due to an Intrinsic Contradiction

Rule 28(2) EPC requires that '*Under Article 53(b), European patents shall not be granted in respect of plants or animals* exclusively *obtained by means of an* essentially *biological process*.' [*Emphasis added*] According to the AC Proposal the term '*exclusively*' is intended to soften the requirement in G 2/07 that '*the step of a technical nature [which] introduces or modifies a trait in the plant genome*' has to be *within* the steps of crossing and selection. Descendants of a plant obtained – for example – by genetic transformation should remain patentable even if made by crossing and selection.[75]

The combination of the terms 'exclusively' and 'entirely' in Rule 28(2) EPC reminds of Rule 26(5), which defines that '[a] process for the production of plants or animals is *essentially* biological if it consists *entirely* of natural phenomena such as crossing or selection.' [*Emphasis added*] In G 2/07 the EBA found that the contradiction between the terms 'essentially' and 'entirely' cannot be further clarified, put aside Rule 26(5) EPC and created its own definition.[76]

Now the AC has coined a Rule, which comprises the term 'exclusively' – which is similarly as narrow as the term 'entirely' – in relation to the term 'essentially'. This combination does not only bring an intrinsic contradiction, it also opens the door for circumvention and creates legal uncertainty especially in combination with the disclaimer practice (see below under 3.4.3.). Clever claim drafting can ensure that a plant comprising a native trait becomes patentable simply by combining it with a trait selected from a laundry list of prior-art traits obtained by a technical process. Most plant varieties today comprise at least one 'man-made' trait obtained by mutagenesis or other technical processes like protoplast fusion. While the 'essence' of the invention is still biological in the meaning of G 2/07, the plant is not exclusively obtained by an essential biological process as it comprises also a technical trait, irrespective of whether this trait contributes to the inventive step or not. It would require a decision that only traits which contribute to the inventive step will be considered for an assessment under Rule 28(2) EPC in analogy to computer-implemented inventions, but such decision would be in contradiction with the term 'exclusively'. This 'contradiction by design' will obviously require further case law for clarification and may lead to a decision of the EBA that also Rule 28(2) EPC – like Rule 26(5) EPC – cannot be clarified and needs to be put aside.

3.4.2 The Scope of Rule 28(2) EPC

The AC missed an opportunity to create more legal clarity by avoiding the term 'essentially biological processes' in Rule 28(2) EPC and replacing it by a less ambiguous term as suggested by the Swiss delegation (see below).[77] While there is reason to assume that the definition for essentially biological processes in Rule 28(2) EPC is the one coined in G 2/07–G 1/8 (Broccoli/Tomato I) this is neither confirmed nor 'cast in stone'. There are at least two reasons why a more narrow definition might be appropriate if not required:

(i) As discussed elsewhere in detail[78] the definition for essentially biological processes in G 2/07 does not only deviate from the narrow definition in the Biotech Directive, it also conflicts with Rule 27(c) EPC that '*technical processes and the products resulting therefrom*' should remain patentable. While conflict already applies for processes, it creates an even bigger issue for products.

(II) Both the Biotech Directive and the national law of the EU Member States include the narrow definition for essentially biological processes. While the Com Notice does not specifically addresses the definition, it is based on a narrow meaning that essentially biological processes are 'neither inventive nor reproducible'[79] i.e., non-technical. As the Com Notice has initiated the AC Proposal and eventually Rule 28(2) EPC, there is no legal basis to

75) AC proposal (Fn. 15), No. 39.

76) G 2/07–G 1/08 (Fn. 4), Under 4.

77) Fn. 93.

78) Kock MA, Morgan G (2017) *Bio-Science Law Review* 16(3):123–128.

79) Kock MA, *Bio-Science Law Review* (2016), 15(6), 231–238; Com Notice (Fn. 13), p.5. Emphasis added. 'Essentially biological procedures', i.e. crossing and selection of the whole genome [...] do not meet the general conditions for patentability, as they are *neither inventive nor reproducible*. Breeding is a reiterative process, in which a genetically stable end-product with the required characteristics is attained only after much crossing and selection. This process is so strongly marked by the individuality of the initial and intermediate material that *an identical result will not be obtained upon its repetition*. Patent protection is not appropriate for such procedures and their products.

Table 1: Consequences of the definition for essentially biological processes for products

	Definition of essentially biological processes	Extensions to products	Scope of product exclusion
Directive 98/44	Narrow: 'A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection'.	No	Specific varieties
Commission Notice	Narrow: Processes which are neither inventive nor reproducible.	Yes	Specific varieties
National laws DE, FR, IT	Narrow: 'A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection'.	Yes[80]	Specific varieties
EPC (for patents with priority before July 1 , 2017)	Broad: 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 [...].	No	Specific varieties
EPC (for patents with priority on or after July 1 , 2017)	Broad: 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 [...].	Yes Rule 28(2)	All plants with native traits irrespective of their technical character.

combine the broad definition for essentially biological processes in G 2/08 with the conclusions of the Commission Notice, especially as the results are fundamentally different as shown in Table 1 above.

While the term '*technical character*' is subject to legal interpretation, its analysis is a question of facts. Criteria are a technical effect by the invention[81] or technical considerations required to carry out the invention[82]. For breeding inventions, a technical character requires – in line with the Com Notice – reproducibility, or – as expressed by the German Federal Supreme Court in the 'Red Dove' decision – a '*teaching for plan-conformant action utilizing controllable forces of nature for achieving a causally overseeable result*'.[83] While natural processes lack reproducibility and therefore technical character, modern breeding can be technical and sexual crossing per se does not conflict with a technical character as reproducibility can be ensured by molecular markers and other technologies.[84]

The AC did not delete or revise the original, narrow definition for 'essentially biological processes' in Rule 26(5). This could provide a basis to define the term in Rule 28(2) EPC differently than in G 2/07–G 1/08 to ensure that plants obtained by technical processes remain patentable.

3.4.3 The Implementation of Rule 28(2) EPC: The Disclaimer Solution

For implementation of Rule 28(2) EPC the EPO requests a disclaimer. The issues of the disclaimer have been assessed

80) For some countries this is explicit, for others likely only implicit based on the Com Notice.

81) T 931/95; T 1173/97, OJ 1999, 609.

82) T 769/92, OJ 1995, 525.

83) Bundesgerichtshof (Federal Supreme Court) 27.03.1969 File: X ZB 15/67 'Rote Taube' (Red Dove) GRUR 1969, 672. English translation published in IIC 1970 (1), 136ff.

84) Breeding has made substantial progress in the last few decades. The Com Notice acknowledges '[s]ince the late 1990s, there has been significant technological progress in the plant sector, through the introduction of gene markers in the crossing and selection of new plants/plant varieties. These markers allow for far more rapid – and improved – results than could be achieved with the classical techniques of selecting and crossing plants.' Com Notice (Fn. 13), p.3.

in detail elsewhere.[85] The guidelines state that '*a disclaimer is necessary to delimit the claimed subject matter to the technically produced product*'.[86] In practice the EPO requests a specific wording for the disclaimer: '*A plant … provided that the plant is not exclusively produced by means of an essentially biological process*'. The disclaimer practice is up for several challenges:

(i) There is a general question whether a disclaimer is required for cases related to Rule 28(2) EPC. There does not seem to be a legal basis for the disclaimer practice and the guidelines do not provide any legal authority by reference to standing case law of the EPO. A disclaimer requires a 'whole content' approach which normally is limited to exclusions based on ethical and related considerations like for example the requirement to limit mammalian sequence claims to 'non-human' sequences. Otherwise claims are deemed allowable as long they – in addition to excluded matter – also cover in a credible way non-excluded subject matter. There is clear precedent for not requiring a disclaimer even though the claims may encompass embodiments excluded from patentability: G 1/98 allowed claims on plants without a disclaimer for plant varieties although plant varieties are clearly not patentable under Article 53(b) EPC.[87] Furthermore, the EPO routinely grants claims directed to (human) stem cells without requiring a disclaimer to exclude stem cells obtained by a method which involves destruction of a human embryo although such methods are excluded from patentability under Art 53(a) and Rule 28(1).[88] In the present case no ethical or other related considerations can be found which would justify a 'whole content' approach.

(ii) The disclaimer adds a process element to a subject matter claim. In contrast to the practice for product-by-process claims that the process does not limit the absolute scope of the subject matter claim, here the subject matter gets deliberately limited. This is a substantial deviation from the principle of absolute compound protection. It de facto reduces the scope of a composition matter claim to a process claim and denies the full scope of protection required for patentable subject matter. It also raises a question whether the disclaimer practice is compliant with TRIPs requirements.

(iii) Even the AC Proposal does not seem to favour a disclaimer solution. With respect to claims which cover both natural and artificial mutant plants, the AC proposal states[89]: *Some forms of mutagenesis occur in nature (usually called spontaneous mutagenesis). However, whether a specific mutation indeed would occur as the result of spontaneous mutagenesis is entirely speculative. Application of an exception to patentability cannot depend on hypothetical considerations and on whether specific process elements are traceable in the claimed product, in particular when taking into account the considerable developments in the technical field of plant breeding in the past and the unpredictable nature of future developments*. In consequence, the AC considered an invention related to a mutation patentable as such, irrespective of whether such mutant could also happen in nature. This intent is contradictory to the required disclaimer solutions.

(iv) The AC Proposal comprises an entire section about use of disclaimers[90] but seems rather cautious regarding a use in the case of Rule 28(2) EPC. The AC Proposal emphasises that the underpinning issue is rather related to the enforcement of rights than the scope of claims.[91] Nowhere in the AC Proposal is any suggestion that a disclaimer should be mandatory.

(v) The AC Proposal stresses that the '*[d]isclaimers must in particular comply with the clarity requirement*'.[92] Also G 1/03 only permits a non-disclosed disclaimer for '*subject-matter which, under Articles 52 to 57 EPC, is excluded from patentability for nontechnical reasons*' provided that the '*disclaimer must meet the requirements of*

85) Fn. 71.

86) Examination Guidelines Part G II 5.2 (ii).

87) In this regard it may be important to note that Art 53 (b) and Rule 28(2) in defining exceptions to patentability use similar wording : 'European patents shall not be granted in respect of…'.

88) See e.g. EP 2455452, EP 2548950 or EP 2611910.

89) AC Proposal (Fn. 15), No.41.

90) AC Proposal (Fn. 15), No.52–58.

91) AC Proposal (Fn. 15), No.53.

92) AC Proposal (Fn. 15), No.57, 58.

clarity and conciseness of Article 84 EPC'. Both are not the case: the disclaimer deals specifically with the interface between technical and non-technical matter i.e., a technical reason. In addition, as laid out above the term 'essentially biological processes' is neither clear nor concise due to the various conflicting definitions in Rule 26(c) and G 2/07.

(vi) The specific mandatory language of the disclaimer is problematic. Even in the guidelines the form of a disclaimer is at the discretion of the applicant. As explained above (see 3.4.1) the language of Rule 28(2), which is reflected in the disclaimer, enables circumvention. The Swiss disclaimer proposal is slightly but importantly different: '*A plant characterized by […], provided that said characteristic is not the result of a sexual crossing of whole genomes*.' This links to the specific characteristic of the invention instead of the entire plant and thereby avoids circumvention by simply adding a non-inventive technical trait, which may exist anyway in the plant, to the claim.[93]

(vii) As laid out in the EPI submission[94] the disclaimer introduces legal uncertainty for applicants and third parties, which could materialise in national enforcement proceedings (see also under 3.5).

However, the alternative to a disclaimer i.e., limiting the patent scope to products obtained by specific technical processes is potentially even worse. It would not only exclude products made by essentially biological processes but also those obtained by other technical processes.[95] Even when using a long listing of all possible technical processes, resulting claims can easily be circumvented especially by new technologies. The protection would become effectively limited to the specific plant made by the patentee and its progenies.

As the Examining and Opposition Divisions of the EPO are bound by the Guidelines, they have no choice but to impose a disclaimer or reject the application. Applicants will have no choice but to appeal. The Boards of Appeal are only bound by the EPC (Art 23 (3) EPC) and not by the Guidelines. Thus, the disclaimer requirement will likely cause a series of appeals, potentially again up to the EBA, which contradicts the principle of efficiency of proceedings and equity and good faith which an applicant can rely on in a constitutional system.

In conclusion, the disclaimer solution is 'the lesser evil' and – with the 'right' wording – can create legal certainty.[96] However, its legal intent to reduce the impact of patents on conventional breeders can better be met by a limitation to rights of a patent instead of by complex prerequisites for grant. France has implemented such solution and other countries may follow (see under 4.2 iv.).

3.4.4 Beyond methods of breeding to other methods of plant production?

The official languages for Article 53(b) EPC show a significant deviation. While the English version ('*production*') is using a rather general term, the German term ('*Züchtung*') and the French term ('*obtention de vegetaux*') only relate to the activities of breeders and excludes those of farmers and seed producers. In at least one decision the opposition division deemed a process of hybrid seed production as 'essentially biological' and refused the patent.[97] Also this point will likely trigger further decisions by the Boards of Appeal or even the EBA as the languages of the convention have obviously a different scope.

3.5 Impact on National Proceedings

While some stakeholders have the hope that patent on plants with 'native traits' may get invalidated in national proceedings despite the denied retroactivity of Rule 28(2) EPC[98], one needs to keep in mind that all EU member countries still have the narrow definition for 'essentially

93) AC Proposal (Fn. 15), No.55, Fn. 46: Switzerland also proposed to add a clear legal requirement and basis for a disclaimer during the preparatory meetings by adding an additional Rule: 'If the protection conferred by a claim extents to a plant or animal or any part thereof as defined under paragraph 2, a disclaimer is to be added to exclude said non-patentable plants or animals, even if such disclaimer it is not disclosed as such in the application as filed.'

94) Fn. 71.

95) *Hospira UK Ltd v Genentech Inc.* [2014] EWHC 3857 (Pat); http://www.bailii.org/ew/cases/EWHC/Patents/2014/3857.html#para125.

96) Parties operating within the disclaimed portion would have freedom-to-operate and no need to check validity or oppose the patent.

97) Decision of the Opposition Board dated 29.04.2013 regarding Patent No. EP 2.002.711. The patent related to process of producing hybrids seed. Despite the fact that there was no crossing of different genomes, no 'breeding' and the use of a man-made mutant the opposition board considered the method essentially biological. An appeal was not filed.

98) Fn. 63.

biological processes' in their patent law. Even if the national patent law comprises an explicit extension to products – as for example the laws of France, Germany, and Italy[99] – the impact is unlikely to be the same due to the different definition. As the disclaimer demanded by the EPO is in essence a limitation to the rights resulting from a patent, which will be interpreted in a national infringement proceedings, the question will arise 'What is the applicable definition for an essentially biological process in the context of Rule 28(2) EPC and the disclaimer?' As the EBA in G 3/19 observed, the Court of Justice of the EU has not yet interpreted Article 4(1)(b) of the Biotech Directive. Thus, in view of the appeal decision in the Taste of Nature case[100], Article 267 TFEU requires that any final judicial instance that is inclined to reach a contrary conclusion (i.e., the conclusion of G 3/19) must make a preliminary reference to the CJEU.

However, even if the CJEU would render such a decision, it may not lead to a consistent interpretation of the law. Whilst it undoubtedly will have an impact on EU Member States if the CJEU rules on the interpretation of Article 4(1)(b) Biotech Directive, many EPC Contracting States are not EU member states, including important countries like the UK, and so the G 3/19 is setting a future with an increased probability of a divergent practice across the EPC Contracting States.

Even if the patents are held valid, enforcement will not be a 'slam dunk': claims on native traits are normally limited to the specific genetics in the deposited material.[101] In consequence of the natural variation over multiple propagation cycles it is possible – if not likely – that not even the products of the patentee are covered by the narrow claims.[102]

Also the disclaimer language will create headaches. Is it a limitation to absolute compound protection? And how to interpret the term 'obtained' in view that the EPO case law on product-by-process claims consistently equates 'obtained' as meaning 'obtainable'. Additional concerns regarding the burden-of-proof and a potential misuse of the disclaimer are discussed in the EPI submission.[103]

4. Conclusion and What Can be Expected

4.1 Will the Tectonic Shift in Powers at the EPO Trigger an Earthquake?

The EBA has been considered the highest judicial authority under the EPC to ensure the uniform application of the EPC. This role is challenged by G 3/19. It is unlikely that '*a change of interpretation effected by a Rule complies with the rule of law*', as questioned by the EBA.[104] Indeed the process 'smells' like rule-by-law simply to avoid the lengthy and thorny process of a change of the Articles and is even more questionable as the requirements of Article 35(1)(b) EPC have not been met.

As the EPO is in charge of granting the Unitary Patent, G 3/19 might be the final death stroke to the Unitary Patent and the associated UPC, which have been under scrutiny e.g., by the German Federal Constitutional Court.[105] The court assumed that based on Article 17(a) UPCA[106] judicial independence and that 'judges shall not be bound by any instructions' is ensured. Whether after G 3/19 this assumption is still unquestionable needs to be seen, especially as the members of the Boards of Appeal are subject to the disciplinary and reappointment authority of the AC. Thus, G 3/19, while 'resolving' a point of law of vanishing relevance,[107] has – like a lightning rod – drawn attention to a fundamental weakness of the EPC that now requires urgent attention.

99) Article L 611-19 I. 3°bis of the French Code de la Propriété Intellectuelle; Article 2a (1) No. 1 of the German Patent Act; Article 81*quater* (e) of the Italian Industrial Property Code.

100) The provisions of Article 4(1)(b) of the Biotech Directive have been interpreted by a judicial authority of an EU Member State. The decision of the Court of Appeal of The Hague of 28 May 2013 in *Cresco v Taste of Nature* (http :// bit.ly/2rH5S8o) was that the products of essentially biological processes for the production of plants are not excluded from patentability.

101) A deposit – in general – only discloses what has been deposited. Extensions to variants or derivatives, while usual for claims on sequences, do not meet the patentability requirements as they would extend to not further defined embodiments and would in view of the missing sequence information for the gene related to the 'native trait' cause an unpredictability of the related art and require undue experimentation. See Case Law of the EPO II.C.6.3; T 1466/05; T 727/95.

102) Kock MA, Zech H (2017) GRUR 10:1004–1016.

103) Fn. 71.

104) G 3/19 (Fn. 1); XX., p.56.

105) The Constitutional Court invalidated and sent back the German ratification law to parliament as – in the view of the court – it required a 2/3 consent in parliament. BVerfG, 13. Feb. 2020, 2 BvR 739/17; http://www.bverfg.de/e/rs20200213_2bvr073917.html.

106) Agreement on a Unified Patent Court (UPCA) (published in OJ EPO 2013, 287). Article 17 Judicial independence and impartiality (1) The Court, its judges and the Registrar shall enjoy judicial independence. In the performance of their duties, the judges shall not be bound by any instructions.

107) The PINTO data base (Fn. 111) currently shows only the small number of 801 plant varieties protected by patents.

4.2 Reaction of Member States

The EU Commission and the EPC member states may now recognise that the solution to the problem associated with patents on native traits cannot be left to the EPO alone, but needs to be found where it should have been sought from the beginning: in a clarification of the rights resulting from a patent in national laws.

Several elements for a sustainable solution have been discussed.[108] The solution could not only solve the vanishing problem of native trait patents but also the emerging challenge of patents on traits based on new breeding technologies. Maximum impact can be achieved by a combination of industry initiatives and legislative changes designed to be mutually supportive. That legislative flexibility is possible under the framework of the Biotech Directive has been shown by the implementation of the patent law breeders exemption[109] and the 'clarifications' for products obtained by essentially biological processes[110]. The following elements are key.

(i) **Increase transparency and legal certainty**: The PINTO database[111] of the European Seed Association (ESA) discloses the patent status of many varieties approved for marketing in the EU. However, it has been criticised as a voluntary instrument with uncertainty about how comprehensive it is. This 'deficiency' can be overcome by implementing in national patent laws a duty to disclose the patent status of a commercially available variety.[112] Such duty can be fulfilled either on request by any interested party, by declaring the patent status in the context of obtaining seed market authorisation, or in a publically accessible database such as PINTO. The 'duty to disclose' can be given teeth by linking it to the enforceability of the patent: If a patentee does not make the disclosure even on a written request of an interested party he should not be entitled to enforce the patent against a use in good faith by said party.[113] Such 'forfeiture of rights' would already be the consequence under the existing laws of most EPC countries and therefore nothing more than a clarification. However, it would provide breeders with a clear process on how to obtain legal certainty and support initiatives like PINTO by encouraging a broader participation and maybe expansion to other territories.

(ii) **Improve access to genetic diversity**: The breeders exemption in Art. 27c UPC and in the patent laws of several EPC member states including Germany, France, The Netherlands and Switzerland[114] prevents the presence of a single patented gene or trait depriving the entire plant genome from use for further breeding. A breeder can use – without authorisation by the patentee – any plant variety covered by a patent for breeding of new varieties including a subsequent commercialisation if the new variety no longer comprises the patented gene. If the new variety still comprises the patented gene the commercialisation can be enabled by a licence or compulsory licence (see below under iii.).

(iii) **Enable Access to Patented Traits**: The International Licensing Platform has established a widely accepted open innovation system based on the guiding principle 'free access but not access for free' to enable access to patented traits under fair and independently determined financial

108) Zech, Kock Fn. 102.

109) This exemption enables breeders to utilise biological material covered by a patent for the purpose of breeding. A licence is only required if the resulting new variety still comprises the patented gene and is commercialised. German Patent Act §11 (2a). Article L613-5-3 French Intellectual Property Code; Dutch Patent Act Art.53b(2); Swiss Patent Act §9e; Agreement on the Unified Patent Court Article 27(c).

110) Fn. 99, 114.

111) The Patent Information and Transparency On-line ('PINTO') data base of the European Seed Association enables transparency on which commercial plant varieties are covered by patents. Access under: http://pinto.euroseeds.eu/About/Home.

112) Linking effective enforceability to the public listing of the patents protecting a commercial product is also one of the principles behind the Orange Book FDA listing in the US, which triggers the Hatch-Waxman ANDA litigation procedure. Hence this is a tried and tested way to 'manage' the interests of patentee sand third parties in high stakes litigation on valuable products.

113) A possible language could be as follows: A patent cannot be asserted against anyone who has produced a new plant variety in good faith by using biological material of a plant variety approved for seed marketing. A breeder is considered to be in good faith if he has asked the owner of the said plant variety, who is also the patent owner or a company associated with it, and within 30 days of receipt of this request: a) does not receive a response confirming the patent protection of this biological material; and b) could not find any patents in the plant variety register or in a database recognised and recognised by breeders regarding the plant variety used.

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conditions.[115] Again, critics complain that the participation in the platform is voluntary and limited to vegetables. This concern could be overcome by a clarification to the compulsory cross-licence provision for dependent plant breeders rights provided under Article 12 of the Biotech Directive.[116] With respect to required '*significant technical progress of considerable economic interest*' Switzerland improved legal certainty by linking it to the seed market authorisation[117], while leaving room for further clarification: If an agricultural plant variety demonstrates a 'value for cultivation and use' (VCU) required for the market authorisation, the requirement of a 'technical progress' could be automatically satisfied. VCU requires '*a clear improvement either for cultivation in general or for the specific uses which can be made of the crops or the products derived therefrom*'[118] which can be deemed the plant specific equivalent of a '*significant technical progress of considerable economic interest*'. Such interpretation seems reasonable and could be implemented without a change of the Biotech Directive, e.g., by a further Commission Notice. It also needs to be considered whether the right to a licence needs to depend on obtaining a plant breeders rights as suggested by the wording of Article 12. Plant breeders rights as such are not dependent and not commercialised as requested in Art. 12(1), the specific variety protected by such rights is. In view of the intent, the requirement to obtain plant variety protection for a specific variety seems unnecessary.[119] Thus, a variety would be automatically entitled to a licence if it fulfils the requirement for seed marketing.[120] The only outstanding issue for a judge would therefore be determining the fair compensation, unless such compensation is determined under the framework of a licensing platform like the ILP, which most likely will lead to a more educated decision.

(iv) **Expand legal certainty and freedom-to-breed for conventional breeders**: It could be considered to limit the effects of a patent in a 'disclaimer-like' solution to ensure that products obtained independently from the material of the patentee by an essentially biological processes are not covered by the patent. France has implemented such a solution in their national patent law.[121] While the wording may be improved[122], such provision in national patent laws could achieve what G 3/19 will unlikely achieve: legal certainty for conventional breeders as it would be applicable to all patents irrespective of their filing date. While not a limitation to patentability, it would achieve the legislative intent of the EU Commission while avoiding ambiguity and a substantial limitation of the rights of the patentee.[123]

115) Kock, M (2015) *Bio-Science Law Review*, 14(4), 123-129; P. van der Kooij, M. Suelmann. Berichten Industriële Eigendom (BIE) 2014, 12, p. 260; *Kock/ten Have*, Journal of Intellectual Property Law & Practice, 2016, 11(7), 496–515. Detailed information is available on the ILP web page: http://www.ILP-vegetable.org. If parties cannot bilaterally agree, a fair price is determined by a unique and simple 'baseball arbitration' system.

116) Biotech Dir. 98/44 (Fn. 14) – Art. 12(1).

117) Swiss *Patent Law – Art. 36a-1* If a plant variety right cannot be claimed or used without infringement of an earlier patent, the breeder or the owner of the plant variety rights is entitled to a non-exclusive licence with the scope necessary for the claiming and utilisation of the plant variety rights provided that the plant variety demonstrates a significant technical progress of considerable economic interest with respect to the patented invention. *For varieties relating to agriculture and food the criteria of the seed regulation of Dec. 7, 1980 shall to be taken as a point of reference*. [*Non-official translation by the author. Emphasis added*] The use of the term 'point of reference' creates an unnecessary ambiguity, which could be resolved by making the requirements for seed market authorisation the decisive criteria for a licence.

118) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL On the production and making available on the market of plant reproductive material (plant reproductive material law) /* COM/2013/0262 final – 2013/0137 (COD) * final – 2013/0137 (COD); Article 58.

119) A potential wording for an Article complementary to Article 12a in national laws could read as follows: Anyone who has grown a new plant variety by using patent-protected biological material of a plant variety is – subject to Articles 12(1) – entitled to a non-exclusive licence for his new plant variety if it is approved to be placed on the market as commercial seed in accordance with the [Plant Reproductive Material Law].

120) *Metzger*, GRUR 2016, 549, 552 f.; *Kock*, in: Matthews/Zech (Hrsg.), Research Handbook on Intellectual Property and the Life Sciences, 2017, p.132 ff.

121) Article L613-2-3, Art. 10 para 3 : The protection conferred by a patent relating to a biological material possessing, by virtue of the invention, specific charteristics does not extend to biological matters possessing said specific characteristics obtained independently of the patented biological material and by essentially biological processes, nor biological materials obtained from them, by reproduction or multiplication. [Non-offical translation by the author].

122) In view of the deviating definition for 'essentially biological processes' it should be considered to avoid this term and to rather use the alternative 'crossing of entire genomes' suggest by Switzerland. With respect to the criteria of independent breeding it needs to be considered that a third party can also reproduce the teaching of patent without using the material of the patentee. Therefore independence should also be from a use of the teaching of a patent. A possible wording could be: The protection conferred by a patent relating to a biological material possessing, by virtue of the invention, specific charteristics does not extend to biological matters possessing said specific characteristics obtained independently of the patented biological material and the teaching of the patent by an essentially biological process, nor biological materials obtained from them, by reproduction or multiplication.

123) Kock, Zech Fn. 102.

This author would not be surprised if some initiatives will emerge even in 2020. This leaves two options for patentees and their opponents: Either (i) to cooperate and develop a sustainable solution to broadly foster plant related innovation while considering the interests of small and medium breeders or (ii) to enter into a fierce fight and lobbying campaign which would make the current calm after the Rule 28(2) 'storm' look like the eye of a hurricane. The second scenario will likely only see losers, with plant innovation being the biggest one. This would be deeply frustrating in times where climate change and population growth require plant innovation at an unprecedented pace and scale. This author hopes that this time the view for the bigger picture prevails and that consensus solutions become reality.