

# Quis custodet custodes? Referral G-3/19 before the EPO Enlarged Board of Appeal and the imperative of challenging the board's interpretation of Art. 53(b) EPC

Julian Cockbain<sup>1</sup>  | Sigrid Sterckx<sup>2</sup>

<sup>1</sup>Bioethics Institute Ghent, Ghent University, Ghent, Belgium

<sup>2</sup>Faculty of Arts and Philosophy, Ghent University, Ghent, Belgium

## Correspondence

Julian Cockbain, Bioethics Institute Ghent, Ghent University, Belgium, Blandijnberg 2, 9000 Ghent, Belgium.  
Email: [julian.cockbane@btopenworld.com](mailto:julian.cockbane@btopenworld.com)

## Abstract

The European Patent Office Enlarged Board of Appeal was asked in April 2019 to answer two questions regarding the exclusions from patentability under Art. 53 European Patent Convention (EPC), the dominant patent law in Europe. The first related to the manner in which EPC Articles should be interpreted, and the second to whether Art. 53 EPC excluded plants and animals that are the products of the excluded “essentially biological processes.” Since product claims are infringed by all processes for making the product, the second question was important—if the products are patentable, the exclusion of the processes is rendered meaningless, something which cannot have been the intention of the legislators drafting the EPC. The questions are in case G-3/19 Peppers and the Enlarged Board of Appeal handed down its opinion on May 14, 2020. In this paper we examine the background to this case, the strength of the arguments presented, and the Enlarged Board's decision which we find to dangerously undermine the Article of the EPC, Art. 164 EPC, which requires changes to the principles of what can be patentable to be democratically agreed by the parliaments of the EPC

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2020 The Authors. The *Journal of World Intellectual Property* published by John Wiley & Sons Ltd

member states rather than by an administrative body of government-appointees.

**KEYWORDS**

European, patents, plants

## 1 | INTRODUCTION

An international convention, the European Patent Convention (EPC),<sup>1</sup> discussed and negotiated over more than 20 years, was signed in 1973 and later ratified by the parliaments of its member states. The EPC caused an institution, the European Patent Office (EPO) to be set up which could grant European Patents which could be brought into force in the member states with the same effects as patents granted by their national patent offices. The EPO is headed by a President and run by the European Patent Organisation, itself governed by an Administrative Council on which each member state has a *government*-appointed representative. The principles on which the EPO may grant patents are set out in the Articles of the EPC, while more practical matters concerning the operation of the EPO are set out in the legally subordinate Implementing Regulations or Rules of the EPC. In principle, the legally dominating Articles have to be approved democratically by the parliaments of the member states, while the Rules are set by the Administrative Council without requiring any parliamentary approval. Thus, in general, changing the Articles requires approval by a diplomatic conference of the member states and subsequent ratification by the individual parliaments. To ensure that the principles agreed by the parliaments are not overridden by administrators, Art. 164 EPC specifies that if the Rules and the Articles conflict then the Articles prevail.

The decisions of the operating departments of the EPO which can refuse or reject patent applications or grant, maintain or revoke patents, the Receiving Section and the Examining and Opposition Divisions, are appealable to the EPO's Boards of Appeal, these being part of a further, quasi-independent, department of the EPO. Board of Appeal decisions are not appealable further, but there exists an Enlarged Board of Appeal (EBoA), the members of which are mostly drawn from the Boards of Appeal, which points of law can be referred to. The Boards, including the EBoA, are required to follow the EPC but are not bound by the national laws or court decisions of the member states or the laws or court decisions of the European Union (EU). Indeed, while all EU member states are also EPC member states, there are EPC member states that are not in the EU.

With the rise in commercial importance in the 1980s of biotechnology in general, and genetic modification of life forms in particular, the administrative arm of the EU, the European Commission, sought to persuade the European Parliament and the European Council to adopt a Directive requiring the EU member states to ensure that their national laws permitted the patenting of many of the new techniques and their products, in particular genetically modified plants and animals. After prolonged discussion, this Directive (Directive 98/44/EC, the Biotech Directive) was issued in July 1998. This Directive was of particular relevance to Art. 53(b) EPC which, then and now, forbids the grant of European Patents for "plant or animal varieties or essentially biological processes for the preparation of plants or animals." Having initially hoped that the EPC was compliant with the Directive, in September 1999 the EPO's Administrative Council introduced new EPC Rules which sought to ensure that compliance. The timing was critical since a case was then pending before the EBoA on the patentability of genetically modified plants and animals. The EPO was under pressure to ensure compliance, and while this could have been done by way of a diplomatic conference to amend the Articles of the EPC, this would have taken time and might not have received the required approval of the parliaments of all the EPC member states.

The exclusion of Art. 53(b) EPC might on first sight seem to be clear—all new forms of plants and animals could not be patented (old forms being inherently unpatentable due to the law's requirement for an invention to be new before it can be patented) and that new biological (rather than technical) ways of producing plants or animals,

whether old types or new types, could not be patented. New technical processes could be patented, and patents for processes extend their cover to the products obtained directly by the claimed process, but not to the progeny of such products. This interpretation, however, is at odds with the terms of the Directive and, in December 1999, a few months after the introduction of the new Rules, the EBoA decided in G-1/98 Transgenic plants/NOVARTIS II that new types of plant or animal could be patented as long as the claims were worded at a “higher taxonomic level,” for example, as claims to rodents rather than to house mice. Such claims, however, encompass and are infringed by real plants or animals, and the first part of the exclusion seemed to have been emasculated.

Companies then sought to patent plants produced by “conventional” biological processes such as crossing and selection, initially arguing that the processes were not excluded as long as they contained a technical step, and subsequently by adopting the higher taxonomic level approach to claiming the plants themselves. This reached the EBoA in cases G-2/12 Tomatoes II/STATE OF ISRAEL and G-2/13 Broccoli II/PLANT BIOSCIENCE and, after a lengthy interpretation of the process exclusion of Art. 53(b) EPC, it concluded in March 2015 that it could see no basis for rejecting the higher taxonomic level claims to conventionally bred plants, even though the patentees had disclosed no other way of producing such plants than by the excluded essentially biological processes. Since claims to products are infringed by all processes used to produce the products, the product claims would cover the use of conventional plant production techniques, and would cover the progeny of the originally used process. The emasculation of Art. 53(b) EPC seemed complete.

Then the European Parliament passed a resolution (EP, 2015) later in 2015 calling on the European Commission to confirm that the Biotech Directive was *intended* to exclude the products of essentially biological processes from patentability and the Commission duly issued a notice (EC, 2016) to this effect. Once more under pressure to show that the patent law in Europe was harmonized, in June 2017 the EPO's Administrative Council agreed to introduce a new rule, Rule 28(2) EPC, confirming that Art. 53(b) EPC did not allow the patenting of such products. A case on the matter was heard by one Board of Appeal which decided in December 2018 (in T-1063/18 Extreme dark green, blocky peppers/SYNGENTA) that the new Rule, conflicting with the EBoA's decision in G-2/12, did not apply. Again under pressure, the President referred the matter back to the EBoA in April 2019 and on May 14 2020 the EBoA handed down its opinion in G-3/19 Peppers.

In G-3/19, the EBOA fully endorsed its reasoning in the five previous cases it had heard relating to Art. 53(b) EPC, that is, G-1/98, G-2/07, G-1/08, G-2/12, and G-2/13, but nonetheless decided that circumstances had changed since the G-2/12 decision in March 2015 and that a “dynamic interpretation” of Art. 53(b) EPC now required it to abandon the interpretation of G-2/12 and decide that “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.”

Here, we should note, the *product* exclusion that the EBoA is creating flows from the *process* exclusion in Art. 53(b) EPC and not from the *product* exclusion to be found there. This is important since the EBoA is in effect saying that the higher taxonomic level manner of claiming plants and animals that it approved in G-1/98 stays unchanged.

So, what precisely were the changes in circumstances that allowed this “dynamic” reinterpretation. Very simple—the introduction of Rule 28(2) EPC. Nothing more, nothing less.

This brings us to the most unsettling aspect of the EBoA's opinion. If exhaustive attempts in 2015 to interpret Art. 53(b) EPC (which has not been changed since its adoption in 1973), showed that the “correct” meaning was that the EPC legislators had *not* intended to exclude the products of essentially biological processes, then is the Rule not in conflict with the Article? If it is, then the Rule is inoperative. If it is not, then either the EBoA was wrong in its 2015 interpretation, something it strenuously denies in G-3/19, or the EPO's Administrative Council have got away with something Art. 164 EPC was intended to prevent, the alteration of the scope of the Articles, something that is reserved to a diplomatic conference requiring later, democratic, ratification by the parliaments of the member states. If this is the case, then there is nothing to stop the Administrative Council from doing the same with the other pesky exclusions from

patentability that the drafters of EPC 1973 so inconveniently chose to include. Here, we would draw attention to the discussions leading up to the adoption of the EPC where the UK government's suggestions in October 1971 that exclusions be left out of the Articles (to allow later flexibility) were firmly rebutted (see IGC, 1971, p. 51).

To put the EBoA's new opinion into context, we will now discuss some of the background before making a suggestion as to what the truly correct decision might have been.

## 2 | EXCLUSIONS FROM PATENTABILITY IN THE EPC

Whether or not patents, that is, temporary monopolies, can be granted for living things is fraught with social, ethical, and political problems. In the drafting of a uniform patent law for Europe, the framers of the EPC decided that certain things should not be patentable, and the EPC contains two sets of exclusions from patentability: Art. 52(2) EPC which excludes certain things as not being inventions (for European Patents can only be granted for inventions); and Art. 53 EPC which, for socioethical reasons, excludes other things, which could be inventions. In this paper, we are concerned only with Art. 53(b) EPC:

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

The wording of Art. 53(b) EPC raises two problems—what is meant by the exclusions—and in what manner must the wording of a patent claim be interpreted to determine whether the resulting European Patent would be in respect of excluded subject matter?

A lot of ink has been spilt on determining the scope of the exclusions of Art. 53 EPC, and the Boards of Appeal and the EBoA have handed down many decisions in this regard. This has caused a further severe problem to come to the fore: since their decisions cannot be appealed, what can be done if the Boards of Appeal decide on a meaning of the terms of the EPC that is incorrect?

The most final and effective manner of “correcting” a decision is for the contracting states to arrange a diplomatic conference to amend the EPC's Articles. However, this takes many years and there is always the risk that one or more parliaments may reject the reinterpretation desired by the other states.

An alternative is for an applicant or opponent to persuade a Board of Appeal in a *further* case to decide on a different interpretation of the Article or to refer the interpretation of the Article to the EBoA. In the former case, the EPO President can then ask the EBoA to interpret the Article to determine which interpretation is correct, or what the correct interpretation is. In the latter case, however, the Board of Appeal can frustrate the attempt by rejecting the referral request. This is not unusual, as can be seen for example from T-1673/11 Treatment of Pompe's disease/ GENZYME.<sup>2</sup> In any event, the option for a patent *applicant* is only available if the “incorrect” interpretation is one which gives a *broader than desired scope* to an exclusion. An applicant can only appeal a decision unfavorable to her, thus acceptance of a claim covering excluded subject matter can only be appealed by an opponent.

## 3 | RULE 28(2) EPC

In its decision of March 25 2015, G-2/12, the EBoA stated:

1. The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants...

2. ... the fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants ... other than a plant variety unallowable.
3. ... it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC.

As mentioned above, this caused consternation in the European Parliament, which passed a Resolution calling on the European Commission to declare that this interpretation was contrary to the intention of Biotech Directive. The Rules of the EPC had been amended in 1999 to declare that the Biotech Directive should be taken into account when the Articles of the EPC were interpreted. Specifically, Rule 26(1) EPC states:

*For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter [of the Rules]. Directive 98/44/EC ... shall be used as a supplementary means of interpretation.*

For the purposes of this paper, the relevant provisions of the Biotech Directive are Art. 4(1), Art. 2(2), Art. 2(3), and Art. 4(2) EBD. Art. 4(1) EBD states:

*The following shall not be patentable:*

- (a) *plant and animal varieties;*
- (b) *essentially biological processes for the production of plants and animals (emphasis added).*

The two exclusions are worded as in Art. 53(b) EPC; however, particularly narrow meanings are ascribed to them in Art. 2 EBD:

- (2) *A process for the production of plants and animals is essentially biological if it consists entirely of natural phenomena such as crossing and selection;*
- (3) *The concept of "plant variety" is defined by Article 5 of Regulation (EC) No. 2100/94 (emphasis added).*

Also of concern is Art. 4(2) EBD:

*Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not constrained to a particular plant or animal variety (emphasis added).*

Here, a first question arises as to whether Art. 4(2) EBD overrides the exclusions of Art. 4(1) EBD. Thus, if an essentially biological process is technically feasible for more than just one variety, is it patentable? Secondly, what is meant by "which concern"? Does this mean that the claims must be *directed to* (i.e., have as their directly defined subject matter) plants or animals, or is it sufficient that the claimed subject matter has *some interaction with* plants or animals?

Moreover, just like Art. 53(b) EPC, the Biotech Directive does not specify explicitly that the *products* of essentially biological processes are unpatentable; however, in 2016 the European Commission duly issued a Notice arguing that this should be the correct interpretation. The Commission did concede that the power to interpret the Directive lay not with itself or the European Parliament but with the Court of Justice of the European Union (CJEU).

Nonetheless, in view of the Notice, the EPO's Administrative Council decided in June 2017 to amend the EPC to introduce Rule 28(2) EPC which states:

*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.*

The Administrative Council has the power to introduce such a Rule under Art. 33(1)(c) and 35(2) EPC. However, under Art. 164(2) EPC, such a Rule is ineffective if it contradicts Art. 53(b) EPC, that is, expands or restricts the scope of the Article's exclusion.

Following Rule 28(2) EPC, a patent application of Syngenta was rejected in March 2018. Syngenta appealed, and in December 2018 the TBoA decided in T-1063/18 that Rule 28(2) EPC was invalid as it conflicted with Art. 53(b) EPC as interpreted by the Enlarged Board of Appeal in G-2/12:

*Having established that Rule 28(2) EPC is in conflict with Article 53(b) EPC as interpreted by the EBA and in view of Article 164(2) EPC, it must be concluded that the provisions of the Convention prevail.*

Frustrated by decision T-1063/18, the EPO's Administrative Council agreed that the President of the EPO should refer the matter to the EBoA. The President is entitled to refer questions to the Enlarged Board under Art. 112(1)(b) EPC on points of law on which two Boards of Appeal have given different decisions.

## 4 | THE PRESIDENT'S REFERRAL

On April 4 2019 the EPO President, António Campinos, referred two questions (Campinos, 2019) to the EBoA. Rather than coming straight out and ask whether Rule 28(2) EPC was in conflict with Art. 53(b) EPC, the President had first to find a contradiction between the decisions of two Boards of Appeal. The contradiction chosen was the manner in which a Board of Appeal should decide whether or not a *Rule* contradicts an *Article* of the EPC: must the Board consider the meaning of the Article *simpliciter* or must it consider the meaning of the Article *as determined by the Boards of Appeal/EBoA*? The primary cases chosen as displaying this contradiction were T-315/03 Transgenic animals/HARVARD representing the first approach, and T-1063/18 representing the second (supported by T-39/93 Polymer powders/ALLIED COLLOIDS).

Thus, for example, T-315/03 from July 2004, states:

*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 (emphasis added).*

In contrast, T-39/93 Polymer powders/ALLIED COLLOIDS from February 1996 had stated that:

*the meaning of an Article of the EPC (here, Article 114), on its true interpretation as established by a ruling of the Enlarged Board of Appeal cannot, in the Board's view, be overturned by a newly drafted Rule of the Implementing Regulations, the effect of which is to conflict with this interpretation (emphasis added).*

T-1063/18 had followed this reasoning:

*An interpretation of the EPC by the EBA is thus to be applied to all cases pending before the departments of the European Patent Office and before the Boards of Appeal and in all subsequent cases, unless the EBA provides transitional provisions.*

Having used this perceived divergence in the decisions of the Boards of Appeal to justify his first question, the President pressed on in his second question to ask whether Rule 28(2) EPC was valid.

## 5 | THE AMICI

The EBoA invited comments and 41 *amicus* briefs were received, some in favor of the President's position, some against. An inordinate amount of effort went into arguing that the President's referral was inadmissible, meaning that many parties (especially in the agrochemical industry and the patent attorney profession) were deeply concerned that the EBoA might limit the scope of patentability by giving a *broader* interpretation to the exclusions of Art. 53(b) EPC.

The President and many *amici* focused heavily on the meaning of the Biotech Directive. This is hugely problematical, for several reasons. *First*, the terms of the Directive have not been incorporated into the Articles of the EPC. *Second*, the EPC is not a EU instrument and the EPC contracting states which are not EU member states are therefore not bound by the terms of the Biotech Directive. As a result, the Boards of Appeal are not bound to apply the terms of the Directive. *Third*, the Directive does not explicitly contain a passage corresponding to Rule 28(2) EPC and the true meaning of the relevant terms of the Directive can only be established by the CJEU, something the CJEU has not done. *Fourth*, in some cases the terms of the Directive *are* in conflict with the meaning of the Articles of the EPC. Accordingly, the Directive can only be used by the Boards of Appeal as a *nonbinding means of assistance* in their task of determining the true meaning of Art. 53 EPC in accordance with the Vienna Convention on the law of treaties (VCLT) which requires that a "treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose." Art. 31 VCLT allows subsequent agreements and practices to be taken into account, and, if the meaning is still ambiguous or obscure or leads to an absurd or unreasonable result, Art. 32 VCLT allows reference to the preparatory work for the treaty, the *travaux préparatoires*.

Before turning to the President's questions, we will first comment very briefly on the *amici*. The *amici* fall into two sets, one supporting Rule 28(2) EPC and a second considering the Rule to be invalid and the President's referral to be inadmissible. The *first set* can be split into four: (a) governmental level *amici*; (b) associations of plant breeders; (c) activists and lay-persons; and (d) a handful of European patent attorneys and academics. The *second set* can be split into three: (e) industry associations; (f) patent practitioner associations; and (g) a handful of academics and European patent attorneys.

A comment by one *amicus* should be noted before we proceed. Prof. Fritz Dolder (Dolder, 2019) argued that Dr Ingo Beckedorf should not be the Rapporteur for G-3/19 in view of his presence on the EBoA in G-2/12 and G-2/13. Indeed, he was the Rapporteur for these cases and thus a very active participant in their outcome.

## 6 | THE PRESIDENT'S FIRST QUESTION

As mentioned above, for the referral to be admissible, the President had to cite two conflicting Board of Appeal decisions on the point. For the *first* question, whether or not the Boards were bound by *earlier* Board's interpretations, he did this. Needless to say, the second set of *amici* referred to in Section 5 above were adamant that the President's first question was *not* admissible.

The EBoA has had a mixed approach to referrals by the President, in some cases stating that the President's ability to refer should not be restricted, in others arguing that referrals cannot be of abstract points of law and so are limited to situations where clarification is required for the EPO to go about its normal business of granting patents (see G-3/08 Computer programs). While the Administrative Council precipitated the barrier to going about normal business by introducing Rule 28(2) EPC, it is entitled to introduce new Rules and, given the Boards' past

history of (occasionally) misinterpreting the Articles of the EPC, it is difficult to see that the President's first question related to an entirely abstract point of law.

Nonetheless, the EBOA did indeed consider this to be the case, arguing that the first question was "drafted in somewhat general terms and is directed to the abstract legal concept of the relationship between the EPC and its Implementing Regulations." They continued, stating that the second question left "no doubt as to the real purpose of the" referral ... to request the Enlarged Board to review and, in the end, abandon its interpretation of Article 53(b) EPC in decision G 2/12 ..., and to reinterpret the exception to patentability to the effect that Rule 28(2) EPC gives a conclusive interpretation of the legal scope of that Article." The EBoA found the wording of the first question to be "too general and unspecific in that it broaches an institutional topic which reaches well beyond the ultimate object of the referral." Accordingly, while accepting the referral to be admissible, the EBoA decided to reformulate the two questions into one:

*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 and 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 features define an essentially biological process?*

The second question posed by the President had been:

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

The reader will note that the EBOA focused the discussion on the process exclusion, rather than allowing the rest of Art. 53(b) EPC to be taken into account.

This is where the value of the *amicus* briefs lies. As mentioned above, the EBoA has in the past accepted that some of its decisions were wrong. G-3/19 thus gave the EBoA the opportunity to review matters in light of all the arguments presented, and to decide whether its March 2015 decision in G-2/12 was in fact correct. In view of the political, social and legal importance of the point at issue, the patentability of conventionally bred plants and animals, it was important the EBoA agree to answer the question. Politically, it was important because of the stances taken by the European Parliament, the European Commission, and many of the national governments of the EPC contracting states in their *amici* and their revisions of their national patent laws. Socially, it was of importance because of the strength of public opinion (as evidenced e.g., by the *amici* of group (c) referred to in Section 5 above). Legally, it was of importance since the then current interpretation of Art. 53(b) EPC robbed at least one of the exclusions from any realistic effect, something that the legislators of the EPC, in particular of the 1973 text, could not have intended. Thus, we should now turn to the interpretation of Art. 53 EPC.

## 7 | ARTICLE 53 EPC

The crafting of the wording of the exclusions took decades of careful work and the two sets of exclusions are presented not just in different Articles of the EPC but in different fashions. Accordingly, the manner in which they should be interpreted *can* reasonably be expected to differ, and, in practice this is what has happened. European Patents are only granted for inventions, and Art. 52(2) EPC declares that certain things, for example, discoveries, *are not inventions*, so European Patents cannot be granted for them. However, a *narrow interpretation* of this



exclusion is mandated by Art. 52(3) EPC which says that patentability is excluded “only to the extent to which a European patent application or European patent *relates to such subject-matter as such*” (emphasis added). This has been read to mean that a patent claim which recites something additional, that is, is not limited to reciting as its subject only an excluded item, can be accepted. Thus, for example a process which involves in part of its application a mathematical method (excluded) is not itself excluded. The manner in which the exclusions of Art. 52(2) EPC have been interpreted by the EPO's Boards of Appeal is described in Sterckx and Cockbain (2012, pp. 67–134).

In contrast, Art. 53 EPC relates to subject matter *that might be an invention*, and hence otherwise patentable under Art. 52 EPC. The subject matter is excluded for socioethical or political reasons, *and thus there is no reason to consider that the exclusions should be construed narrowly*—they are there for a socioethical/political purpose, and one can reasonably expect that they should be given a construction that achieves that purpose. The Boards of Appeal have acknowledged this, at least as regards some of the exclusions of Art. 53 (a) and (c) EPC. With the exclusions of Art. 53(b) EPC, however, the tendency of the Boards of Appeal has been toward a narrow interpretation, one that finds no basis in the EPC.

Central to the case before the EBoA in G-3/19 was the fact that Rules of the EPC are invalid under Art. 164(2) EPC if they force an interpretation of the exclusions of Art. 53 EPC which is either broader or narrower than the correct interpretation of that Article from its own words or in accordance with the principles of treaty interpretation set forth in the Vienna Convention.

Of relevance here is the statement in G-2/12 concerning its narrow interpretation of Art. 53(b) EPC:

it might even be inferred from the similarities in the wording of both Article 4(1)(b) Biotech Directive and Article 53(b) EPC that *the exclusion from patenting is to be understood restrictively*, to the effect that claims directed to a product ... are not automatically excluded from patenting in the same way that “essentially biological processes for the production of plants” are. *Article 4(2) Biotech Directive appears to confirm this idea*. In the same way as *Rule 27(b) EPC*, it stipulates that: “inventions which concerns plants ... shall be patentable if the technical feasibility of the invention is not confined to a particular plant ... variety.” Thus the Biotech Directive, to which Rule 26(1) EPC refers as a supplementary means for interpreting the EPC in relation to biotechnological inventions, *does not provide a basis for extending the process exclusion under Article 4(1) Biotech Directive and Article 53(b) EPC to products of such processes* (emphasis added).

Rule 27(b) EPC, it should be noted, dates from 1999, when the EPO's Administrative Council sought to align the Rules of the EPC with the terms of the Biotech Directive. *The EBoA was thus using a Rule to force, or at minimum support, a narrow interpretation of an Article of the EPC.*

## 8 | THE UNDERLYING PROBLEM, THE “ELEPHANT IN THE ROOM”

The problems with the interpretation of the exclusion of “essentially biological processes” to a huge extent arise from the manner in which the EBoA chose to interpret the exclusion of “plant or animal varieties” in Art. 53(b) EPC in its December 1999 decision G-1/98 Transgenic plants/NOVARTIS II. Why is G-1/98 so important?

Art. 53(b) EPC says that European patents shall not be granted in respect of plant and animal varieties. G-1/98 decided that the exclusion only applied to the lowest taxonomic level of plants and animals and that European Patents could validly contain claims to plants and animals expressed at a higher taxonomic level, *even though such claims would encompass and be infringed by plant and animal “varieties.”*

So, the point at issue in G-3/19 was twofold: (a) does the exclusion of essentially biological processes *also* exclude their products (as otherwise the exclusion might be meaningless); or (b) does the exclusion of plant and animal varieties *itself* exclude the products of the excluded essentially biological processes? The first point required

an analysis only of the process exclusion, whereas the second required the EBoA to revisit G-1/98 and determine whether its “higher taxonomic level” manner of interpreting the exclusion of plants and animals was in fact correct. This second point is politically explosive in view of the terms of the Biotech Directive which came into effect shortly before the G-1/98 decision was handed down and risked upsetting the major players in the agrochemical industry, something which might explain the desperation shown in the *amici* opposing the President's referral.

To understand this better, a short deviation to consider the adoption of the Biotech Directive, the background to G-1/98, and the EPO's efforts to comply with the terms of the Biotech Directive is needed.

## 9 | THE BIOTECH DIRECTIVE

Here, the reader must understand that the drive of the European Commission has consistently been to *minimize* exclusions from patentability, to optimize the position of commercial operators in the field of biotechnological innovation. This aim can be detected as a continuous thread throughout the drafting of the Biotech Directive and can be seen in the Commission's qualifications on the interpretation of the Directive in its Notice when the European Parliament resolved that the *intention* of the Directive had been to exclude from patentability the products of conventional plant-breeding procedures.

Biotech, and its ability to produce new life forms, exploded in the 1970s and 1980s with the development of techniques such as recombinant DNA and the Polymerase Chain Reaction and the ability to insert functional exogenous DNA into bacterial, plant and animal cells. The stance of the US patent authorities changed from considering life forms not to be patentable to granting patents on them following the US Supreme Court decision in *Diamond v. Chakrabarty* in 1980. The European Commission worried that the EU would be left behind and started its attempts to have the European Parliament agree a Directive confirming the patentability of the new techniques and their products.

As a result, a first proposal for the Biotech Directive was put to the European Parliament by the European Commission in January 1989. On the patentability of plants, animals and essentially biological processes, the Articles of this proposal said:

*Article 3 ... plants ... shall be considered patentable subject matter...*

*Article 4 Uses of plant or animal varieties and processes for the production thereof shall be considered patentable subject matter (emphasis added).*

This could hardly be clearer. Art. 53(b) EPC was to be scrapped. This was most explicitly *not* the intention of the drafters of the EPC. In June 1992, the European Parliament approved the Proposal, subject to certain amendments, in particular:

*a) Introduction of new Recital 16*

*Whereas substantial innovations in patent law may be introduced only by means of a revision of the European Patent Convention.*

*b) Introduction of new paragraph (b) to Art. 1*

This Directive shall *not* be binding on the Member States as regards the interpretation and implementation of the ...European Patent Convention (EP, 1992, emphasis added).

In effect, the European Parliament was saying that the Directive should not affect the interpretation of the EPC. That, of course, was not the European Commission's goal and in February 1994 it adopted a revised version in its Common Position (EC) No. 4/94. The Common Position (EC 1994) did not adopt the amendments set out above. The back and forth between the European Commission and the European Parliament continued until May 1998 when, with some concessions concerning the morality exclusion which appear in Art. 53(a) EPC, the Parliament eventually agreed the Directive's provisions relating to plants and animals:

Article 2 (2) A process for the production of plants or animals is essentially biological *if it consists entirely of natural phenomena such as crossing or selection.* (3) The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.

Article 4 (2) Inventions *which concern* plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety (emphasis added).

However, this was not to the taste of all countries, and in October 1988, the Netherlands sought annulment of the Directive. The Netherlands, joined by Italy and Norway, argued that such changes should instead be made by renegotiation of the EPC. In its decision in *Netherlands v European Parliament* in October 2001 the CJEU rejected the Dutch request.

## 10 | AFTER THE BIOTECH DIRECTIVE: THE AMENDING OF THE EPC RULES AND EBoA DECISION G-1/98

While initially considering that the EPC was compliant with the Biotech Directive, the EPO did consider introducing new Rules. Critical to the background of this was a case then pending before the EBoA, G-1/98 *Transgenic plants/NOVARTIS II*.

G-1/98 resulted from a referral in October 1997 in T-1054/96 *Transgenic plant/NOVARTIS* regarding the interpretation of the exclusion in Art. 53(b) EPC of "plant and animal varieties." The first three questions referred were:

1. *To what extent should the instances of the EPO examine an application in respect of whether the claims are allowable in view of the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants, ... and how should a claim be interpreted for this purpose?*
2. *Does a claim which relates to plants but wherein specific plant varieties are not individually claimed ipso facto avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?*
3. *Should the provisions of Article 64(2) EPC be taken into account when considering what claims are allowable? (emphasis added).*

The referral was made in view of the various interpretations that were possible for the plant and animal variety exclusion. The TBoA considered the approaches that had been made to the "as such" exclusions of Art. 52(2) EPC and the different approaches to interpretation of Art 53 EPC in earlier cases. Questions 2 and 3 however focus on the question as to whether a "novelty" (referred to as *substantive*) or a "higher taxonomic level" approach should be adopted (Sterckx & Cockbain, 2012, p. 310). In the "novelty" approach, favored by the referring Board, a claim is not acceptable if it would be infringed by an excluded product or process; in the "higher taxonomic level" approach, that of T-19/90 *Onco-mouse/HARVARD*, the claim is acceptable if, although *encompassing* excluded matter, the relevant feature is defined at a more generic level than is the exclusion. Thus, for example, a claim to a rodent is acceptable,

but a claim to *Mus mus domesticus* is not. This framing of the referral placed the EBoA in the position of choosing between two unsatisfactory approaches rather than of finding the correct approach.

The EBoA invited the EPO's President to comment on the referral, and in March 1999 he submitted an extensive comment (Kober, 1999) confirming that he believed that the Directive should be considered when interpreting Art. 53 EPC, and that the approach that he considered to be correct, the "higher taxonomic level" approach, was supported by the Directive and should be adopted. In June 1999, the Administrative Council decided to amend the EPC to introduce new Rules suggesting that the EPC should be interpreted in such a way as to be compliant with the Biotech Directive. These new Rules, Rules 23a to 23e EPC, came into force in September 1999. In its decision a couple of months later in December 1999, the EBoA chose the less obviously incorrect approach, the *higher taxonomic level* approach, an approach that was apparently in conformity with the Directive and with the new Rules, and therefore in line with the interests of the Administrative Council and the President. On this basis, the plant and animal variety exclusion did not exclude plant and animal claims in general, and accordingly the exclusion of essentially biological processes was deprived of its mechanism for automatically considering the products of such processes to be excluded. This was the basic underlying reason for the current G-3/19 referral.

## 11 | THE TOMATOES I AND BROCCOLI I DECISIONS, G-2/07 AND G-1/08

Things might have rested there, with the EPO accepting that the Biotech Directive and the EPC were in conformity. However, the Directive and the new Rules had given an interpretation to the exclusion of "essentially biological processes" that offered a window of opportunity to the parts of the agrochemical industry interested in plant breeding using techniques that involved "technical" steps. Art. 2(2) of the Directive had stated 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). Clearly, *essentially* does not necessarily mean *entirely*.

The British company Plant Bioscience and the State of Israel filed patent applications in 1999 and 2000 for methods of breeding healthy broccoli and wrinkly tomatoes, EP-B-1069819 and EP-B-1211926 respectively. The methods included "technical" steps and the patents were granted in July 2002 and November 2003. The Broccoli patent was opposed by Syngenta and Limagrain, and the Tomato patent by Unilever. The Opposition Divisions decided that the subject-matter was allowable under Art. 53(b) EPC. The opponents appealed, giving rise to cases T-83/05 Broccoli/PLANT BIOSCIENCE and T-1242/06 Tomatoes/STATE OF ISRAEL. In its decisions of May 2007 and April 2008, the TBoA decided to refer questions regarding the Art. 53(b) EPC exclusion to the EBoA (as G-2/07 Broccoli/PLANT BIOSCIENCE and G-1/08 Tomatoes/STATE OF ISRAEL, which the EBoA decided to consolidate). The questions were:

1. Does a nonmicrobiological process for the production of plants which contains the steps of crossing and selecting plants 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, an additional feature of a technical nature?
2. ... what are the relevant criteria for distinguishing nonmicrobiological plant production processes excluded from patent protection under Article 53(b) EPC from nonexcluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?
3. Does a nonmicrobiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

4. ... does a nonmicrobiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?
5. ... what are the relevant criteria for distinguishing nonmicrobiological plant production processes excluded from patent protection under Article 53(b) EPC from nonexcluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

After reviewing the legislative history of the Biotech Directive, the EBoA concluded in Reasons 5:

*... the consequence of the self-contradictory wording of Article 2(2) Biotech Directive having been transposed verbatim into Rule 26(5) EPC is, regrettably, that Rule 26(5) EPC does not give any useful guidance on how to interpret the term "essentially biological process for the production of plants" in Article 53(b) EPC and therefore that term must be interpreted on its own authority. This is for the Enlarged Board to do.*

Rule 26(5) EPC (introduced as Rule 23b(5) EPC in September 1999 to bring the EPC into compliance with the Biotech Directive) stated that a process:

*is essentially biological if it consists entirely of natural phenomena such as crossing or selection (emphasis added).*

The EBoA then turned to Art. 53(b) EPC itself. First it considered the terms "plant variety" and "plant" used respectively in the product and process exclusions of Art. 53(b) EPC. Given the relatively recent decision G-1/98 by the EBoA under the same Chairman, Peter Messerli, it will come as no surprise that G-1/98 was followed unquestioningly:

*The importance of the difference between the terms "plant" on the one hand and "plant variety" on the other hand was examined in ... G 1/98... In that decision the Enlarged Board held ... with reference to the definition in Article 1(vi) of the UPOV Convention 1991, that "the term (plant) "variety" means a plant grouping within a single botanical taxon of the lowest rank, which grouping... can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes..." More importantly ... the difference in wording ... "plant" on the one hand and "plant variety" on the other hand must be supposed to have some meaning. With respect to the term "plant variety," the provision would use the more general term "plants" as used for the processes if it was the intention to exclude plants as a group embracing in general varieties as products. The converse also holds true when it comes to determining the meaning of the excluded processes for the production of plants vs. the excluded protection for plant varieties (emphasis added).*

It is of course interesting to ponder the logic that a term employed in EPC 1973 and the Strasbourg Patent Convention (SPC) from 1963 should be interpreted to have a meaning *as set down in a law from 1991*. It is also well understood that, while the term "plant variety" may have come to have a well-defined meaning, Art. 53(b) EPC refers to "plant or animal varieties" and "animal variety" has no such known definition. Since the term "varieties" was used for both plants and animals it can be assumed to have the same meaning. Nonetheless, UPOV 1991 provides no immediate basis for a definition of "animal varieties."

The EBoA accepted the inconsistency of the terminology used by the legislator in the period when the wording of Art. 53(b) EPC was being settled, 1960–1963, but it stuck with G-1/98's approach:

Admittedly, the comments reproduced in ... T 83/05 show a certain interchange between the use of the terms “plant,” “plant species” and “plant variety.” Furthermore, no real explanation can be derived from the preparatory documents as to why the initial terms “plant variety” or “plant species” were eventually replaced by the term “plants.”

However, in the absence of any indication in the legislative history that the term “plants” was meant to signify only “plant varieties,” and *in view of the importance of the difference in legal meaning of the term “plant” on the one hand and “plant variety” on the other, as demonstrated by the Enlarged Board’s decision G 1/98, any interpretation of the term “plant” as meaning, contrary to its wording, only “plant varieties,” is ruled out.*

Hence, the Enlarged Board concludes that the exception of “essentially biological processes for the production of plants” cannot be read as only applying where the result of such a process is a plant variety. In other words, it cannot be read as being limited to processes for the production of plant varieties (emphasis added).

The “importance of the difference in legal meaning” referred to is of course that the meaning settled on for “plant varieties” allowed G-1/98 to conclude that European patents *could* be granted for plants and animals if claimed at a “higher taxonomic level.” Thus, with negligible effort to interpret the terms “plant” and “plant variety” beyond accepting the stance of G-1/98, and with a brief diversion to consider the meaning of the words “for the production of,” the EBoA turned to the meaning of the words “essentially biological” and threw up its hands in horror:

Any attempt to determine a reliable literal meaning for the term “essentially biological” process *appears futile*. Under the EPC, the legal situation today is that jurisprudence has existed for many years—for the cases underlying the referring decisions, this is above all decision T 320/87 ...—that has set a standard for the interpretation of the exclusionary clause. *Hence, what the Enlarged Board must now consider is whether the approach as adopted in decision T 320/87 holds good* (emphasis added).

Thus, to begin, what was the approach in T-320/87? There, the Board was faced with a claim to a process for rapidly developing hybrid plants. In its decision of November 1988, the Board accepted that the “essentially biological process” exclusion was modeled on Art. 2(b) SPC from 1963 and stated:

*Like any exception to a general rule of this kind the exclusion of “essentially biological” processes for the production of plants (or animals) has to be narrowly construed. ...The Board takes the view that whether or not a (nonmicrobiological) process is to be considered as “essentially biological” within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being “essentially biological.” Human interference may only mean that the process is not a “purely biological” process, without contributing anything beyond a trivial level* (emphasis added).

The “totality of human intervention” approach simply acts as an incentive to the patent applicant to overegg the importance of any “technical” features. The EBoA decided that this approach was not appropriate and then turned to the two other approaches mentioned by the referring Board in T-83/05 (the “contamination” and the “anything added” approaches referred to by Sterckx & Cockbain, 2012, p. 310). Regarding the first, the EBoA commented:

*The first approach would be analogous to that used under Article [53(c) EPC] ... in relation to methods of treatment by surgery and therapy and would result in the inclusion in a claimed process of a step of an essentially biological nature not being allowable. However, it already follows from the wording of the exclusion, which requires the claimed process, i.e., the process as a whole, to have a biological "essence" (whatever that may mean precisely), that the mere presence of one biological feature in a process cannot automatically confer an essentially biological character on the process as a whole.*

Regarding the second approach, the EBoA noted that it was analogous to the approach taken to Art. 52(2) EPC for computer-implemented inventions and that it would:

*require, in order for the process to escape the prohibition of Article 53(b) EPC, at least one clearly identified "non-biological" process step, while allowing any number of additional "essentially biological steps," which would be carried into allowability by the "non-biological" process step.*

The EBoA considered that the mere presence of a technical feature was not enough since however:

*narrowly one might wish to construe the reference to some kind of "essentiality," any possibility of interpreting the exclusion in the sense that any technical feature, irrespective of its importance for an otherwise biological process for the production of plants, makes the process escape the exclusion under Article 53(b) EPC, is thereby also ruled out from the outset (emphasis added).*

The EBoA then decided that it had to look to the purpose of the exclusion:

*since the respective legislative purposes behind the sub-items in Article 53 EPC and even those behind the alternatives of Article 53(b) EPC are quite different, the systematic context of the exclusion of essentially biological processes from patentability, namely its place in Article 53(b) EPC, does not as such indicate what the purpose of the provision is. It only allows the conclusion that some kinds of processes must be excluded even though they are inventions, and that, hence, the exclusion may not be interpreted in such a way that it would be entirely deprived of any field of application and thereby rendered obsolete (emphasis added).*

The EBoA decided that it found the purpose of the exclusion in the *travaux* from 1960 to 1963. The draft of 14 March 1961, prepared with the drafting of UPOV (which contained a ban on dual protection by patents *and* plant variety rights) in mind, had an exception from patentability for "inventions relating to the production of or a process for producing a new plant variety or a new animal species." By December 1961, this had become "essentially biological processes for the production of plants and animals." The EBoA considered that the reasons for this were of particular importance and referred to T-83/05 in which they were reproduced verbatim:

*According to the explanations given, the (essentially biological) processes for the production of plants or animals should include those which may produce known varieties as well as those which may produce new ones. Selection or hybridization of existing varieties are mentioned as examples of such processes. The replacement of "purely" by "essentially" is explained by the reasoning that it was evident that the exclusion should be extended to cover processes which were fundamentally of this type, even if, as a secondary feature, "technical" devices were involved ..., it being understood that while such technical devices may perfectly well be patented themselves the biological process in which they are used may not (emphasis added).*

It is a pity that the EBoA did not quote further from the Committee report EXP/Brev (61) 8 of 13 December 1961:

The processes for “the production of plants or animals” referred to in the new text include those which may produce *known* varieties as well as those which may produce *new* ones it being understood that *only new varieties* can eventually qualify for protection *in themselves* (CoE, 1961, some emphasis added).

This seems to be a clear statement that the only protection that new plants could qualify for was plant variety protection and that the Art. 53(b) EPC exclusion (apart from the microbiological exemption) firmly closed the door on the patentability of plants however claimed and on biological processes for the production of all plants, whether old or new. However, quoting this passage would have risked calling the validity of the G-1/98 decision into question.

Accordingly, in its decisions in December 2010, the EBoA answered the questions referred to it as follows:

1. A nonmicrobiological 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.

With the cases remitted to the TBoA, Plant Bioscience and the State of Israel amended their claims to ones directed to the products of the processes, defined of course at a “higher taxonomic level.” This looked like it might succeed until opponent Unilever and *amicus* Sigrid Sterckx submitted letters in October and November 2011 (Sterckx, 2011; Unilever, 2011) arguing that such claims too should be excluded. This led to the TBoA issuing further decisions in July 2013 and June 2012 referring further questions to the EBoA (as G-2/13 and G-2/12, which the EBoA again decided to consolidate).

## 12 | THE EBoA's INTERPRETATION OF ART. 53(b) EPC IN G-2/12

Before turning to the specifics of this case, we would point out that there has long been controversy as to whether the EPO Boards of Appeal are truly independent of the EPO administration. The head of the Appeals department, generally also the Chairman of any EBoA, was also a deputy of the EPO President concerned with the EPO's administration. Given the tendency for the EPO President to argue for the emasculation of the EPC provisions limiting patentability, the possible lack of independence of the Boards of Appeal was of concern. This was brought to a head in a case regarding a petition for review of a TBoA decision in which the EBoA, with a membership



restricted to exclude the Chairman, decided that he had to be removed from the EBoA. The decision, R-19/12 *Ablehnung wegen Besorgnis der Befangenheit/IXETIC*, was handed down in April 2014, that is, before the oral proceedings and decision in G-2/12, but the Administrative Council took until June 2016 to decide to change the structure of the appeals department so that its now head, its President, is an EBoA member, but not the EBoA chair.

The questions put to the EBoA in G-2/12 and G-2/13 were:

1. Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants ...?
2. In particular, is a claim directed to plants ... other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?
3. Is it of relevance ... that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?
4. Is a product-by-process claim directed to plants ... other than a plant variety allowable if its process features define an essentially biological process for the production of plants?
5. If a claim directed to plants ... other than a plant variety is considered not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability under Article 53(b) EPC, is it possible to waive the protection for such generation by “disclaiming” the excluded process?

Here, it must be stressed, the referring Boards of Appeal did *not* ask the simple question as to whether a claim to a plant or animal which was the product of an essentially biological process was excluded by Art. 53(b) EPC. Their focus was *entirely* on the effect of the *process* exclusion in Art. 53(b) EPC. This is important since it shows that the Boards were avoiding challenging the correctness of the sacrosanct decision G-1/98. As a result, the EBoA never did reconsider its decision in G-1/98 and indeed relied on its correctness.

Holding up a fig-leaf to cover their interpretation, and referring favorably to the Vienna Convention, the EBoA set out to create the impression that the question of interpretation had been investigated exhaustively. This required seven rounds of interpretation: grammatical, systematic, teleological, subsequent agreement or practice, historical, dynamic, and legal erosion. Before commencing, it did accept that the *a priori* principle that exclusions from patentability should be construed narrowly had been declared in its earlier decisions G-1/04 *Diagnostic methods* and G-1/07 *Broccoli/PLANT BIOSCIENCE* (and indeed in its G-2/06 *Use of embryos/WARF* decision) *not to be implicit or binding* in the interpretation of the EPC. Thus, we must look to each of the seven interpretative rounds.

## 13 | THE APPROACHES TO INTERPRETING THE EXCLUSION

### 13.1 | The grammatical approach

This approach was to involve determining the *literal* meaning of the words at issue, followed by investigating whether the literal interpretation was reasonable and was confirmed by the context in which the words appeared. Since the key word was “processes,” as it was only the process exclusion that was being interpreted, it will come as no surprise that the EBoA could not conclude that an instruction to exclude processes was also literally an instruction to exclude products. However, noting that various *amici* had argued that the wording did not rule out a broad reading of the process exclusion as also excluding claims to the products of the excluded processes, the EBoA decided to move on to the next round of the approaches. Before doing so, it made no suggestion that the exclusion

as a whole (i.e., of plant and animal varieties and essentially biological processes) needed to be construed instead, and thus G-1/98 was not challenged.

## 13.2 | The systematic approach

The EBoA introduced this approach saying:

In applying this second method of interpretation the meaning of the wording in question is to be established *in the context of the relevant provision* itself. In addition, the provision as such must be interpreted *taking into account its position and function within a coherent group of related legal norms* (emphasis added).

Thus, the next stage was to identify a coherent group of related legal norms in which the essentially biological processes exclusion is located.

The EBoA found that, in G-1/98, it had given a very narrow and specific scope to the related norm, the exclusion of plant and animal varieties:

[The exclusion of plant and animal varieties] is restricted to very specific requirements and conditions that need to be fulfilled to justify the verdict “unpatentable.” *Even the scope of the exclusion is limited.* In case G 1/98 ..., the Enlarged Board concluded that where specific plant varieties are not claimed individually, the claimed subject-matter was not excluded from patentability under Article 53(b) EPC, *even if it might potentially embrace plant varieties.* ... Hence, it is *rather difficult* to derive from this *very specific and narrow exclusion* a systematic approach leading to a broad understanding of the second exclusion, extending its scope from process claims to product claims (emphasis added).

In other words, since we decided on a narrow approach for the plant and animal varieties exclusion, it would not be systematic to apply a broad approach to the process exclusion. Nonetheless, on its own, the product exclusion might have been evadable by claiming a process for producing an excluded product, and such claims would be infringed by their (unpatentable) product. This had to be mentioned:

In this context, it needs to be borne in mind that, *if it were not for the process exclusion in Article 53(b) EPC, patenting of an essentially biological process for the production of plants or animals would mean that the protection conferred by a process claim extended to the product directly obtained by such process* (Article 64(2) EPC), which could well encompass a plant or animal variety. In consequence ... the process exclusion is *inevitable* to avoid a contradiction (emphasis added).

This is important because the EBoA here *is* taking into account the question of whether the excluded can nonetheless be *covered* by a patent claim, something it had considered irrelevant in G-1/98. Moreover, it might be pointed out that, had this been the intention of the process exclusion (which the *travaux* clearly show was not the case), then the process exclusion could simply have related to processes for the production of plant and animal varieties. This was not done, and this attempt to deduce from a systemic interpretation that the exclusions “as a coherent group of legal norms” are to be interpreted narrowly is a sham.

The EBoA then broadened up to see if Art. 53 EPC, the socioethical exclusions, represent “a coherent group of legal norms.” The individual exclusions of the Article were listed, and coherence was waved away by referring to earlier decisions (which of course may have been incorrect):

The “system” of exclusions from patentability according to Article 53 EPC is characterised by a listing of specific inventions for which a European patent is not to be granted. Article 53 EPC ... *has been interpreted by the boards of appeal rather restrictively* ... Thus, Article 53 EPC does not envisage a system of general exceptions to patentability that per se *would allow or even necessitate a broad interpretation of any of the exclusions* (emphasis added).

Of course, relatively broad interpretations *have* been found to be allowed and necessitated for most of the exclusions other than that of plant and animal varieties by G-1/98 (consider, e.g., the therapy, surgery and morality exclusions).

Broadening even further to consider Art. 52 EPC, the EBoA then added insult to injury before proceeding to rely on one of the Rules of the EPC introduced in 1999 in response to the Directive (one of the set of Rules which gave the EBoA cover in G-1/98 to construe Art. 53(b) EPC narrowly):

Article 52(1) EPC lays down the general principle that European patents are granted for any inventions, in all fields of technology ... Therefore, considering the exception to patentability of inventions according to Article 53(b) EPC in its context ..., one could deduce two things: *first, there is no clear basis for broadly interpreting Article 53(b) EPC; second, one could rather infer from the systematic position and function of Article 53(b) EPC that exceptions to patentability are to be narrowly construed.* ... Furthermore, Rule 27 EPC ... is to be considered in the wider context of Article 53(b) EPC. ... Rule 27(b) EPC stipulates that biotechnological inventions *relating to plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety*. In addition, Rule 27(c) EPC allows patenting of a product other than a plant variety obtained by means of a microbiological or other technical process. ... Hence, Rules 27(b) and (c) EPC *appear to be guided by a rather wide notion of the patentability of biotechnological inventions concerning plant-related processes and products other than plant varieties* (emphasis added).

It was convenient for the EBoA to rely on an argument from authority (the suggestion that the Rules correctly interpreted Art. 53 EPC), when it could refer to a Rule deriving from the Biotech Directive that supported the narrow interpretation of the plant and animal varieties exclusion it had jumped at in G-1/98. Thus, this systematic approach led the EBoA to conclude that it did “not support giving the process exclusion a broad meaning to the effect that product claims or product-by-process claims are thereby excluded from being patentable.” The EBoA then turned to the third approach.

### 13.3 | The teleological approach

Here the name of the approach implies that it is intended to unearth the purpose behind the exclusions of Art. 53(b) EPC. The EBoA started by confirming this:

the Enlarged Board applies the method of teleological interpretation in the construction of legislative provisions *in the light of their purpose, values, and the legal, social and economic goals they aim to achieve*. In this, the Enlarged Board examines their *objective sense and purpose* ... The starting point is marked by determining *the general object of the relevant provision (ratio legis) because the interpretation must not contradict the provision's spirit* ... (emphasis added).

The EBoA then proceeded to decide that this had already been done and did not need to be done again:

In respect of the ratio legis of Article 53(b) EPC, the Enlarged Board in the two previous referrals concluded (*G 2/07* and *G 1/08*, ...): “However, since the respective legislative purposes behind the sub-items in Article 53 EPC and even those behind the alternatives of Article 53(b) EPC are quite different, the systematic context of the exclusion of essentially biological processes from patentability, namely its place in Article 53(b) EPC, does not as such indicate what the purpose of the provision is.” ... This conclusion is still valid (emphasis added).

This superficial teleological approach led the EBoA to conclude that “the object and purpose of the exclusion 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.” Then they turned to the fourth approach.

### 13.4 | The subsequent agreement or practice approach

This approach of course is based on Art. 31(3) of the Vienna Convention whereby, if (all) the parties to a treaty reach an agreement or adopt a (binding) practice, the terms of the treaty can be interpreted to comply with that agreement or practice. This is of particular importance in relation to anything specified by the Biotech Directive which affects the scope of the provisions of the EPC, since the Directive was adopted by the EU and not by the noncoextensive set of the contracting states of the EPC.

Nonetheless, not only did the EBoA draw inspiration from the Directive, but it also compounded this by again referring to Rules of the EPC introduced by the Administrative Council in 1999. It found that Art. 3 EBD did “not support a broad reading of the exclusion under Article 53(b) EPC” and that the similarity of wording of Art. 4(1)(b) EBD and Art. 53(b) EPC might infer that “*that the exclusion from patenting is to be understood restrictively*, to the effect that claims directed to a product ... are not automatically excluded from patenting in the same way that ‘essentially biological processes for the production of plants’ are.” The EBoA went on to say that:

*Article 4(b) Biotech Directive appears to confirm this idea.* In the same way as *Rule 27(b) EPC*, it stipulates that: “inventions which concerns plants shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety” [and thus that] ... *the Biotech Directive*, to which *Rule 26(1) EPC* refers as a supplementary means for interpreting the EPC in relation to biotechnological inventions, *does not provide a basis for extending the process exclusion under Article 4(1) Biotech Directive and Article 53(b) EPC to products of such processes* (emphasis added).

The EBoA then moved on to the next interpretative approach.

### 13.5 | The historical approach

At last, it was time for the EBoA to turn to the negotiating history, the *travaux*, of the EPC, more particularly the 1973 text since Art. 53(b) EPC was unchanged in the 2000 revision.

The EBoA chose to begin by saying “we’ve done this already”:

The Enlarged Board has dealt with the legislative history of Article 53(b) EPC on previous occasions. ... In case *G 1/98* ... the Enlarged Board ... held that the purpose of Article 53(b) EPC corresponds to the purpose of Article 2(1) UPOV Convention 1961 and Article 2(b) Strasbourg Convention, *i.e.*, *that European patents should not be granted for subject-matter for which the grant of patents was excluded under the ban on dual protection in the UPOV Convention 1961* (emphasis added).

The EBoA read G-1/98 as concluding that inventions ineligible for protection under the plant breeders' rights system were *intended* to be patentable and that the *travaux* contained no suggestion that Art. 53(b) EPC “*could or even should exclude subject-matter for which no protection under a plant breeders' rights system was available*” (emphasis added). This had been the EBoA's stance in G-2/07, in other words the legislator's intention had been to exclude from patentability the processes which were the “conventional methods of plant-variety breeding at the time.”

The conclusion that the purpose of the product exclusion was *only* to avoid dual protection *cannot* be drawn since the SPC and the EPC refer to animals as well as plants, since there is no system equivalent to UPOV for animals, and since “variety” had and has no immediately clear meaning for animals. Thus, it cannot be the case that the avoidance of dual protection was the entire *telos* of the exclusions.

The EBoA then turned to the *travaux*. The first version referred to was to the exclusion of:

“inventions the subject-matter of which is the *breeding* of a new plant variety.” This wording actually occurs in a draft (Haertel, 1961) dated March 3, 1961 by Dr Kurt Haertel, the President of the West German (BRD) Patent Office, and continued “or a new type of animal.” The text was in German and the German word “Züchtung” can of course mean growing or cultivating as well as breeding. It is not a committee suggestion and thus cannot be taken to reflect the view of the relevant committee, here the Patents Working Party, which indeed, in the Comments dated March 14, 1961 (Document IV/2071/61, Section 14 (EEC, 1961b)) states that it:

concluded that European patents should not be granted for inventions relating to new plant varieties. ... [These] comments also apply *mutatis mutandis* to the patentability of new animal species.

The EBoA found a second version of the exclusion in Document IV/2071/61, Section 13 (EEC, 1961a) reading:

*European patents shall not be granted in respect of: ... Inventions relating to the production of or a process for producing a new plant variety or animal species. This provision shall not apply to processes of a technical nature.*

Leaping to the Minutes of the 9th Meeting of Working Party I of October 12–22, 1971 (IGC, 1971), that is, 10 years later, the EBoA noted that:

*The UK delegation even requested that the term “essentially biological processes” be deleted because it was not clear and there was no reason why: “any biological processes other than for the treatment of the human body should be specifically excluded by the Convention.”*

However, this passage in the Minutes continued: “This proposal found no support from any other delegation,” that is, that the then current exclusion should stay. Having referred to Minutes from 1971, the EBoA returned to the “subsequent” developments in 1962 and 1965, and 1969:

However, the drafting committee of the Patents Working Party *subsequently* rephrased the wording in the form of what later became Article 53(b) EPC (see Preliminary Draft Convention relating to a European Patent Law, May 1962; travaux préparatoires, Amendments to the Preliminary Draft Convention relating to a European Patent Law, 22 January 1965). The discussion was predominantly focused on the issue of “microbiological processes or the products thereof,” *the intention being to bring the exclusion clause into line with Article 2 Strasbourg Convention* (travaux préparatoires, minutes of the meeting of Working Party I, July 8–11, 1969, Article 2(b) Strasbourg Convention) (emphasis added).

This passage refers to four documents, in order: 4488/IV/62 (EEC, 1962); 2335/IV/65 (EEC, 1965); BR/7/69 (IGC, 1969); and Art. 2(b) SPC. The Preliminary Draft, 4488/IV/62, proposed the wording:

*European patents shall not be granted in respect of ... plant or animal varieties or essentially biological processes for the production of plants or animals*

This is identical to the wording of Art. 53(b) EPC adopted in 1973, except for the absence of the microbiological exemption. 2335/IV/65, from January 1965, and based on intervening work not cited by the EBoA, amended this wording to add the microbiological exemption in the words used in Art. 2 SPC, that is, almost the present form of Art. 53(b) EPC. Thus, we must turn to the third document, BR/7/69, the Minutes of a meeting in July 1969. Interestingly, the only relevant passage, is the statement on page 10, that the exclusion “corresponds to Article 2 of the 1963 Strasbourg Convention.” The documents cited do not leave us with any grounds to believe that the intention of the framers of Art. 53(b) EPC had changed since May 1962, other than to acknowledge that some might have worried that an exclusion of microbiological processes, for example, fermentation, might in future be read into the plant and animal exclusions. The EBoA did not establish the intention of the framers in relation to the plant and animal exclusions themselves. A deeper reading would have been required.

Nonetheless, the EBoA concluded its “historical approach” by stating that:

The legislative history of Article 53(b) EPC in respect of the legal term in question *is rather vague*. The discussion *in the Working Party* never concerned the question of whether or not the wording “essentially biological process for the production of plants” included a product that is defined or obtained by such a method for its production. Thus, in the context of the historic discussion ... *there is no reason* in the travaux préparatoires *to assume 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* (emphasis added).

The five standard approaches to interpretation had given the EBoA no reason to exclude plants and animals other than *varieties as defined by UPOV* from patentability and so, following an issue raised by various *amici*, it turned to the two extra approaches, *dynamic* and *legal erosion*, to test the conclusions it had reached.

### 13.6 | The dynamic approach

In G-1/98, the EBoA had referred to a further approach, a “dynamic interpretation” which might come into play where factors have arisen since the EPC was signed which might give reason to believe that a *literal interpretation* would conflict with the legislator’s aims. The EBoA noted that Art. 53(b) EPC had remained unamended since the drafting of the 1973 text, even though the science relating to plant and animal breeding had advanced enormously. However, while the Article showed “the legislator’s clear intention to exclude from patenting essentially biological processes of the kind known at the time of the signing of the EPC,” the “subsequent developments in the field of plant breeding techniques did not *prompt the legislator to revise the process exclusion* such that it was extended to plant products obtained by essentially biological processes” (emphasis added). This can only be construed as meaning that the contracting states saw no reason to call a diplomatic conference to revise Art. 53(b) EPC and that they saw no reason to include a revision of Art. 53(b) EPC in the diplomatic conference of November 2000.

First, one might comment that perhaps no reason was seen because the legislator was under the impression that the products of essentially biological processes were already excluded by the Article. That this was the case seems clear from the explanation given to the Dutch government when the ratification of EPC 1973 was being decided in the mid 1970s:

no patents can be obtained for plant and animal varieties or for essentially biological processes for the production of plants and animals; *in fact, the products of these processes will accordingly also not be patentable* (Staten-Generaal, 1976, p. 18, our translation from Dutch, emphasis added).

Secondly, the 2000 diplomatic conference was arranged following the adoption of the Biotech Directive and under the aegis of a President of the EPO who strongly favored limiting the EPC's exclusions from patentability (see Sterckx & Cockbain, 2012, pp. 56–66). The major proposed revisions were set out by the President in June 2000 in CA/PL 25/00 (EPO, 2000a), and the draft text, MR/3/00 (EPO, 2000b), for the revised EPC was produced in October 2000 by the Administrative Council of the EPO, the same body that had pushed through Rule changes in 1999, the same Rules that had facilitated the EBoA's decision in G-1/98 in December 1999. There can be little surprise that there was no push toward clarifying the exclusions in any way that conflicted with the Directive. Accordingly, the EBoA concluded that:

*This decision of the legislator not to amend Article 53(b) EPC can neither be ignored when interpreting Article 53(b) EPC, nor be reversed by means of a dynamic interpretation. The Enlarged Board cannot see why the legislator's original intention to direct the exclusion from patentability in respect of plants to only two groups, i.e., "plant varieties" and "essentially biological processes for the production of plants," would no longer be justified, just because today there are new techniques available in this sector. Thus, the concept of a dynamic interpretation does not require revising the result of the interpretation established by applying traditional rules of construction.*

This left only "legal erosion."

### 13.7 | Legal erosion

There has been much written about patent attorneys' use of crafty language when drafting claims to avoid rejection on the basis of statute and case law. This, after all, is part of the reason for employing a patent attorney. The TBoA which referred the G-2/12 and G-2/13 cases had mentioned this skillful drafting, as the EBoA put it, raising:

*the question whether allowing patenting of a product claim or a product-by-process claim for a plant or plant material other than a plant variety that is obtained by means of an essentially biological process could be qualified as circumvention of the process exclusion. Thus, it was said, the legislator's intentions could be frustrated by the choice of the claim category and by "skilful" claim drafting.*

The EBoA noted that:

*it could be contended that the legislator's intention to exclude from patentability method claims for an essentially biological process for the production of plants would be frustrated if an applicant or patent proprietor ... succeeded in acquiring patent protection for a product which was directly and inevitably obtained by said process. ... This argument might apply particularly if the product was explicitly determined by the process, making the method features a required part of the claim defining the extent of protection conferred by the patent*

The EBoA had even commented on this in G-2/06 Use of embryos/WARF, stating that: "to restrict the application of Rule 28(c) ... EPC to what an applicant chooses explicitly to put in his claim would have the undesirable

consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.”

The EBoA acknowledged that the cases before it had involved various different claim formats, initially method and product claims, but by this stage only product and product-by-process claims. It considered, however, that:

to describe these amendments and the patent proprietors' procedural behaviour as an evasion of the exception to patentability of “essentially biological processes for the production of plants” rendering Article 53(b) EPC meaningless, or without any substance in its scope of application, *would be to assume that the legislator intended—or envisaged—a broadening of the term “process” as a matter of jurisprudence*” (emphasis added).

Given the EBoA's interpretation of the exclusion under the approaches so far considered, that assumption would have to be tested against certain “considerations of fact as well as of law.” The argument on facts was that to determine whether a product infringed, one would have to know whether it had been produced by the excluded process. This is ridiculous since it is an everyday problem with granted claims to processes to determine whether a particular product infringes by virtue of being the direct product of the claimed process. For patent application examination purposes, it can be dealt with by including an exclusion in the product claim “other than a product produced directly by an essentially biological process.”

On the “legal issue,” the referring TBoA had raised the question whether it was of relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC. The EBoA, however, considered that the question of law put to it by the TBoA was only whether a product claim is excluded by virtue of the excluded nature of the process for making it, and that the scope of protection conferred by the product claim has no direct impact on this point of law. The EBoA considered that a distinction has to be made between the questions of what can be patented and the scope of the resulting claims—in other words, there is no problem granting claims whose subject matter, according to their precise wording, is not excluded, even if the performance of an action or the production or use of a product, which action or product are unpatentable, would infringe those claims. This is essentially the head-in-the-sand attitude of G-1/98, and, indeed, G-1/98 was used to support this conclusion.

The EBoA then confirmed its awareness of the various ethical, social and economic aspects in the general debate, documented in for example: European Parliament resolutions; reports of national parliamentary committees; reports of national governments to national parliaments; draft resolutions of national parliaments; explanatory notes by national governments; changes in national laws; and in the *amici* submitted during the case. Considering such general arguments, however, was considered not to “fall under the judicial decision-making powers of the Enlarged Board.” After all, it “has to be borne in mind that the role of the Enlarged Board of Appeal is to interpret the EPC using generally accepted principles of interpretation of international treaties. It is not mandated to engage in legislative policy.”

Alternatively put, if regional or national governments or parliaments disagree with the EBoA, they should convene a diplomatic conference and amend the EPC. The EBoA considered that the District Court of The Hague in Netherlands had followed similar reasoning to reach the same conclusion. The case in question was the “Purple radish” case *Cresco v Taste of Nature* of May 2013. The Dutch Court found that product claims were not excluded by the process exclusion of Art. 53(b) EPC and declined to consider the fact that they might be excluded by the product exclusion:

*In the appeal, Cresco has for the first time argued ... that claim 4 of the patent relates to a plant variety and thus is ... excluded from patentability on the basis of the first part of Art. 53(b) EPC. The introduction of*



*such a new ground for invalidity during appeal seems to the Court to be in conflict with good procedure. Accordingly, this plea will be put aside (our translation from Dutch).*

Thus, the EBoA concluded “the choice of one or the other claim category is not a matter of some sort of “skillful claim drafting” or circumvention of legal hurdles but of the prerequisites for ... patentability.”

The EBoA did not address the question as to whether the EPO's own Boards of Appeal might themselves have been guilty of “legal erosion” of the exclusions from patentability set out in the EPC. That they have done so, and have realized that they have done so, is evident, for example, from G-2/08 Dosage regime/ABBOTT RESPIRATORY when it removed approval from the so-called Swiss-type second medical indication claims that it had approved in its first decision G-5/83 Second medical indication/EISAI.

Having found that exhaustive interpretation using all the different approaches had not changed its position, the EBoA gave its answers to the questions the TBoA had posed.

## 14 | THE EBoA'S ANSWERS IN G-2/12 AND G-2/13

In its decisions in March 2015, the EBoA answered the questions as follows:

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

It was these answers that precipitated the European Parliament Resolution (EP, 2015) of December 2015 and the European Commission Notice (EC, 2016) of November 2016, which in turn precipitated the President's referral of April 4, 2019 which gave rise to G-3/19. We must now turn back to the arguments by the President and the *amici* in G-3/19 for what the answer to the rewritten question, might or should be.

## 15 | THE POSSIBLE ANSWER TO THE REVISED QUESTION

In the discussion below, no account will be taken of resolutions or notices that do not represent a binding agreement taken by all the contracting states of the EPC, and no account will be taken of the *wishes* or *desires* of the *amici* that they be freed from worrying about patents for plants and animals. The EBoA seems to be correct in interpreting the Vienna Convention in that fashion. Even the Biotech Directive is not relevant, since it binds only the EU member states and its incorporation into the Rules of the EPC can have no broadening or narrowing effect on the correct scope of Art. 53 EPC. So, what does this leave?

The President's referral letter (Campinos, 2019) is decidedly unhelpful. Virtually the only relevant argument is made in paragraphs 103 and 111 regarding subsequent agreement and practice to be taken into account in accordance with the Vienna Convention. In paragraph 103, the President states that, since the European Commission Notice of November 2016, “all 38 Contracting States of the European Patent Convention have indicated and declared that under their national law and practice the products (plants and animals) of essentially biological processes are excluded from patentability.” However, this does not relate to a

binding agreement between the contracting states, and, in any event, it does not seem to be correct. Thus, for example, the *Manual of Patent Practice* of the UKIPO (in its current form of April 1 2020—UKIPO, 2020) makes no such statement and refers to the examiners' guidelines *Examining patent applications for biotechnological inventions* which (in its current form of October 21, 2016—UKIPO, 2016), in paragraph 104, instead suggests that G-2/12 and G-2/13 should be followed.

We must therefore turn to the comments in the two sets of *amici* referred to in Section 5 above, that is, first groups (a) to (d) supporting Rule 28(2) EPC, and second groups (e) to (g) rejecting it.

## 16 | THE AMICI

We begin with the *amici* of group (a), namely those of the national or regional governments or departments. The German *amicus* (BJV, 2019) reviewed the EBoA's interpretation following approaches discussed above and concluded that these approaches showed that a narrow interpretation of the exclusion of Art. 53(b) EPC was *not required*, and that therefore a broad interpretation, as in Rule 28(2) EPC *might be correct*. The Danish *amicus* (MFAD, 2019) pointed out that allowing the patentability of the products of essentially biological processes would leave the process exclusion void, inherently an interpretation of Art. 53 EPC that would be contrary to the Vienna Convention requirement to consider the purpose of a treaty term. This point was further elaborated in the European Commission *amicus* (EC 2019) which, in paragraph 82 states:

The principle of effectiveness (*ut res magis valeat quam pereat*), following from Article 31 of the Vienna Convention and generally recognised as a fundamental tenet of treaty interpretation, holds that an interpretation which renders part of a treaty redundant is to be rejected.

The Dutch *amicus* (MFA, 2019) referred to the explanatory memorandum (Staten-Generaal, 1976) for the Dutch law of 1975 approving accession to the EPC. This memorandum illustrates *the understanding of the legislators of EPC 1973, shortly after the finalization of the EPC*, that the products of essentially biological processes were excluded from patentability by Art. 53(b) EPC.

Turning now to the group (b) *amici*, those of Euroseeds and Bundesverband Deutscher Pflanzenzüchter also raised the point made by the Danish and European Commission *amici* that it could not have been the intention of the EPC legislator to adopt a provision without practical effect. The Plantum *amicus* (Plantum, 2019), like the Dutch *amicus*, drew attention to the explanatory memorandum (Staten-Generaal, 1976), and added a reference to a paper by the Oxford University intellectual property law lecturer Justine Pila (Pila, 2009) regarding the *travaux* relating to Art. 53(b) EPC. Plantum argued that, in her paper, Pila suggested that the difference in the terms “plants or animals” and “plant or animal varieties” was not understood as having a substantive effect, thereby supporting the reasoning that there was no perceived need to exclude the products of the excluded processes, since they were already excluded.

From group (c) of the *amici*, No patents on seeds! echoed the concerns of the European Commission and Danish *amici*, pointing out that the interpretation of the process exclusion must take into account the product exclusion in the first part of the sentence. The petition and the multiple organization *amici* did little more than show the widespread concern within the public about the EPO's erosion of the EPC's exclusions from patentability.

From group (d) of the *amici*, Dolder (2019) again argued that a treaty term should not be interpreted in such a manner as to have no useful effect, and drew attention to the interpretation approach adopted by the EBoA in G-2/06 Use of embryos/WARF, where attention was given not just to the wording of the particular claims at issue but to the “*whole content*” of the patent or patent application. In this way, the problem of “mere skillful drafting of claims” could be avoided. This could be seen to some extent as a criticism of the EBoA's decision G-1/98, which was the focus of the *amicus* of Julian Cockbain (Cockbain, 2019) which drew attention to the *travaux* of the EPC and the

erosions to the exclusions from patentability that had resulted from the Board of Appeal decisions. Cockbain's argument was that Art. 53(b) EPC provided a comprehensive exclusion of claims to plants and animals and only allowed the claiming of essentially technological processes for producing them, according to which only the plants and animals obtained as the *direct product* of the technological process would benefit from patent protection, and not any plants or animals produced by subsequent biological processes, such as mating, crossing, and so forth.

Also falling in group (d) was the *amicus* of Metzger et al. (2019) of the law faculty of the Humboldt University of Berlin. Metzger et al. argued that Rule 28(2) EPC should be seen as a valid interpretation of Art. 53(b) EPC, but that a reinterpretation of the term "essentially biological processes" was required to avoid exclusion of processes having a novel and inventive *technical* component. They argued that the exclusion of Art. 53(b) EPC could be seen to have an overarching purpose, that of requiring technicality rather than that of excluding a field, namely breeding. To the extent that their *amicus* suggested that Art. 53(b) EPC could be interpreted as having an overarching purpose, it added to the suggestions of the other *amici*.

In groups (e) and (f) were the *amici* of the agrochemical industry groups and of six of the national, regional and international associations of the professionals in the field of intellectual property law. These added nothing of relevance here except the one from the UK association CIPA (CIPA, 2019), which argued that the only reason for departing from the EBoA's decisions G-2/12 and G-2/13 would be if there had been very clear flaws in the EBoA's reasoning.

Of the final group of amici in the second set, group (g), only two (Malek, 2019; Steenbeek, 2019) are relevant here. Leo Steenbeek and Olaf Malek argued that Rule 28(2) EPC is contrary to the *grammatical* interpretation of Art. 53(b) EPC since it adds a fourth and further exclusion to the three exclusions already listed. If the Rule, under the *correct interpretation* of Art. 53(b) EPC, did add a further exclusion, then Steenbeek and Malek would have been correct.

## 17 | HOW COULD THE QUESTION HAVE BEEN ANSWERED?

The question put to the EBoA was essentially: Does Art. 53(b) EPC permit European patents to be granted for plants or animals which are the direct product of essentially biological processes for the production of plants or animals?

If the word "variety" has a meaning narrower than "any type of," the literal answer to the question is that there are two sets of direct products of such processes, things that are varieties, and things that are not varieties. The first set is excluded by the first part of the Art. 53(b) EPC exclusion, while the second is not. This raises the question: what is meant by a "variety"? For plants, some would argue that the term has come to have a meaning, essentially that set out in Art. 1(vi) UPOV 1991:

"variety" means a plant grouping within a single botanical taxon of the lowest known rank, which grouping ... can be

1. defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
2. distinguished from any other plant grouping by the expression of at least one of the said characteristics and
3. considered as a unit with regard to its suitability for being propagated unchanged

Thus, a plant variety is a plant grouping within a single botanical taxon of the lowest known rank which can be defined by a distinguishing phenotype resulting from a genotype *and which can propagate unchanged*. This is supported by the definition in Council Regulation (EC) No. 2100/94 of "protectable varieties":

*Article 6 Protectable varieties:* Community plant variety rights shall be granted for varieties that are: (a) distinct; (b) uniform; (c) stable; and (d) new. ...

*Article 7 Distinctness:* ... A variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety ...

*Article 8 Uniformity:* A variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description.

*Article 9 Stability:* A variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle (emphasis added).

Applied to both plants and animals, this means that a “variety” is a grouping within a single taxon of the lowest known rank which can be defined by a distinguishing phenotype resulting from a genotype and which can propagate unchanged.

In other words, a plant or animal is not a “variety” if it is not distinguishable by reference to the “novel” characteristics that result from its modified genotype, and if those characteristics do not remain unchanged on propagation. Thus, a mouse modified to produce a particular human protein is not a variety if, when mated with another such mouse, the progeny do not produce that protein. But if the progeny *do* produce that protein, it is a variety. A mouse characterized by having had its tail cut off, is not a variety. Likewise, a mouse characterized by having enhanced resistance to disease *as a result of having been vaccinated* is not a variety.

Returning to the question, it appears that there are two forms of possible plant or animal, those which propagate retaining the phenotype characteristic of a particular genotype (varieties), and those that do not (nonvarieties). The first are not patentable whilst the second are. Does this give a coherent picture to the exclusions of Art. 53(b) EPC? Before answering this, we must look to what could be patentable in respect of a product. Here the answer is three things: the product itself; a process for producing it; and a process using it.

What would our interpretation yield for plants (or animals). A plant variety is not patentable, but a nonvariety is patentable. A process for producing any plant is not patentable if it is “essentially biological,” but patentable if it is not. Thus, a technical process for producing a plant or animal is patentable, *whether or not the product is a variety*, and that results in the *direct* product of the technical process being covered by the process claims, but not the *progeny* of such products. A process using a plant is patentable as long as it is not itself an essentially biological process for producing a(nother) plant. Accordingly, technical processes are patentable, their direct products can be covered by claims to the technical process, nonvarieties are patentable, and technical and nontechnical processes (other than the excluded processes) using plants are patentable.

How does our interpretation fit with the apparent intentions of the legislator of EPC 1973? First, there is no overlap between patents and plant variety protection. Second, the performance of technical processes and their direct products are patentable.

In the 1955 Gajac Report (CoE, 1955), an early milestone in the *travaux*, reference was made to methods of treating seeds—these would be patentable both as processes and products (since the treatment would not be heritable). In *travaux* document EXP/Brev (56) 8 (COE, 1956), reference was made to *action* exercised on the *development* of plants and animals and the *utilization* of natural products such as flowers, fruits, seeds, and so forth—these processes would be patentable. Document IV/2071/61-E (EEC, 1961b) referred to European patents as having to be granted for “processes

which, while being applicable to plants, are of a technical nature, for example, processes for producing new plants by irradiation of the plants themselves or the seed with isotopes”—these processes would be patentable.

Thus, the interpretation we propose does seem to be both coherent and in line with the discussions in the *travaux*. But how would it apply in practice? This seems simple. A claim to a plant or animal characterized by feature X would be unpatentable if feature X was heritable. A claim to a process for producing a plant or animal with characteristic X would be unpatentable if the step involving introduction of feature X is *followed by* an essentially biological process step (propagation) or is *in* an essentially biological process step. A claim at a higher taxonomic level, for example, to rodents having feature X, would then be unpatentable if the feature was heritable, but otherwise it would be patentable. As made clear above, the EBoA has swapped back and forth between arguing that a claim cannot be valid if it encompasses excluded matter and arguing that it can be valid if defined at a “higher taxonomic level.” This is abundantly clear since Art. 53(b) EPC has to be interpreted in light of the time of its adoption in 1973 and, at that time, Art. 1 UPOV 1961 forbade protection of any variety by *both* patents and plant variety rights. Thus, no valid claim of a European Patent to “plants with feature X” could encompass varieties with feature X.

How does our proposed interpretation compare with the desire in the Biotech Directive to give broad patent protection to novel technical processes? In its recitals, the Biotech Directive states:

(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

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

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

Regarding Recital 2, the interpretation proposed guarantees legal protection for the technical processes and the direct products thereof in the field of genetic engineering. Regarding Recital 31, our interpretation guarantees protection for those parts of a generic claim that are not themselves excluded plant varieties. Regarding Recital 32, our interpretation is fully in line with this.

Finally, we must turn to the second part of Art. 53(b) EPC, the microbiological exemption, to see if this fits with our interpretation of the first part of the Article:

*this provision shall not apply to microbiological processes or the products thereof.*

The provision could only apply if the microbiological processes in question are otherwise viewable as “essentially biological processes for the production of plant or animals” as otherwise it is unnecessary. In effect it covers the event where a microbiological process could be viewed as being a biological process. Thus, in effect, processes are deemed technical rather than biological if they are microbiological. However, zygote formation by combination of gametes clearly could not be seen as “microbiological” in this context. What seems to be intended is production of a plant (or animal) having feature X by extraneous introduction of something giving rise to that feature, for example, perhaps by gene modification to give the treated plant or animal some (nonheritable) trait. The process, being microbiological, is not excluded, and the product, a nonvariety, is also not excluded.

Alternatively, if the concern was that microbes might incorrectly have been considered to be plants or animals, the effect of the exemption is merely to confirm that they are not.

In the context of 21st century biotechnology, genetic manipulation of a plant or animal cell to introduce a new gene or to modify an existing gene might be considered to be a microbiological process and accordingly the process itself would be patentable as well as its product, a genetically transformed cell. For a transformed cell to grow into a plant or animal as such, however, involves a subsequent essentially biological process for the production of a plant or animal, and that process (and its product) would not be covered by the exemption of microbiological processes and their products.

## 18 | THE EBoA'S APPROACH IN G-3/19

Throughout its opinion, the EBoA confirms in G-3/19 that it stands by the reasoning and conclusions of its five earlier pronouncements on the interpretation of the exclusions of Art. 53(b) EPC, including the results of all of the different interpretation techniques applied in G-2/12. The *only* basis for changing its interpretation would be the “dynamic interpretation” technique taking account of developments between its G-2/12 decision in March 2015 and the adoption of Rule 28(2) EPC in June 2017. The EBoA concluded that the actions of the European Parliament, the European Commission and the national parliaments of the EPC Member states had no effect. What did have effect however was the action of the EPO's Administrative Council in adopting Rule 28(2) EPC—did this justify a dynamic re-interpretation of Article 53(b) EPC? The EBoA concluded that it *did* and decided on that basis to abandon the interpretation it had reached in G-2/12; the interpretation set out in the new Rule had *become* the correct interpretation simply by virtue of the Rule being adopted. G-2/12's interpretation had been correct, but the adoption of the Rule made the Rule's interpretation now the correct one.

This is an astounding emasculation of Art. 164 EPC whereby if a Rule conflicts with the correct interpretation of an article of the EPC, the Article must prevail. As the EBoA put it, 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.”

Since the interpretation was new to the extent that it contradicted an earlier, then correct, interpretation, a period of grace had to be granted and the EBOA Decided that the old interpretation was still valid for patents granted before July 1, 2017 when the new Rule came into effect and for applications with a filing or priority date before then.

Also of concern is the exact wording of the EBoA's reply to its rewritten question:

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 (emphasis added).

In its earlier decision regarding compositions of human embryonic stem cells, G-2/06 Use of embryos/WARF, the EBOA had decided that such compositions were not patentable if, at the time the patent application was filed, reproducing the invention would necessitate destroying human embryos. It left a “deposit loophole” whereby, as long as a culture of human embryonic stem cells had been deposited before the filing date, reproducing the invention would not involve embryo destruction, since such a culture could be used. In G-3/19, the EBoA has left a similar loophole; as long as the applicant explains in her patent application how the gene combination could be achieved in a technical fashion (e.g., to produce a plant with features X and Y, one could transform a plant with feature X by CRISPR gene-editing to introduce the gene for feature Y), then the plant *can* be patented.

## 19 | CONCLUSION

Our conclusion therefore is that the EBoA has satisfied political pressures while still maintaining its “higher taxonomic level” approach of G-1/98. It has left a loophole, and more worryingly, it has opened the door to the EPO's Administrative Council doing away with other pesky exclusions from patentability that the drafters of EPC 1973 so inconveniently chose to include. G-3/19 is a bad and dangerous decision.

### CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

### ENDNOTES

<sup>1</sup>EPO publications, Appeal Board decisions, submissions to the EPO in relation to cases, *travaux* relating to the EPC, Rule changes, referrals to the EBoA by the President of the EPO, and *amici* are all accessible on the EPO website, [www.epo.org](http://www.epo.org). The documents from the EU referred to herein may be found in the *Official Journal of the European Union*.

<sup>2</sup>The EPO decisions are listed in the References section. They may be accessed at <https://www.epo.org/law-practice/case-law-appeals/advanced-search.html> by entering the decision number, for example, T 1063/18.

### ORCID

Julian Cockbain  <http://orcid.org/0000-0002-3662-876X>

### REFERENCES

- BJV. (2019). *Amicus* brief by Bundesministerium der Justiz und für Verbraucherschutz, the German Ministry of Justice, to the EBoA on G-3/19 dated 10 September 2019.
- C/09/416501/HA ZA. 12-452 Cresco v Taste of Nature, decision of the Rechtsbank Den Hague, 8 May 2013. Retrieved from <https://www.navigator.nl/document/id0b7c82a143a940b3a34b27ef325af272/ecli-nl-rbdha-2013-10271-rb-den-haag-08-05-2013-nr-c-09-416501-ha-za-12-452>
- C-377/98. Kingdom of the Netherlands v European Parliament and Council of the European Union, ECR 2001, I7079.
- Campinos, A. (2019). Letter to the EBoA initiating G-3/19. Retrieved from [http://documents.epo.org/projects/babylon/eponet.nsf/0/F3CCF99E734851C1C1258474002CA7E0/\\$FILE/G\\_3\\_19\\_procedural\\_documents.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/F3CCF99E734851C1C1258474002CA7E0/$FILE/G_3_19_procedural_documents.pdf)
- CIPA. (2019). *Amicus* brief by the Chartered Institute of Patent Attorneys, the British patent attorney association, to the EBoA on G-3/19 dated 30 September 2019.
- Cockbain, J. (2019). *Amicus* brief by Julian Cockbain to the EBoA on G-3/19 dated 24 September 2019.
- CoE. (1955). EXP/Brev (53) 18 rev, Étude comparative du droit matériel en vigueur dans les pays représentés aux comités d'experts, présentée par le Secrétariat Général, Committee of Experts on Patents, Council of Europe, 12 January 1955.
- COE. (1956). EXP/Brev (56) 8, Observations and proposals of the German experts on the unification of general conditions for patentability, Committee of Experts on Patents, Council of Europe, 26 October 1956.
- CoE. (1961). EXP/Brev (61) 8 (1961) Memorandum by the Secretariat on the meeting held at Strasbourg from 7th to 10th November 1961, Committee of Experts on Patents, Council of Europe, 13 December 1961.
- Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions., Strasbourg, 27.XI. 1963, *European Treaty Series*, No. 47, Council of Europe: Strasbourg.
- Council Regulation (EC). No. 2100/94 of 27 July 1994 on Community plant variety rights, OJ L271/1 1.9.94.
- Diamond v Chakrabarty. (1980). US Supreme Court decision, 447 U.S. 303.
- Directive. 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L213/13 30.07.98.
- Dolder, F. (2019). *Amicus* brief by Prof. Fritz Dolder to the EBoA on G-3/19 dated 30 September 2019.
- EC. (2016). C/2016/6997 Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, OJ C411/3, 8.11.16.
- EC. (2019). *Amicus* brief by the European Commission to the EBoA on G-3/19 dated 1 October 2019.
- EEC. (1961a). IV/2071/61-E, Section 13, First Preliminary Draft Convention relating to a European Patent Law: Articles 11 to 29, Patents Working Party, EEC, 14 March 1961.
- EEC. (1961b). IV/2071/61-E, Section 14, Comments on the First Preliminary Draft Convention relating to a European Patent Law: (Articles 11 to 29), Patents Working Party, EEC, 14 March 1961.

- EEC. (1962). 4488/IV/62-E, Section 2, VE May 1962: *Preliminary Draft Convention relating to a European Patent Law*, Patents Working Party, EEC, 26 May 1962.
- EEC. (1965). 2335/IV/65-E, Section 1, *Amendments to the Preliminary Draft Convention relating to a European Patent Law*, Patents Working Party, EEC, 22 January 1965.
- EP. (1992). Legislative Resolution A3-0286/92, OJ C305/160, 23 November 1992.
- EP. (2015). 2015/2981(RSP) Resolution on patents and plant breeders' rights (P8\_TA-PROV(2015)0473). Retrieved from [https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2015/2981\(RSP\)](https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2015/2981(RSP))
- EPO. (2000a). CA/PL 25/00, Basic proposal for the revision of the European Patent Convention, President of the EPO, 16 June 2000.
- EPO. (2000b). MR/3/00, Draft Revision Act, EPO Administrative Council, 30 October 2000.
- European Patent Convention*., 16th Edn., 2016, EPO: Munich.
- European Patent Convention*., 1st Edn., 1979, EPO: Munich.
- G-1/04. Diagnostic methods, 16 December 2005, OJ EPO 2006, 334.
- G-1/08. Tomatoes/STATE OF ISRAEL, 9 December 2010, OJ EPO 2012, 206.
- G-1/98. Transgenic plants/NOVARTIS II, 20 December 1999, OJ EPO 2000, 111.
- G-2/06. Use of embryos/WARF, 25 November 2008.
- G-2/07. Broccoli/PLANT BIOSCIENCE, 9 December 2010, OJ EPO 2012, 130.
- G-2/08. Dosage regime/ABBOTT RESPIRATORY, 19 February 2010, OJ EPO 2010, 456.
- G-2/12. Tomatoes II/STATE OF ISRAEL, 25 March 2015, OJ EPO 2016, A27.
- G-2/13. Broccoli II/PLANT BIOSCIENCE, 25 March 2015, OJ EPO 2016, A 28
- G-3/08. Computer programs, 12 May 2010, OJ EPO 2011, 10.
- G-3/19. Peppers, 14 May 2020.
- G-5/83. Second medical indication/EISAI, 5 December 1984, OJ EPO 1985, 64.
- Haertel, K. (1961). Erster Arbeitsentwurf eines Abkommens über ein europäisches Patentrecht: Artikel 11 bis 29, 3 March 1961.
- IGC. (1969). BR/7/69, *Minutes of the meeting of Working Party I (Luxembourg)*, 8–11 July 1969, IGC, 29 July 1969.
- IGC. (1971). BR/135/71, *Minutes of the 9th Meeting of Working Party I held from 12 to 22 October 1971*, in Luxembourg, IGC, 17 November 1971.
- International Convention. for the Protection of New Varieties of Plants adopted by the Diplomatic Conference on December 2, 1961.
- International Convention. for the Protection of New Varieties of Plants adopted by the Diplomatic Conference on December 2, 1961, as revised at Geneva on November 10, 1972, on October 23, 1973, and on March 19 1991.
- Kober, I. (1999). Letter of 25 March 1999 to the EBoA commenting on G-1/98. Retrieved from <https://register.epo.org/application?documentId=EICLA8UTZ9JVE02&number=EP91810144&Ing=en&npl=false>
- Malek, O. (2019). *Amicus* brief by Olaf Malek of Vossius and partner to the EBoA on G-3/19 dated 21 October 2019.
- Metzger, A., Vollenberg, C., & Zech, H. (2019). *Amicus* brief by Prof. Axel Metzger, Charlotte Vollenberg and Prof. Herbert Zech of Humboldt-Universität zu Berlin, to the EBoA on G-3/19 dated 30 September 2019.
- MFA. (2019). *Amicus* brief by the Dutch Ministry of Foreign Affairs to the EBoA on G-3/19 dated 26 September 2019.
- MFAD. (2019). *Amicus* brief by the Ministry of Foreign Affairs of Denmark to the EBoA on G- 3/19 dated 30 September 2019.
- Pila, J. (2009). Article 53(b) EPC: A challenge to the Novartis theory of European patent history. *Modern Law Review*, 72(3), 436–62.
- Plantum. (2019). *Amicus* brief by Plantum, a Dutch plant breeders association, to the EBoA on G-3/19 dated 30 September 2019
- R-19/12. Ablehnung wegen Besorgnis der Befangenheit/IXETIC, 25 April 2014.
- Staten-Generaal. (1976). Tweede Kamer der Staten-Generaal (1975-6) 13899 (R1013) Goedkeuring van het Europees Octrooiverdrag ..., Nr. 3, Memorie van toelichting, p. 18. Retrieved from [https://repository.overheid.nl/frbr/sgd/19751976/0000197842/1/pdf/SGD\\_19751976\\_0005059.pdf](https://repository.overheid.nl/frbr/sgd/19751976/0000197842/1/pdf/SGD_19751976_0005059.pdf)
- Steenbeek, L. (2019). *Amicus* brief by Leo J Steenbeek to the EBoA on G-3/19 dated 24 September 2019.
- Sterckx, S. (2011). *Amicus* letter of 1 November 2011 to the EPO in T-1242/06. Retrieved from <https://register.epo.org/application?documentId=ESET0IOO5129F14&number=EP00940724&Ing=en&npl=false>
- Sterckx, S., & Cockbain, J. (2012). *Exclusions from patentability*. Cambridge: Cambridge University Press.
- T-1054/96. Transgenic plant/NOVARTIS, 13 October 1997, OJ EPO 1998, 511.
- T-1063/18. Extreme dark green, blocky peppers/SYNGENTA, 5 December 2018.
- T-1242/06. Tomatoes/STATE OF ISRAEL, 4 April 2008, OJ EPO 2008, 523.



T-1673/11. Treatment of Pompe's disease/GENZYME.

T-19/90. Onco-mouse/HARVARD, 3 October 1990, OJ EPO 1990, 476.

T-315/03. Transgenic animals/HARVARD, 6 July 2004, OJ EPO 2006, 15.

T-320/87. Hybrid plants/LUBRIZOL, 10 November 1988, OJ EPO 1990, 71.

T-39/93. Polymer powders/ALLIED COLLOIDS, 14 February 1996.

T-83/05. Broccoli/PLANT BIOSCIENCE, 22 May 2007, OJ EPO 2007, 644.

UKIPO. (2016). *Examining patent applications for biotechnological inventions*, Newport: UKIPO.

UKIPO. (2020). *Manual of patent practice*, Newport: UKIPO.

Unilever. (2011). Letter of 10 October 2011 from Unilever (Opponent) in T-1242/06. Retrieved from <https://register.epo.org/application?documentId=ESBY2V813399163&number=EP00940724&lng=en&npl=false>

Vienna Convention on the law of treaties., *UN Treaty Series* 1155, 331–53.

## AUTHOR BIOGRAPHIES



**Julian Cockbain**, after taking a degree and a doctorate in chemistry at the University of Oxford, Julian trained to become a European Patent Attorney and, in 1985, became a partner at the British IP firm Dehns. He has written extensively on IP matters and in 2012 coauthored with Sigrid Sterckx a book published by Cambridge University Press on the exclusions from patentability under European patent law. He is a European Patent Attorney, a consultant, based in Ghent, Belgium and is a member of the Bioethics Institute Ghent.



**Sigrid Sterckx** is Professor of Ethics and Political and Social Philosophy at Ghent University, Belgium. After taking a Master's and Doctorate in Moral Philosophy at Ghent University, Sigrid held lectureships at the University of Antwerp, Ghent University and the Free University of Brussels (VUB) in Belgium before becoming Full Professor at Ghent University. She teaches and research in the fields of political philosophy, medical ethics, and climate ethics. She is the author of numerous publications in these areas.

**How to cite this article:** Cockbain J, Sterckx S. Quis custodet custodes? Referral G-3/19 before the EPO Enlarged Board of Appeal and the imperative of challenging the board's interpretation of Art. 53(b) EPC. *J World Intellect Prop.* 2020;23:679–711. <https://doi.org/10.1111/jwip.12168>