

## European Plant Patent-Eligibility Update - Enlarged Board of Appeal Decision G3/19

G3/19 is the latest in a line of cases and controversies stretching back 25 years, to around the time the first genetically modified plants were becoming a commercial reality. There has long been a measure of agreement that such transgenic (and more recently, gene-edited) plants should be patent-eligible, but plant breeders and many EPC member states have always had great difficulty accepting that plants that have been bred more conventionally could also be patented. Whether this is possible in Europe has for a long time been unclear because Article 53(b) EPC excludes from patentability “essentially biological processes for the production of plants”, but is silent as to whether it is nonetheless possible to patent the products of such processes, i.e. plants obtained by breeding.

It might seem obvious that the exclusion should not be undermined by allowing claims to the products of an unpatentable process, but it is not as simple as that. There has always been a counter-argument that exclusions from patentability should be construed narrowly, and that, if the EPC had intended to exclude the products as well as the process, it would have been simple to say so explicitly (as the national laws of some EPC member states now do). In addition, plant variety rights (PVRs) and plant breeders’ rights (PBRs) (analogous to plant variety protection (PVP) in the USA) do not fully compensate for the protection lost if plants obtained by breeding cannot be patented. This is because PVRs are both weaker and narrower rights than patents. PVRs confer a lower degree of exclusivity because of the so-called breeders’ exemption that allows for the development of new varieties from the protected germplasm, and relate always to a single variety or those “essentially derived” from that variety.

A patent claim, on the other hand, can be written to cover all plants containing a novel and inventive trait. In the case of a genetically modified or edited plant, such a trait will typically be defined via the sequence that has been introduced or changed. In contrast, a plant obtained by introgressing a so-called “native trait” might be defined by reference to a sequence if possible, failing which by reference to a chromosomal position as defined by markers, and/or the phenotype of the plant. With the advent of more advanced techniques (such as marker-assisted selection and doubled haploidy), breeding has also become much more sophisticated, so it is no longer necessarily appropriate to classify such developments as non-technical even if conventional breeding carried out for centuries can be thought of that way.

In its earlier “[Broccoli and Tomatoes II](#)” decisions (G2/13 and G2/12), the enlarged board of appeal held in 2015 that the plant products of essentially biological processes could be patented. This triggered a political intervention from the European Union’s European Commission, which was able to persuade the EPO’s Administrative Council (which is composed of representatives from

the (mostly EU) member states) to implement a rule ([Rule 28\(2\) EPC](#)) to the contrary in July 2017. Some applications were refused under this rule, and others were abandoned. However, in December 2018, a technical board of appeal held [Rule 28\(2\) EPC inapplicable](#) under [Article 164\(2\) EPC](#) because it conflicted with Article 53(b) EPC as previously interpreted by the enlarged board (case [T1063/18](#)). This prompted the president’s referral to the enlarged board in G3/19, and affected applications and oppositions were [stayed](#) pending a decision.

It was apparent from the start that the president’s referral was problematic. Most such referrals come from regular boards of appeal and, although [Article 112\(1\)\(b\) EPC](#) also permits the president to refer points of law to the enlarged board, this is only “*where two Boards of Appeal have given different decisions*”. There was, however, *prima facie* no such conflict here. Namely, the technical board in T1063/18 was in agreement with the enlarged board in in G2/13 and G2/12 (and had itself specifically declined to make a referral to the enlarged board for that reason). The president therefore sought to identify a different conflict, in relation to Article 164(2) EPC rather than to Article 53(b) EPC *per se*.

The questions referred thus read as follows:

1. *Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal?*
2. *If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?*

There was nevertheless still a risk of rejection of the referral as wholly or partly inadmissible by the enlarged board, as had happened twice before on patent-eligibility issues, once in relation to earlier plant patent-eligibility issues ([G3/95](#)), and once in relation to computer-implemented inventions ([G3/08](#)). A further issue was that the president self-evidently wanted a particular answer, namely that Rule 28(2) EPC was valid, and that the earlier case law was wrong and could be disregarded. Accordingly, his referral was not neutral.

Presumably recognising the political complications and ongoing disruption and delay to examination of applications and oppositions in this area, the enlarged board addressed the

president's questions quickly by its standards, in little more than a year.

The enlarged board's conclusion is that *"the exception to patentability ... in Article 53(b) EPC has a **negative effect on the allowability of product claims ... directed to plants ... if the claimed product is exclusively obtained by means of an essentially biological process ..."***. This aligns with Rule 28(2) EPC and contradicts and over-rules the earlier case law. Plants that are the products of breeding processes are therefore patent-ineligible, like the processes themselves.

In reaching this conclusion, the enlarged board first had to resolve the question of whether the referral could be accepted at all, and then take a view on the substantive question under Article 53(b) EPC. It also clearly had some concerns about the referral, as it rejected question 1 above as too general and sweeping, covering situations other than the real underlying Article 53(b) EPC issue in this case. It also noted that question 2 *"contains, in thinly disguised form, the answer that it seeks"*. Nonetheless, it proceeded to reformulate and answer the questions, rather than holding the referral inadmissible. This was undertaken using a so-called "dynamic interpretation" of the EPC, by which the enlarged board allowed itself to overrule its earlier 2015 decisions in the light of subsequent events. Thus, the implementation of Rule 28(2) EPC, amendments to the national laws of various EPC member states to make the exclusion of the products of essentially biological processes explicit, and the large majority in favour of the implementation of Rule 28(2) EPC when it was passed by the EPO's administrative council were taken as justifications to reverse previous case law.

Legitimate questions were of course immediately raised by patent professionals and users of the EPO as to whether this decision calls into question the independence of the EPO's boards of appeal from its president, or of the EPO from the EU. The EPC had previously been interpreted in one way by the enlarged board, and all that has actually changed since is that some EPC member states have, via the EU, said they do not approve of that decision. However, it is also true that the interpretation now taken by the enlarged board was always a possibility, even at a purely legal level, and that the member states could rewrite the EPC itself to adopt it if they wanted to. However, the EPC is a difficult piece of legislation to amend because to do so requires agreement between a large number of states at an intergovernmental conference (at which unrelated issues would probably be dragged in for political reasons). Therefore, the enlarged board's decision can also be seen as a pragmatic way to give effect to the wishes of the majority of EPC member states.

The conclusion of the enlarged board is one that we think many stakeholders in the system can probably accept. Some lobby groups that fundamentally oppose technology and patents in agriculture, or patents in general, have welcomed the enlarged board's ruling, but called for further clarification to avoid exploitation by applicants of loopholes in the new framework of law. However, it is not clear exactly what those loopholes are supposed to be, or that the claims they might permit are not legitimate. On the other hand, the European Seed Association, Euroseeds, welcomes the enlarged board's findings without suggesting that more inventions should be removed from patent-eligibility.

For patent applicants, while it is true that some protection is lost as compared to what is available in more permissive jurisdictions

such as the USA, the "native trait" claims that the enlarged board has now ruled out were in practice extremely difficult to get granted for other reasons (especially lack of clarity in view of the difficulty of defining the traits in the absence of sequence information). Therefore, the actual, effective loss of available protection may not be so great. Partly as a consequence of these difficulties, but also just as a result of changing times and technological developments, practice has also already drifted towards claims to plants that are mutated, transgenic, or gene-edited. Thus, although the enlarged board's decision is undeniably disappointing for patent applicants in the agricultural sector and may have some wider ramifications for the European patent system as a whole in terms of its balance and separation of powers, in practice it is probably not excessively damaging, and there is some value to the relative certainty it brings after a long period of disruption and confusion. The risk of obtaining a European patent that cannot be enforced under a national law that explicitly prohibits claims to the products of essentially biological processes is also reduced.

This risk has not been entirely eliminated, however, as the enlarged board also took the sensible step of avoiding a fully retroactive effect to its decision. It states that the "negative effect" does not apply to patents granted before 1 July 2017, when Rule 28(2) EPC was introduced, or to pending applications filed before that date. Therefore, existing patents granted under the regime established by G2/13 and G2/12 have not been invalidated, and older applications that have been stayed can be granted even though newer ones will have to be refused. The enlarged board of appeal has only given decisions of this type a few times, but here is some precedent for it. There is, of course, a category of applications in between patents granted before 1 July 2017 and applications filed before that date and still pending now, namely patents granted on applications filed before 1 July 2017, but granted after that date. However, these should hopefully not be invalid, as Rule 28(2) EPC was in force during that time, which should have prevented the grant of claims not now allowable in the light of the enlarged board's decision. Strangely, the negative decision that the enlarged board has given is, in fact, positive for some older patents and applications, in that it clarifies that these are valid or can be granted.

However, it is important to note that the enlarged board of appeal's decision will not bind national courts. Thus, even the claims that the enlarged board says were correctly granted, or can be granted now, may not be upheld in litigation in countries opposed to them, even if they have a filing date before 1 July 2017. It is impossible to predict whether national courts in countries whose laws have been amended to make native trait claims unallowable without time cut-offs corresponding to those set by the enlarged board will follow the EPO. However, the enlarged board's approach is at least consistent with previous EPO case law, and will allow cases that pre-date Rule 28(2) EPC to reach the national systems and be decided finally there (as opposed to pre-judging them centrally at the EPO).

By way of reaction, the EPO first indicated that [examination and opposition proceedings stayed while the referral was pending would be gradually resumed](#) then issued a [formal notice to confirm this](#). Examination of those cases will therefore soon be back underway. The EPO already has [examination guidelines](#) intended to cover these situations, as these were updated after Rule 28(2) EPC was introduced and will hence become applicable once more now that it has been endorsed by the enlarged board of appeal.

Some ongoing board of appeal cases will also be affected, for example case [T2734/18](#), on which an oral hearing is scheduled for October 2020. Before the enlarged board of appeal issued its decision in G3/19, the technical board responsible for T2734/18 had indicated that it was planning to follow its earlier decision in T1063/18 in relation to patent-eligibility. Notwithstanding the enlarged board's generally negative findings, this should also still be the course the technical board takes, as the refused application underlying T2734/18 has a filing date before 1 July 2017 (so the exception provided by the enlarged board is applicable). [T1935/16](#), an appeal from an opposition with an oral hearing scheduled for November 2020, is in a similar position.

To summarise the situation as it now stands:

- Following the earliest enlarged board of appeal decision in this area, [G1/98 \("Novartis"\)](#) in 2000, claims to individual plant varieties are patent-ineligible (whether or not the plants are transgenic or otherwise technologically changed as opposed to conventionally bred).
- In the light of the "[Broccoli and Tomatoes I](#)" decisions from 2010 (G2/07 and G1/08), in general any method claim containing even a single step of crossing and selection is patent-ineligible, even if the method also contains other technical steps (such as transformation).
- Having regard to the recent G3/19 decision, plants that are products of essentially biological processes are also patent-ineligible.

Therefore, although G1/98 did not originally exclude claims to conventionally bred plants, so long as the claims were presented at a taxonomic level higher than that of a single variety and other patentability requirements were met, the combined effect of the later case law is essentially that no breeding process or plant obtained through a breeding process can now be patented. This is irrespective of how innovative the process is, or how beneficial a trait contained in the resulting plant is. Article 53(b) EPC also applies to animals, so the same can be assumed to be true in the case of animal breeding/biotechnology.

However, transgenic, gene-edited, and artificially mutated plants and processes for creating them are generally seen as patent-eligible, and individual plant varieties containing the trait are protectable by plant variety rights (although there is no analogous right relating to animal varieties). It is also important to note that [Article 64\(2\) EPC](#) extends the protection of a process claim to the direct products of that process, and [Articles 8.1 and 8.2 of the EU biotechnology directive](#) of 1998 and the provisions that implement these in national laws also extend protection to downstream generations containing "specific characteristics as a result of the invention" (e.g. the same transgenes or edits as their parents). Therefore, a claim to a transformation or editing process, or to a plant that is transgenic or edited, in effect covers the progeny of that plant even though the progeny generations could not be claimed directly without claiming an ineligible process or product.

As noted above, the EPO also has an existing framework of practice and examination guidelines for examining applications in this area. These guidelines contain some useful [examples](#) of patent-eligible and patent-ineligible subject matter. These deal with many but not all possible situations. Some of the issues to look out for in the coming years are as follows:-

- Claims to the use of a novel and inventive, but patent-ineligible plant (which might be a single variety or a more generically defined product of a breeding process) to produce food, feed, or another plant product.

- These processes are arguably novel and inventive because any use of a novel and inventive product is by definition itself novel and inventive, and patent-eligible because they are processes for the production of plant products rather than plants. However, allowing claims to them might also arguably undermine the position taken in G3/19. The EPO's examination guidelines indicate that flour or oil produced from a patent-ineligible plant would be patent-eligible, which is a similar issue, but not quite the same, as products such as flour and oil would also have to be novel and inventive in their own right to be patentable. This will not be the case if the invention is in some other aspect of the plant's biology. In contrast, a process claim to the use of a novel and inventive plant to produce a processed plant product would not in principle require the product to be patentable in its own right.

- Claims to a plant that has a conventionally bred trait that makes it novel and inventive, but also a transgenic one, or claims to a process of transforming a novel and inventive, but conventionally bred, plant with a known transgene that confers another trait unrelated to the invention.

- In these situations, it is not clear whether it is possible to derive novelty and inventive step from the conventionally bred parts of the plant's genome, but to argue at the same time that the transgenic aspects mean the plant is not "exclusively" obtained by an essentially biological process as prohibited by Rule 28(2) EPC.

- Claims to plants that are the progeny of two transgenic or edited parents.

- These are probably not allowable if framed in terms of a cross between those two parents, but other options might exist, such as claiming the parents individually if they are independently inventive, or as a "breeding pair" if both transgenes/edits are required to give effect to the invention.

- Situations where a mutation is made artificially (whether by chemical or radiation-based methods, or by gene editing), but where the same mutation could arise naturally and may have done so and been "copied" artificially (and the naturally occurring version has not previously been disclosed).

- The EPO's guidelines currently suggest that such plants would be patentable if plants produced by essentially biological processes are disclaimed, but this may come under pressure in the future, and claims incorporating such disclaimers may also be hard to enforce if it cannot be discerned how the alleged infringer made its corresponding mutation.

It is also, of course, important to keep in mind that Article 53(b) EPC is only one requirement. Examination on other grounds of patentability is frequently also challenging in plant-related cases, so compliance with Article 53(b) EPC is more a threshold test than an indicator of overall patentability.

Therefore, there will probably be a need for at least some further codification of the position via technical board case law in the next few years, and maybe even more enlarged board referrals. For now, however, G3/19 has effectively resolved the single

biggest outstanding question under Article 53(b) EPC. The outcome will be disappointing to patent applicants who make inventions via plant breeding as opposed to via biotechnology, but

does at least allow them and the EPO to move forward with some degree of clarity about what inventions and types of claim can and cannot go forward for examination on other grounds.

**For more information, please contact:**

Andrew Bentham – [abentham@jakemp.com](mailto:abentham@jakemp.com)

Daniel Shaw – [dshaw@jakemp.com](mailto:dshaw@jakemp.com)

Carsten Reinhard – [creinhard@jakemp.com](mailto:creinhard@jakemp.com)