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Patenting plant inventions via the EPO after G 3/19

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Patenting plant inventions via the EPO after G 3/19

By Natalie Kirchhofer, Julia Sauerwald and **Jan Desomer**

Over the past decade, the Enlarged Board of Appeal (EBA) of the EPO has changed its case law several times on the patentability of plants (and animals) produced by essentially biological processes according to Article 53(b) of the European Patent Convention (EPC). Rather than achieving the envisioned legal certainty, the decisions have created a gap in patent protection for biotechnological inventions owing to the different interpretations of the phrase 'essentially biological process' and the EPO's more recent practice of forcing applicants to expressly disclaim plants obtained by such processes from claims directed at plants obtained by technical processes. While allowing the patentability of plants in principle, Article 53(b) was originally introduced to exclude plant varieties and essentially biological processes of plant breeding from patentability to avoid an overlap with the available national, regional and international protection of plant varieties. In this way, plant breeders would have the freedom to breed and cross in the traditional biological ways without needing to worry about patent protection.

However, looking at the wording of Article 53(b), for example, it is only plant varieties as such that are excluded. As soon as a plant with a trait or mutation is claimed, it is from that point not limited to a single plant variety and the invention becomes patentable. Similarly, a claim to a new and inventive allele, haplotype, mutated protein or DNA sequence remains patentable and will include in its scope plants incorporating material of this kind, even if produced by essentially biological processes. Therefore, despite Article 53(b)'s exclusion from patentability, plant breeders still face potential infringement of existing patent rights, as is the case with any innovative area of research and development. Plant breeders should, at least to a certain extent, be required to accept this if they want to participate in a new innovative area of research and development.

It should not be forgotten that patents are an essential driver of innovation, especially in the life sciences sector, which involves highly specialised research, higher risks of failure and significant investment into basic research. Without strong patent protection, green biotechnological innovations in Europe risk being stifled, as they will not generate enough return on investment to attract further investments in this already highly regulated market. In addition, without the promise of strong and reliable patent protection, companies and research institutions will not disclose their innovations early on, which is key for the much-needed collaboration between established corporate entities and innovative start-ups. In the end, breeders, farmers, consumers and society will pay the price if we allow plant patent protection in Europe to further erode. Green biotechnology and plant-breeding innovations offer unprecedented solutions to some of the world's greatest challenges. These include mitigating the consequences of climate change and ensuring food security; for example, by creating more resilient or nutritive plants and by increasing crop yields from less arable land.

Prior to the latest EBA decision G 3/19 (*Pepper*), it was unclear whether plant products, themselves derived from essentially biological processes, were also excluded from patentability. The EBA in G 2/12 and G 2/13 (*Broccoli* and *Tomato II*) initially said yes to the patenting of plants derived from essentially biological processes. In response to a European Commission notice on the interpretation of certain articles of the Biotech Directive, advocating for an EPC-implemented ban on the patenting of plants obtained by essentially

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biological processes, the Administrative Council of the EPO tried to achieve this goal by introducing a new paragraph (Paragraph 2) into Rule 28 of the EPC stating that "Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process". Upon challenge by an affected patent applicant, a Board of Appeal of the EPO in decision T 1063/18 declared the newly enacted Rule 28(2) invalid, holding that the Administrative Council could not simply reverse EBA case law by mere rule changes. In the latest twist in this saga, the president of the EPO again referred the matter to the EBA, which in its 2020 ruling G 3/19 abandoned its earlier decisions using what it called a "dynamic interpretation" of the law, and endorsed the introduction of Rule 28(2) of the EPC.

The EBA held that Article 53(b) of the EPC regarding the scope of its exceptions of patentability could be interpreted in a number of ways and opened up the EPC to a dynamic, time-dependent interpretation of the law. For this dynamic interpretation, the EBA took into account that 10 of the 38 contracting states had already excluded plant (or animal) products exclusively obtained by essentially biological processes from patentability in their national patent laws. The EBA decided to accept the interpretation of Article 53(b) as laid out in the newly introduced Rule 28(2). In the opinion of many legal scholars, patent practitioners and affected industries, this course of rulings, and the way that they were brought about, questions the independence of the EBA from the EPO president and the Administrative Council. However, aside from the protest against the procedural intricacies of the recent decision, one should also discuss the far-reaching and daunting practical consequences of G 3/19 for patenting plant-based inventions in Europe. While presented as a pragmatic and goal-oriented effort of harmonisation, G 3/19 has in fact created considerable legal uncertainty. If left unresolved by the courts and the European Union or by the EPC legislature, it will stifle the R&D environment for green biotechnological innovations in the European agricultural industry even further.

Plant products with technically induced genome modifications must remain patentable and associated claims fully enforceable

The new interpretation of Article 53(b) of the EPC in G 3/19 was not intended to change the fact that plants comprising technically induced genome modifications remain patentable. This includes not only plants containing a transgene, but also plants containing mutations generated by methods based on random mutagenesis (eg, ultraviolet radiation

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or chemical treatment) or targeted genome editing, such as the Nobel Prize-awarded CRISPR-Cas technology.

However, while for some genetic modifications it may be intrinsically clear from their nature that they were obtained by a technical step, and therefore remain patentable, (eg, in the case of the insertion of a transgene or complex multiple gene edits), this is much less clear for other modifications. In particular, if the genome edit is small and targeted, inextricably linking the technical intervention to the creation of the plant may be problematic or at least not easily traceable. In cases where the claimed mutation or trait could in principle also have arisen naturally, even if that would have been extremely unlikely, the EPO has now amended its Guidelines for Examination to force applicants to include a disclaimer into such allegedly ambiguous plant patent claims. Applicants are asked to expressly exclude plants exclusively obtained by essentially biological processes with the aim to delimit such claims to include only technically produced plants. Effectively, however, this practice creates a gap in patent protection and further legal uncertainty, especially regarding the validity, scope of protection and enforceability of such claims.

A mandatory disclaimer is not an appropriate measure for delimitation

Through its mandatory disclaimer practice, the EPO aims to exclude non-patentable subject matter in a seemingly clean way. In reality, it is unclear how such a disclaimer should be worded or how it will be interpreted by infringement courts. Disclaimers are not allowed to remove more subject matter than necessary pursuant to decisions G 1/03, G 2/03 and G 1/16 for undisclosed disclaimers. Considerable uncertainty arises because the EPO has set out three different definitions of 'essentially biological processes':

- Derivable from G 1/08 and G 2/07 in connection with Article 53(b) – "A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle

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excluded from patentability as being 'essentially biological' within the meaning of Article 53(b) EPC".
- According to Rule 26(5) of the EPC, as copied from the Biotech Directive – "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection".
- According to Rule 28(2) of the EPC – "Under Article 53(b) EPC, European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process".

While the definitions of essentially biological processes according to Rules 26(5) and 28(2) of the EPC, by way of their "entirely" or "exclusively" terminology, do not encompass processes that include further technical steps, this may not be the case for the definition derivable from G 1/08 and G 2/07. It is unclear which definition should be adopted for the disclaimers that the EPO now requires.

In view of Article 123 of the EPC regarding problems that can arise for undisclosed disclaimers, it seems inadvisable to include "self-made disclaimer wordings" that are not based on any of the EPO's literal definitions of an "essentially biological process". Moreover, the impact of introducing a disclaimer, particularly an undisclosed disclaimer, should not be underestimated. Once introduced, it is almost impossible to remove the disclaimer after the grant of the patent without unlawfully extending its scope. In addition, the law or practice on disclaimers may change again. Indeed, a number of patents have been granted containing a disclaimer based on the wording of Rule 28(2) of the EPC. However, where these patents were filed before 1 July 2017 (the threshold date set in the transitional provisions of G 3/19), it now turns out that Rule 28(2) was not applicable to those applications. Hence, the introduction of the undisclosed disclaimer violated Article 123(2) of the EPC following the principles laid out in G 1/03.

Disclaimers are also highly unattractive from an infringement perspective, as it is entirely unclear how national courts will interpret them, especially in jurisdictions that only rarely hear patent cases. At worst, a disclaimer in a claim for technically generated genome-edited plants, if not worded carefully or interpreted to the extreme, may bear the risk of being seen to exclude plants obtained through any subsequent steps of sexually crossing or breeding. As technically generated genome-edited plants also need to be bred and propagated to be marketed, this could reduce the scope of protection of such disclaimer-encompassing plant claims to zero. Of course, this was neither the legislature's nor the EPO's intent and would actually run contrary to Article 8(2) of the Biotech Directive, which governs the scope of protection conferred by a patent on a biological material. Applicants should not be forced to take on such risks to claim interpretation and enforceability without the EPO having a proper legal basis for its disclaimer practice.

G 3/19 is entirely silent on any disclaimer requirement. There is also no legal precedent for having to introduce a disclaimer to plants obtained by essentially biological processes. In the parallel case of the exclusion of plant varieties, the EBA decided in G 1/98 that claims to transgenic plants are patent-eligible even if they include many plant varieties in their claim scope. Further, even the preparatory documents leading up to the introduction of Rule 28(2) of the EPC do not mention the requirement for a mandatory disclaimer.

There is no justification for applying double standards. In parallel with decision G 1/98, claims that encompass subject matter excluded from patentability, but that do not explicitly claim such subject matter, should not be excluded from patentability. Accordingly, no disclaimer should be imposed on applicants to exclude subject matter exclusively obtained by essentially biological processes.

For the drafting of new patent applications, best practice post G 3/19 should include the formulation of positive claim features that signal the requirement for a technical (eg, genome editing) step to obviate the need for a disclaimer during prosecution before the EPO. In addition, it seems wise to expressly include appropriate disclaimer wording in new patent applications together with associated definitions instead of leaving its interpretation open for the courts to decide. For example, one could try to make clear that the disclaimer will not exclude breeding (ie, crossing and selection) for plant propagation, for combination with other traits or for introduction into other genetic backgrounds.

Commensurate patent protection for genome-edited plants has become impossible

The charm of targeted genome editing – for example, by way of the much-acclaimed CRISPR/Cas technology – is that it allows for precision

engineering and the mimicking of the natural phenomenon of a mutation at any genomic site of interest. This entails that when looking at the end product of the mutation event, it is simply not possible to determine directly and unambiguously whether the mutation in the plant was originally technically induced or occurred naturally. This may have far-reaching consequences for the enforceability of agricultural patents containing disclaimers on essentially biological processes, especially if the burden of proof was seen to be on the patent owner to demonstrate that the infringing product is a 'technical mutant'. It is necessary for the European Union or EPC legislature to clarify that living organisms produced by reproducible technical methods remain patentable and associated patents enforceable. Applicants should challenge the EPO's current disclaimer practice by escalating prosecution cases to the Boards of Appeal, although in view of the transitional provisions it might take some time before patents with a filing or priority date after 1 July 2017 are sufficiently advanced in prosecution to reach an appealable decision. In addition, stakeholders should alert political decision makers to the need for legislative change and clarification. Green biotechnology and plant breeding innovations should not be hindered further in Europe by the denial of a clear legal framework and the legal certainty necessary for their emergence and existence. Especially now that genome editing may realise its full potential, Europe should not fall behind in incentivising these opportunities by offering strong patent protection and legal certainty. Innovations involving living organisms, and genome-edited plants in particular, must remain patentable and not be subject to any further erosion. With the EPC as the granting authority and the courts deciding on plant patent infringement, EU and EPC legislators have it in their hands to avoid interpretations of G 3/19 and Rule 28(2) of the EPC that would stifle critical innovation in the European agricultural and green biotechnology sector.

Outlook

In the long run, G 3/19 and the EPO's associated disclaimer practice can, if not counteracted, be expected to significantly stifle innovations in the European agricultural and green biotechnology sector. To maintain and foster further innovation and investments into research and development, it will be critical to clarify and strengthen patentability and patent enforceability in the field of genome-edited plants by making clear, through the European and/or EPC legislature, that plants produced by reproducible technical means remain patentable and the obtained patents enforceable.

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