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EPO's Approach to the Patentability of Plant-Related Inventions

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Last month, the European Patent Office (EPO) issued the much anticipated Written Decision associated with case T1063/18. We have previously written about this case in our alert "EPO May Return to Patenting Plants Obtained by an Essentially Biological Process," where we discussed how the EPO's approach has appeared to flip-flop between either excluding or not excluding claims directed to plant products that have been obtained by an essentially biological process. T1063/18 firmly adopts the stance that claims directed to such products **are** patentable. However, whether this position will be maintained by the EPO is unclear.

As we previously reported, the EPO announced the take-home message of this Decision in an earlier press release, such was the interest surrounding the Decision. The now-issued Decision is consistent with that announcement and provides the Board's reasoning. The Board also provides an explanation of when, in its opinion, this issue should be referred to the Enlarged Board of Appeal (EBoA); i.e. when the EPO's approach should be reconsidered.

This Decision is the latest development in a long-running debate relating to the patentability of plant-related inventions under the European Patent Convention (EPC). Broadly speaking, three separate points of law have been the subject of debate since the EPC was adopted. These are: i) when **product** claims directed to plant varieties are patentable, ii) when **methods** for the generation of plant products are patentable, and iii) whether plant **products** are patentable even if they have been **obtained** by unpatentable methods. To put the latest decision in context, we describe this background below.

The legislation

Article 53(b) EPC sets out the relevant exclusions from patentability, and recites:

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;

Product claims directed to plant varieties

The first question, when plant varieties are patentable, was addressed in G 1/98 (Dec 1999). Essentially, the EBoA needed to be decide whether "European patents shall not be granted in respect of: … plant or animal varieties" should be interpreted broadly or narrowly.

Firstly, it is important to know what a "plant variety" actually is. The EPC provides the following definition:

"Plant variety" means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being propagated unchanged. Rule 26(4) EPC
The rationale for excluding plant varieties from protection was apparently to avoid dual protection with that provided by the International Union for the Protection of New Varieties of Plant (UPOV) Convention. As such, it is important to note that the definition within the EPC is identical to that in the UPOV Convention.

In G 1/98, the EBoA decided that a product claim that identified a specific plant variety would not be patentable (Section 3.10). However, it was noted that plant breeders' rights would not protect inventions where the technical feasibility of the invention is not confined to a particular plant or variety, for instance in the case of an invention involving the insertion of a particular gene that would be of benefit to multiple plant varieties. As such, the EBoA

decided that a product claim embracing plant varieties, but not individually claiming specific varieties, would not be excluded from patentability.

The EPO has maintained this approach and it is still applied today.

Method claims for producing plant products

Methods applied to plants, such as genetic engineering techniques, that work primarily through the purposeful insertion and/or modification of one or more genes in a plant are considered to be "technical" and hence patentable. However, the more complicated question is whether methods that involve classical crossing and selection, but also advanced technical methods, are excluded from patentability.

To answer this question the EBoA was required to interpret: "European patents shall not be granted in respect of: … essentially biological processes for the production of plants", and this analysis was provided in two consolidated EBoA decisions (G 2/07 and G 1/08; Dec 2010).

It was decided that non-microbiological processes are excluded from patentability if they contain the steps of sexual crossing the whole genomes of plants and subsequently selecting plants with desired traits, unless the process also includes a step of a technical nature that by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced. If the step of a technical nature merely serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants, then the process remains excluded from patentability.

To simplify: processes to generate plants where a new trait is the result of crossing and selection are not patentable, even if new or advanced technologies are used to assist the process. Only if the new trait is introduced or modified by a technical step, and so is not just the result of mixing the parental genes, are such processes patentable.

This approach is still applied by the EPO.

Product claims directed to plant varieties obtained by unpatentable processes

The above Decisions did not address product claims that are directed to plants that have been obtained by an essentially biological process. It was only stated that the **methods** themselves are not patentable. For instance, it was unclear as to whether tomatoes or tomato plants generated by a new and inventive but essentially biological process would be patentable.

To put this in context, the English translation of the corresponding German provision is set out below:

Patents shall not be granted for
1. plant or animal varieties or for essentially biological processes for the production of plants or animals and plants **and animals exclusively obtained by such processes.**
As can be seen by a comparison of the above provision with Article 53(b) EPC, the final clause is not present in the EPC. There has been debate as to whether Article 53(b) EPC should be interpreted to implicitly state this clause.

EBoA issued consolidated decisions stating that Article 53(b) EPC should be interpreted such that plant products that have been obtained by an essentially biological process are patentable (G2/12 and G2/13; Mar 2015). The Board noted that there is no reason to interpret the process exclusion broadly such that it also included products. It was explicitly noted that jurisdictions that have decided to exclude such products from patentability have updated their legislation in a similar manner to the German approach set out above, and hence have deviated from Article 53(b) EPC.

However, this EBoA decision proved controversial. The European Commission (an EU body) disagreed with the interpretation, and issued a Notice stating that the EU Biotech Directive (98/44/EC), which is written into the EPC, was intended to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by

means of essentially biological processes (2016/C 411/03; Nov 2016). The views of EC are not binding on the EPO; however, in 2017 the EPO's Administrative Council amended the Implementing Regulations to include 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.
This change was made upon the EPO President's recommendation, who stated that the change is "In order to align the EPO's law and practice with the interpretation of the Directive and to safeguard uniformity in harmonised European patent law".

However, according to the Board responsible for new Decision T1063/18, the Administrative Council does not have the power to alter how the Articles of the EPC should be interpreted simply by amending the Implementing Regulations. If the Implementing Regulations and the Articles are in conflict, the Articles prevail (Article 164(2) EPC). As such, introducing an Rule that conflicts with an Article (as interpreted by the EBoA) is not a legitimate way to change the law.

It is explained in T1063/18 that, because Rule 28(2) EPC is set aside, the correct interpretation of Article 53(b) EPC is as outlined in G2/12 and G2/13. Product claims directed to plant products that have been obtained by an essentially biological process are not excluded from patentability.

The future

An outstanding question is: "will the EPO change its mind again?". The present Decision was issued by a Technical Board of Appeal (TBoA), and such Decisions are not binding on later TBoAs or the EPO's Examining Division (the Decision is only binding with respect to the individual application to which T1063/18 relates). However, the Decision is not without effect. Firstly, TBoA Decisions are persuasive, and secondly, if a later TBoA considers it necessary to deviate from this interpretation it must provide the grounds for the deviation and notify the president of the EPO. If two TBoAs have given different Decisions on the same question, the President may refer the point of law to the EBoA. Furthermore, if a later Board were to take a different approach then, at least according to T1063/18, this would deviate from the previous EBoA decisions and would necessitate a referral to the EBoA from the Board in question. As such, if a later TBoA takes a different view, the EBoA will probably need to determine the correct approach, and such a process is likely to take years.

The Board responsible for the present Decision also considered which subsequent developments could render it necessary to deviate from the EBoA's previous interpretation, and hence necessitate a referral. The notice issued by the EC was not considered a relevant development because it has no legal authority. Instead, a decision of the Court of Justice of the European Union (CJEU) seems to be viewed by this Board to be a development that would be sufficient to require a new EBoA referral.

CJEU Decisions, while potentially persuasive, are not legally binding on the EPO which is not an EU body. The EPO has attempted to harmonise its approach with EU law, at least with regards to biotech inventions. However, European patents can provide protection in non-EU states. As such, it is questionable as to what degree the EPO should follow the EU, bearing in mind that the non-EU states may not wish to be bound by EU rulings.

The matter could be unambiguously settled if the Administrative Council amends the Articles of the EPC. However, this is very difficult to do, requiring either a Diplomatic Conference of at least three-quarters of the Contracting States (there are currently 38 Contracting States), or the use of an alternative mechanism that requires unanimity of the Contracting States. The Articles of the EPC have only been revised twice in their history. As such, it is hard to predict whether this is a feasible option for the Administrative Council.

To address this, the EPO has issued the following press release, reproduced in full:

EPO member states discuss patentability of plants obtained by essentially biological processes 20 February 2019 In the meeting of the Committee on Patent Law, the Office and the representatives of the 38 EPO Contracting States, together with the European Commission as observer, had a first exchange of views on possible next steps following the recent decision T 1063/18 of an EPO Board of Appeal on plant patentability. The Committee addressed different potential options for the way forward and particularly supported measures to obtain an opinion from the Enlarged Board of Appeal on the matter. The need for legal certainty in the interest of the users of the European patent system and the general public was strongly underlined in the debate. Discussions will continue with the intention to find a solution in the short term.

The Committee on Patent Law advises the Administrative Council, and it is not clear which “measures to obtain an opinion from the Enlarged Board of Appeal on the matter” are available to the Administrative Council. As described above, there are specific requirements for when an EBoA opinion can be sought. The TBoA are independent and cannot be compelled to refer a question to the EBoA if the TBoA do not view it to be necessary according to the provisions of the EPC. The EPO President can refer a question to the EBoA directly, but only if two TBoAs have given different decisions on same question, otherwise the referral would be held to be inadmissible.

Key takeaways

For the moment, the EPO has returned to granting patents in respect of plants or animals exclusively obtained by means of an essentially biological process. T1063/18 is not binding on the EPO's Examining Divisions (aside from, as mentioned, when assessing the individual application to which T1063/18 relates), but it is likely to be persuasive. Furthermore, a refusal that deviated from T1063/18 could be appealed and, if the TBoA assessing such an appeal diverged from T1063/18, then a referral to the EBoA seems likely (or, according to T1063/18, required) to determine the correct interpretation once again.

It is, therefore, worth considering whether to seek European patent protection for such subject matter, bearing in mind that the latest guidance is favourable, and that protection can extend beyond the EU states. Of course, applicants should also take into account that such patents may not be enforceable in some jurisdictions, and there are specific provisions in the national law of Austria, Germany, France, the Netherlands, and Portugal (from 1 July 2019) that exclude these products from patentability. In addition, applicants should bear in mind that the EPO is free to alter its approach (again).

Finally, it is important to note that T1063/18 relates only to product claims directed to plants or plant material obtained by an essentially biological process. The latest decision does not affect the EPO’s long-standing approach that plants and plant material obtained by a technical process are patentable. Of course, it must still be borne in mind that **individual** plant varieties are not patentable, but it is allowable to have claims embracing plant varieties "if the technical feasibility of the invention is not confined to a particular plant or animal variety" (EPO Guidelines; G-II, 5.2).

Action recommended for companies seeking to protect germplasm in European market

Many companies seeking to protect plant innovation have eagerly followed the developments at the EPO. The current T1063/18 decision is favourable, but as aforementioned, does not permanently settle the issue for the European market. Consequently, it is important for companies to realise that patent terms run for 20 years and that a global filing strategy which includes the European market is still a high priority for many crops. As we have seen, the tides have begun to change for protecting plant innovation and commercial germplasm via patents in the EPO. Companies interested in the European market should consider maintaining EP applications directed to key germplasm and arguing in their own cases that the T1063/18 decision should be persuasive authority. Maintaining a pending application at the EPO will allow companies the ability to protect key germplasm in the European market once the legal certainty around this topic is finally settled at the EPO.

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