THE IP PUZZLE OF NGTS IN EUROPE: UNLOCKING INNOVATION, ACCESS AND FAIR PLAY

FACTS ON HOW PATENTS AND PLANT VARIETY PROTECTION CAN CO-EXIST IN A FUNCTIONAL SYSTEM

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Since the publication by the European Commission of the Proposal for a Regulation on plants obtained by certain New Genomic Techniques (NGTs) in July 2023 (the "Proposal"), the EU institutions have engaged in democratic political debate, involving both the European Parliament and the Council of the EU. Even though the intention of the Commission's Proposal was to address the regulatory status determination of plants obtained by NGTs, the topic of intellectual property (IP) entered the scene through the backdoor and has dominated almost all debates. Political debates on IP are also echoed in the seed sector and Seed World Europe reported several times on the diversity of positions.

In an attempt to shed light on the various claims made about IP and NGTs, CropLife Europe (CLE) contracted independent experts to compile factual data from publicly available sources helping understand what patents actually are and do, and whether the concerns are justified. This article summarises the results of their findings (CLE Study)[1].

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COULD PLANT VARIETY PROTECTION BE SUFFICIENT TO PROTECT NGT TRAITS?

The CLE study reveals that Plant Variety Protection (PVP) rights in the frame of the UPOV Convention are effectively the tool adapted to protect new plant varieties in Europe.

This does not mean that all plant breeding innovations can be protected by PVP. For example, a plant trait developed through NGT is not protected under PVP, which only covers the variety as a whole, not individual traits. Once the PVP protected variety is commercialised, every breeder can use it in their breeding programs to integrate certain traits of that variety into their own ones and create new varieties containing the NGT trait. Those derived new varieties would not be protected by the PVP on the initial variety.

The only IP tool available to protect a technically created element of a plant, like an NGT trait, is the patent. PVP and patents are therefore complementary - not mutually exclusive - because they have a different scope and protect different types of innovation, and plant breeders will either use one or the other, or both, depending on the type and nature of R&D they invest in.

WOULD THE NUMBER OF PATENTS INCREASE DRAMATICALLY WITH NGT?

Some stakeholders are worried that there will be a huge wave of patents rolling over the European market with NGTs. The assumption that every patent applied for will become a granted patent is, however, far from true. As reported in the CLE study, not everything is patentable, and there are exceptions to patentability.

In the field of plants, one exception which has always existed is the exclusion of essentially biological processes to produce plants (or animals). This exclusion is enshrined in the World Trade Organization (WTO) agreement on Trade related aspects of IP rights, TRIPS. The European Patent Office (EPO) includes it in its Article 53(b). This exclusion is expressly directed towards avoiding that conventional breeding methods, consisting essentially in crossing of plants and selecting the ones bearing useful characteristics, be protected by patents, because these methods are deemed not technical and the traits selected would be "native". The EPO's Enlarged Board of Appeal has even clarified that the use of genetic markers in the selection process does not make an essentially biological process patentable. More recently, in July 2017, the EPO has also excluded the plants obtained by such essentially biological processes, i.e. plants that would essentially contain native traits.

The main criterion for an invention being considered patentable subject-matter is that it has been obtained by technical means. Plant traits obtained by technical means such as random or targeted mutagenesis techniques (e.g. NGT) can be considered patentable and enter the field of inventions for which a patent may possibly be granted.

It is however not because a patent application can be filed for a technical invention that this invention will satisfy the criteria for obtaining a granted patent.

The first criterion is that of Novelty. Nothing that was already known or existing can be patented. Regarding plant traits, a specific mutation in a gene responsible for a certain trait may not satisfy the Novelty criterion if that mutation was already known

[1] Data on file from a study performed by Altius law firm, De Clercq & Partners IP law firm and Acutifolius Consultancy Firm are available upon request to CLE (croplife@croplifeeurope.eu)

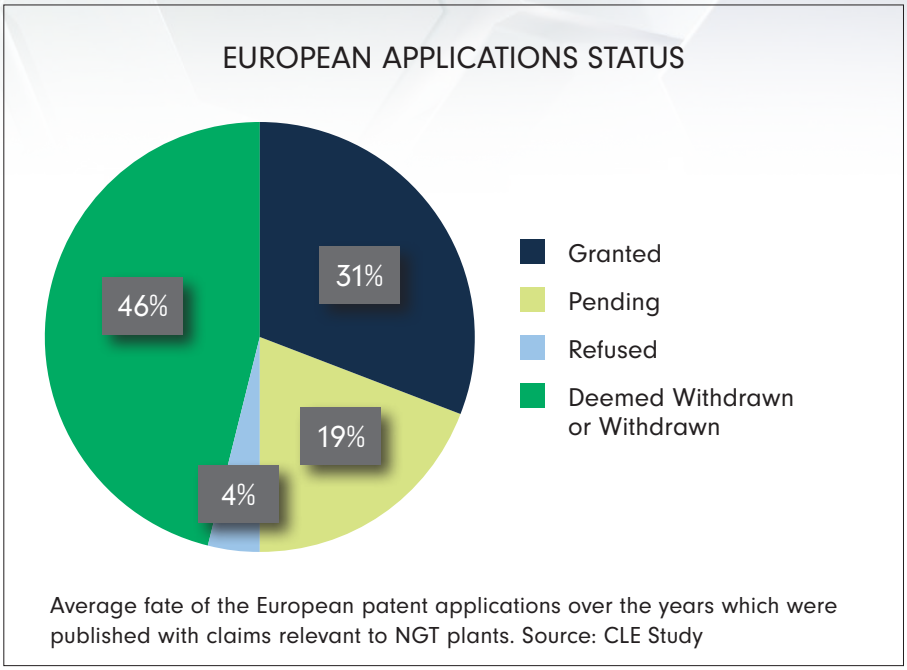
before, either in a scientific publication, in a gene bank, another patent, or even in an existing plant in a collection. For example, a known mutation in a gene cannot become novel simply by having it created again by a technical means.

Assuming a given NGT trait would be novel, it would further have to satisfy the patentability criterion of Inventiveness before possibly being protectable by a patent. Take the example of a "knockout" mutation, which deactivates a given gene that is already known to be involved in a specific physiological pathway responsible for a desired trait. Subsequently, the deactivation of the same gene with a different mutation would make that invention possibly novel, but it would not make it inventive because it would already be known that deactivating that gene would lead to the expected trait.

Lastly, to be granted a patent, inventions must also be Sufficiently Described in the patent application to enable anyone else to reproduce it without excessive efforts. This means providing all the details about what the invention is, how it was obtained and, possibly, how to get the biological material. Only if all these criteria are complete can an invention be approved for patentability.

The EPO reports on its website that its grant rate across all sectors is around 60%, meaning that 40% of the applications are refused or abandoned during the examination phase. The CLE study reveals that, when it comes to plant-related inventions obtained by NGTs, this grant rate reduces to 31%.

What may remain patentable are those NGT innovations involving more complex traits, that may be controlled by more than one gene or that may not be achievable by simply knocking out a gene, but by editing several target genes with very specific mutations at very specific gene locations. Typically, those will require much more R&D efforts to understand the implication and the functioning of genes involved in relevant traits. Companies investing in biotech R&D can only rely on patents to obtain a fair return on higher risk investments.



Average fate of the European patent applications over the years which were published with claims relevant to NGT plants. Source: CLE Study

Strong IP protection also helps keep R&D investment interest alive.

Thinking more broadly, one may in fact consider an increase in the number of patents to be a good sign for EU farmers, reflecting that R&D investments are made to try addressing the problems they face with the crops they grow. Enabling NGT plants for EU farmers requires not only a science-based regulation but also, separate from any regulatory framework developments, an effective IP framework that stimulates R&D investments.

WOULD PATENTS ON PLANT TRAITS BLOCK SME BREEDERS?

PVP laws include one fundamental right, the so-called breeder's exemption. The breeder's exemption allows any breeder to use a commercial variety protected by a PVP of another breeder in its own breeding program for the purpose of creating a new variety.

Historically, there has always been a similar exemption for research purposes in patent laws, but no breeder's exemption. Several EU Member States have remedied this in the last years — among them France, Germany, the Netherlands and Poland, and other Member States having ratified the Unified Patent Court Agreement (UCPA) in 2023.

The breeder's exemption in patent laws has the exact same effect as in the PVP law, i.e. it enables any breeder to use a commercial variety containing a patented trait of another breeder in its own breeding program for the purpose of creating a new variety. If the new variety no longer contains the patented trait, or if the patent has expired or been abandoned at the time of its commercialization, it may be freely commercialized. If however the breeder of the new variety is interested to have the innovative patented trait in its new variety and the patent is still in force, the breeder of the new variety would need to secure a license from the patent owner and pay royalties for the remaining lifetime of the patent, which may be only a few years given the

time necessary to develop a new variety. CLE supports the implementation of such a breeder's exemption by all EU Member States in their patent laws, regardless of whether they ratified the UPCA or not.

WOULD BREEDERS NOT KNOW IF A COMMERCIAL VARIETY IS PROTECTED BY A PATENT?

This is admittedly not as straightforward for a breeder to verify if a commercial variety contains a patented trait. However most recently, to enable breeders to make informed decisions whether to use a given commercial variety under the breeder's exemption, the European seed industry association, Euroseeds, has developed a database named PINTO[2] in which companies list their commercial varieties covered by patents. The database can be searched by the variety denomination, and it indicates immediately if a patent covers a trait in that variety, also indicating the patent number and the name of its holder.

WOULD BREEDERS BE UNABLE TO COMMERCIALISE THEIR NEW VARIETIES BECAUSE OF PATENTS?

If, by using a commercial variety containing a patented trait identified with PINTO, a breeder creates a new variety under the breeder's exemption containing the patented trait, he needs to obtain a license from the patent holder to commercialise it.

To facilitate access to patented material, the majority of seed companies in Europe have committed to license their patented traits to any breeder asking for it through licensing platforms. Notably there are two licensing platforms covering the EU, the ILP for vegetables[3], created in 2014, and the ACLP, for agricultural crops[4], created in 2023. Both oblige their members holding patents on traits to commit granting a license on their patent on fair conditions to any other member requesting it for a new variety created under the breeder's exemption. Only the royalty rate remains to be agreed between the parties. To avoid excessive royalty rates, either high or low, both licensing platforms have established an arbitral mechanism to be activated in case the parties find themselves unable to reach agreement. This arbitral mechanism operates under the principles of "baseball" arbitration.

WOULD FARMERS BE PREVENTED TO SAVE SEEDS WITH PATENTS?

The CLE study clearly highlighted that the right for farmers to save seed exists in both PVP and patent laws in Europe. This right exists under the patent rules of the Directive 98/44/EC, which expressly refers to the legal provisions of the EU PVP Regulation 2100/94 for its implementation.

Farmers therefore not only have the right to save seeds of a variety containing a patented trait, but this right is also applicable under the exact same conditions as under PVP law.

The CLE study shows that the current IP framework in Europe is already well adapted to the development of NGT plants.

CLE considers that for NGT plants to reach European farmers in the coming years, there needs to be both an appropriate regulatory framework, which the current NGT proposal is trying to achieve, and separately there needs to be an appropriate IP framework enabling all actors to protect the results of their R&D efforts.

The CLE members active in seeds are mostly companies that are both breeding companies developing new varieties and biotech companies developing new traits for their varieties. They are also mindful of the negative perception that patents may carry to those not familiar with them. CLE therefore requested this study about the factual nature and effects of patents in the plant breeding sector, as summarized in this article.

Not only do patents not hinder breeding, but they also generate much value to farmers and society as demonstrated in the study on the Ogura trait patented by INRAE[5].

CLE believes that with strong PVP and patents, companies will be incentivised to develop NGT plants. Together with the transparency and licensing tools that have been developed, NGT plants will be accessible to all breeding companies whatever their size, thereby enabling European farmers to be competitive and have access to such plants in a large offering of varieties from the whole European breeding sector. ▲

Editor's Note: Hervé Monconduit is the Head of Patents, Bayer SAS, France, EU and French patent attorney and Chair of the IP expert group of CropLife International.

WHERE ON THE WEB

https://www.seedworld.com/europe/2024/05/21/incentivizing-the-development-of-new-products-for-european-farmers/

https://www.seedworld.com/europe/2024/05/23/is-ip-indeed-an-easy-dossier/

https://www.seedworld.com/europe/2025/01/03/we-cant-do-it-without-patents-2/

[2] https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/

[3] https://www.ilp-vegetable.org/

[4] https://aclp.eu/

[5] https://croplife.org/wp-content/uploads/2014/11/Ogura-Final-report.pdf
This study demonstrated that 80% of the economic value generated with a patented trait has gone to the farmers and to the downstream users in the value chain up to consumers.