

Proposals to Facilitate Identification, Access and Use of Intellectual Property Related to New Genomic Technologies in Plants

In the same way as forty years ago, during early development of plant genomics (molecular markers in particular) and Genetically Modified Plants (GMPs), the introduction of plants resulting from New Genomic Techniques (better known under the abbreviation NGT) has revived the debate on the patentability of biotechnological inventions, in particular on what is called a “native gene”. As then, many recent publications or position statements express concerns that do not always reflect reality.

In support of the EU Commission’s approach, which announced at the same time as the publication of its proposed NGT Regulation that it would conduct a study on the impact of intellectual property (IP) before 2026¹, we conducted an analysis of IP in the field of plant breeding in relation to forthcoming NGT-derived varieties, assuming the draft NGT regulation, currently under discussion at EU level, is adopted. In the course of this analysis, we identified possible adaptations to IP legislation, some of which could be put in place quickly, before the new NGT regulation is applicable in 2026 if the EU were to adopt it before the end of the current mandate. These proposals should allow all players in the sector to benefit from the opportunities brought by the use of NGTs. In the longer term, a more in-depth analysis of the IP system in the field of varietal improvement should be launched in order to further revise the IP system if deemed necessary and if possible, in light of international treaty obligations, a process that is likely to take several years.

These proposals are presented below after a brief review of IP applicable to plants and varieties and an assessment of IP affecting NGT-derived plants. A more detailed version of this note is available on the AFBV² website.

A. General principles of IP at plant and variety level in Europe: The development and availability of new innovative varieties adapted to the needs of farmers and the demands of consumers and processors require an increasingly important research and development effort. In order to sustain this innovation activity, well-functioning IP rights must exist. Existing IP legislation has been adapted to varietal creation. Stakeholders must be able to access plant genetic resources while allowing for the protection of innovations, which has led to the establishment of two coexisting IP systems, each responding to the needs and constraints of varietal innovation. These are Plant Breeders' Rights (PBRs) and patents.

Patents were introduced in 1883 with the aim of protecting the inventor and giving him an exclusive right to exploit his invention for 20 years in exchange for the publication of a detailed description of this invention allowing its improvement, in particular through a research exemption. The PBR was established in 1961 to allow the breeder to protect the variety he or she has developed, granting an exclusive property right for 25 years (30 years in the case of trees, potatoes and vines), while allowing other breeders to be able to use this variety in their breeding programs to produce new ones, through the breeder's exemption. With the development of technologies applicable to plant breeding, particularly in the field of genomics, molecular labeling and transgenic plants, inventors have filed patents for inventions derived from these technologies, which has led to an interference between patent and PBR legislation, introducing difficulties in the application of the breeder's exemption when a variety contains patented elements. The presence of patented elements complicates and hinders the use of the variety as a genetic resource in a breeding program (see various options in the more detailed version of this note)². Over the years, various adaptations have been put in place to facilitate the management of this interference and allow the continuity of innovation without calling into question the basic principles of IP protection for innovative products.

Some basic principles to remember: This analysis focuses on the situation in Europe.

- In Europe, as in a large majority of countries, **a plant variety cannot be patented**, but it can contain patented elements obtained through the use of biotechnologies. A variety containing patented elements can be protected by a PBR.
- Plants obtained exclusively by means of an essentially biological process (crossing and selection, i.e. containing essentially “native traits”) **are not patentable** as decided by the European Patent Office (EPO) since 1st July 2017. However, **plants (plant varieties being excluded) can be patented** if they have been obtained by a **process that is not essentially biological** (i.e., biotechnological) and meet the **criteria for patentability** (novelty, inventiveness, and industrial application). Currently, the use of NGTs is considered a non-essentially biological process.
- **The disclaimer** clause, imposed by the EPO (for patents filed after 1 July 2017), is intended to ensure that plants containing only native traits which are considered equivalent to plants containing patented traits (obtained for example by the use of NGTs) are not dependent upon those patents claiming those traits.
- **The farmer's privilege** to use part of his crop for replanting has existed in the case of PBRs since the 1991 UPOV Convention, and the same privilege for patents (genes, traits, techniques, etc.) since the adoption of Directive 98/44/EC³, according to conditions specific to each species, excluding hybrids and synthetics. **Subject to compliance with the conditions of use of his harvest as seedlings, a farmer is not affected by the PBR on a variety or a patent on a patented element present in that variety⁴.**
- **The breeder's exemption** applicable from the outset (1961) to PBRs applies in an increasing number of Member States (17 as of 1 June 2023), following the entry into force of the Agreement on a Unified Patent Court (UPCA)⁵. It allows the breeder to freely use a variety protected by PBR and/or containing patented elements in its breeding programs. However, an analysis of the IP situation is necessary, as it has an impact on commercialization conditions of the new variety obtained (see more detailed version of this note)².

B. IP Review: There are currently no NGT varieties protected by a PBR in Europe, in particular because regulatory requirements for commercialization are uncertain. An overall assessment at the patent level gives an idea of the IP dynamics in the field concerned, but not the actual impact on a given project. NGT patents can be classified into two categories: The first covering techniques, such as those allowing the production of an NGT plant (technical patents); the second covering genes/traits/plants (trait patents) obtained with NGTs. There is indeed a complex environment for technical patents. In the case of trait patents, significant filing activity is visible, but it is difficult to assess the development of these NGT plant patents today. *An important consideration:* If one wants to develop an NGT plant, a relevant IP analysis can only be (but must be) done after defining the NGT product (the characteristics of the NGT plant, the techniques needed to develop it) and the target markets (the countries where the varieties will be marketed, and the derived products used).

C. Ten proposals for adapting current IP legislation:

These proposals have been prepared taking into account areas of activity using NTGs. Potential challenges related to the presence of IP rights were then identified in these areas. Finally, we looked at what could be done to facilitate the identification, access and use of IP by users, breeders and farmers.

1. Areas of activity covered: We considered four activities in which IP can interfere.

- **The production of an NGT-derived plant:** It is important to verify freedom to operate in terms of the techniques necessary to produce an NGT plant as well as in terms of the trait envisaged. To do this, a search of patent databases must be carried out to identify relevant patents and determine their status (under examination, granted, abandoned, expired, etc.). If patents that could interfere with the development of a project have been identified, it is necessary to define the licensing strategy to be implemented, which may include the search for technical alternatives, challenging the validity of the patent or, when the first two options are not realistic, an attempt to obtain a license. In order to facilitate this research, improvements are proposed below on the identification and status of patents and on access to patents necessary for the proposed project. Proposals 1 through 8 and 10 are expected to have a positive impact on this activity.

- **The production of an NGT variety:** This production will be carried out either by the company that developed the NGT plant or by a seed company that has obtained a license or acquired rights from the company that developed the NGT plant. Proposals 1 through 8 and 10 are expected to have a positive impact on this activity.
- **The use of a protected variety containing patented elements in a breeding program:** This use is possible thanks to the breeder's exemption. However, research into the possible presence of patented elements in the variety is necessary, with a view to marketing the new variety being created if the intention is to preserve the patented trait. Depending on the status of the patents concerned, the consequences for freedom to operate for the variety are different (see details in the more detailed version of this note)².

In order to facilitate access to information on patents covering a protected variety, private initiatives have been set up. These include:

- **The PINTO⁶ database**, set up by Euroseeds, which provides such information. It is, however, incomplete because it is limited to Euroseeds members and its updating is uncertain because it relies on the voluntary work of its members.
- **Two licensing platforms** have been set up by industry players, one for vegetable crops (**International Licensing Platform-Vegetable [ILPV]⁷**) and one for agricultural crops (**Agricultural Crops Licensing Platform⁸**). Members of these platforms undertake to provide information on their patents (genes, traits, markers, etc.), either through the PINTO database (ACLIP) or in the platform's own database (ILPV), to grant a breeder's exemption throughout all of Europe as well as a non-exclusive commercial license to the patents concerned (currently limited to traits) according to partially defined terms.

Proposals 3 through 8 and 10 are expected to have a positive impact on this activity.

- **Breeding of a non-NGT variety:** a breeder carries out a continuous production of new varieties using the genetic background at its disposal. A breeder may be faced with a difficult situation if it is working on a trait found in this background that could be dependent on a patent on the same trait obtained using NGTs. Proposal No. 9, below, aims to improve the disclaimer clause by clarifying its scope.

2. Our Proposals:

They are of two types:

- voluntary initiatives originating, for example, from breeders themselves or from the EPO in a customer-oriented approach, or**
- actions by the European Commission, in particular to clarify or, if necessary, amend existing legislation.**

The voluntary initiatives can also be the subject of discussion between the EU Commission and concerned stakeholders (including the EPO) in the course of the Commission's planned study.

Proposal N°1: Create specific NGT codes applied to plants in the databases of the EPO (European Patent Office) and/or the PCT (Plant Cooperation Treaty).

Facilitate the identification and monitoring of patents: Once a project has been defined, it is necessary to determine whether there are one or more patents that could interfere with its development. This identification is difficult, in particular for companies with little experience and few resources in this field. To facilitate patent searches, one or more NGT-specific codes applied to plants could be established at the level of the EPO database (techniques, genes, traits, plants, etc.). An alternative could be a new "plant trait" code. In addition, contact with the national entity in charge of IP (Institut National de la Propriété Industrielle – INPI, in France) is recommended because it offers various training courses and can help in patent searches.

Proposal N°2: Analyze the possibility of reducing the examination time of a patent to shorten the period of uncertainty between the publication of a patent and its grant.

Reduction of the time between the publication of a patent, its examination and its grant or refusal: This period is a period of uncertainty ranging from four to five years after filing a patent application at the PCT level, which is usually achieved one year after an initial ("priority") filing in a PCT participating country. This is all the more justified for biotechnology inventions since, according to the EPO, only 30% of patents filed

in this field are granted. The duration of exchanges between the EPO and the applicant could be reduced by slightly increasing the number of EPO examiners in this technical area.

Proposal 3: Encourage and facilitate comments to the EPO during the examination phase of a patent. Examine specific modalities for SMEs and consider the possibility of allowing a patent search assisted by examiners at low cost.

Scope of patentability: As stated above, the grant of a patent on plants is based on how the plants were obtained (whether exclusively or not by essentially biological processes). There may be discrepancies in the interpretation of the criteria. Any person may intervene during the examination of a patent and express in writing his or her assessment of the possible non-satisfaction of the patentability criteria by the invention, for example by bringing to the attention of examiners prior publications or public uses of the invention (third party observations). In addition to recommending that entities concerned by a patent comment on ongoing proceedings, could processes be put in place allowing SMEs to intervene, through an appropriate structure which could call upon patent counsel to facilitate appropriate formulation of objections under patent law? Would it also be possible for the EPO to offer at a low price for small breeders and farmers an in-depth and assisted search service in professional patent databases carried out by a patent examiner in the presence and with the help of the client?

Proposal 4: Favor the creation of a new European platform, bringing together public and private actors, to develop and make available to all breeders, in the form of licenses, genome editing technologies under reasonable terms.

Our observation is that despite the explosion of innovations around Cas9 since 2012, it has not been possible to date to create a pool of patents directed to genome-editing technologies to facilitate access under reasonable terms. To date, the only two platforms granting access to patents on plant traits, ILPV⁷ and ACLP⁸, have communicated their inability to include genome editing technologies in their scope. We therefore recommend that the Commission examine as part of its investigation the possibility of encouraging the creation of a new European platform, bringing together public and private actors, to develop and make available to all breeders, in the form of licenses, genome editing technologies on reasonable terms.

Proposal N°5: Put in place mandatory listing of the status of patents that may cover a variety marketed in the Official Catalogue of cultivated plant species and varieties of the EU, for species covered by this regulation, and/or in the CPVO database.

Information on patents related to a protected variety: As the information contained in the PINTO database is incomplete, it would be appropriate to require disclosure of patented traits present in a protected variety, either by including this information in the PBR database (CPVO) and/or in the national and EU catalogue of species and varieties. This obligation could be made to apply to all protected varieties containing a patented trait, not just NGT-derived varieties. All patents attached to a variety (techniques, traits, genes, plants) owned or licensed by the variety owner should be listed.

Proposal N°6: Request EU Member States to ratify the UPCA or to include the breeder's exemption in their national patent legislation.

The breeder's exemption at the patent level: While this exemption has existed for PBRs since their creation (1961), it is more recent at the patent level with its extension to 17 Member States having ratified the Agreement on a Unified Patent Court (UPCA)⁵ (as of 1 June 2023). This exemption could be made to apply to all EU Member States, either by ratifying the UPCA or by integrating the breeder's exemption into existing national patent legislation.

Proposal 7: Confirm that the breeder's exemption at the patent level applies to the use of NGT tools and all pre-marketing steps up to (and including) variety registration and clarify that it also applies to pre-launch seed production.

The scope of this exemption: The breeder's exemption at the patent level provides that the rights conferred by a patent do not extend to "the use of biological material for the purpose of breeding or discovering and developing other plant varieties" (Art. 27(c) of UPCA⁵). If a breeder uses a variety containing a patented trait under the breeder's exemption to create a new variety, and if the resulting new variety still contains this patented trait, its marketing may not take place before the expiry of the patents concerned, unless an agreement is reached with the patent holder(s).

In order to take full advantage of the breeder's exemption it should be clarified that the term "biological material" includes NGT tools used to create the NGT plant and subsequent variety, and that regulatory and legal procedures for the protection and registration of varieties can also be carried out within the scope of the breeder's exemption¹⁰, while patents are still in force, as well as pre-market seed production.

Proposal N°8: Encourage entities developing NGT plants to become members of existing licensing platforms. Incorporate uncovered plant species into these licensing platforms or create new ones for such species (trees, fruit trees, ornamentals).

Patent licensing platforms: NGT technology companies developing plants should be encouraged to become members of existing licensing platforms. As not all plant species are covered, similar platforms for other species such as trees, fruit trees or ornamentals could be set up. Platforms should be requested to include in their databases not only patents on plants, genes and traits, and to keep the status of listed patents updated periodically.

Proposal N°9: Delete the criterion of "considerable economic interest" for compulsory licenses and leave the definition of the terms of the license to the parties concerned on fair, reasonable and non-discriminatory terms (FRAND) or, if amending the legislation is not possible, interpret this criterion so that the breeder knows what results must be satisfied in order for the compulsory license obligation to be triggered and for the judge to determine only the amount of the royalty.

Compulsory License: Currently, a compulsory license is included in Directive 98/44/EC. This compulsory license applies only in the case where a new variety is dependent on a patented element. It assumes however that the applicant demonstrates considerable economic interest of his or her variety, and the conditions are determined by a judge. The criterion of considerable economic interest should be removed and the definition of the terms of the license should be left to the parties concerned on fair, reasonable and non-discriminatory (FRAND) terms. In the absence of an amendment to Directive 98/44/EC permitting the criterion of "significant technical progress of considerable economic interest" to be modified, the Commission should interpret this sentence so that the breeder knows what results must be met for the compulsory licensing obligation to be triggered and for the court only to have to determine the amount of the fee¹¹. It should also be clarified that if the results justifying the "considerable economic interest" required for a compulsory license are satisfied by the breeder, all patents covering traits present in the variety and for which a licensing request was refused fall within the scope of the compulsory license.

In situations where a breeder's variety is dependent upon a PBR-protected variety of another breeder, to clarify the circumstances giving rise to a compulsory license the Commission could interpret the "grounds of public interest" criterion so that the breeder knows which results must be satisfied so that the Community Plant Variety Office (CPVO) can grant the license provided for by Article 29 paragraph 1 of Regulation 2100/94/EC.⁴

It should be noted that the members of the platforms described above will not use this compulsory license with respect to patents accessible through the platform which are licensable to all members under reasonable terms.

Proposal N°10: Confirm that the disclaimer clause covers not only the plant containing a native gene or trait, but also the gene and the corresponding trait.

Disclaimer: The disclaimer clause provides that if a person obtains a variety carrying a gene and a trait obtained by essentially biological means, it may be used freely, even if a patent has been granted for the same gene or trait obtained by non-essentially biological means. In the current wording of the guideline, there may be uncertainty as to the scope of the disclaimer, which should extend to both the claims directed to the plant and those directed to the trait carried by the plant and the corresponding gene. This clause, introduced by the EPO in the context of the application of EPO Rule 28(2)¹² should be supplemented by an additional disclaimer clause covering claims to native traits or to genes corresponding to such native traits.

Proposal N°11: Authorize the farmer's privilege for new species and define the terms of remuneration of the holder of the cultivated variety when appropriate.

At present, the farmer's privilege is limited to a few species³. It could be extended to other species, especially in the field of vegetable species. At the same time, the conditions for the remuneration of the variety holder should be defined where appropriate, bearing in mind that small farmers are exempted from such remuneration.

The above proposals are intended to provide input for ongoing debates on intellectual property relating to NGTs and NGT plants and can be used in the context of the European Commission's planned study on P related to NGTs. We remain at the disposal of the Commission and any other stakeholders for any further information.

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Hervé Monconduit and Franck Tetaz, intellectual property counsel, consulted on this text.

References:

¹ https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3568

² This version, as well as a more detailed annotated version, both in English and French, are available on the AFBV website: <https://www.biotechnologies-vegetales.com/blog/reglementation/>

³ Directive 98/44/EC on the legal protection of biotechnological inventions. <https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=celex%3A31998L0044> and <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000000445183>

⁴ Regulation 2100/94/EC on Community plant variety rights. <https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:31994R2100> and French Intellectual Property Code: https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006069414/LEGISCTA000024945662/#LEGISCTA00024953410

⁵ Agreement on a Unified Patent Court: <https://www.epo.org/xx/legal/official-journal/2013/05/p287/2013-p287.pdf> Agreement on a Unified Patent Court: https://www.unified-patent-court.org/sites/default/files/upc_documents/agreement-on-a-unified-patent-court.pdf

⁶ PINTO Base: <https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/>

⁷ ILPV: International Licensing Platform-Vegetables - <https://www.ilp-vegetable.org/>

⁸ ACLP: Agricultural Crops Licensing Platform - <https://aclp.eu/>

⁹ ALLEA STATEMENT ON MEASURES TO EASE THE IMPACT OF THE IP SYSTEM ON NEW GENOMIC TECHNIQUES FOR CROP DEVELOPMENT, DOI: 10.26356/IP-NGT, p. 7. <https://allea.org/portfolio-item/allea-statement-on-measures-to-ease-the-impact-of-the-ip-system-on-new-genomic-techniques-for-crop-development/>

¹⁰ Kim, Daria and Kock, Michael A. and Lamping, Matthias and Batista, Pedro Henrique D. and Hilty, Reto and Slowinski, Peter R. and Steinhart, Miriam, New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector – Position Statement of the Max Planck Institute for Innovation and

Competition: Munich, 8 January 2024, pp. 9 and 11. GRUR International, XX(XX), 2024, 1–17.
<https://doi.org/10.1093/grurint/ikae017>

¹¹In 2016, the Commission had already acknowledged that 'the double condition relating to technical progress and economic value might be cumbersome for a plant variety right holder to demonstrate ', and that, moreover, 'it is difficult to predict before the placing on the market of a new plant variety whether it will be an economic success'. It had anticipated the usefulness of further reflection on that criterion in the future. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003

¹²EPO Rule 28(2): <https://www.epo.org/fr/legal/epc/2020/r28.html>

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