AFBV
Association Française
des Biotechnologies Végétales

Intellectual Property and New Genomic Technologies: Proposals to Facilitate Identification, Access, and Use of Intellectual Property

I. Introduction

Just as forty years ago during early developments of plant genomics (molecular labeling) and genetically modified plants (GMPs), the introduction of plants resulting from New Genomic Techniques (better known as NGTs) reopens 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 exactly reflect reality.

This note mainly covers the situation in the EU and the two NGT technologies considered in the Commission's regulatory proposal of July 2023: targeted mutagenesis and cisgenesis, including intragenesis, as applied to plants and algae. Our objective is to provide an overview of the possibilities and mechanics of intellectual property protection as applied to plant breeding, to assess of the patent situation with respect to NGTs and suggest a few avenues for improvement that could facilitate their use for the benefit of all stakeholders.

II. Intellectual Property Systems

As in all fields, the development and delivery of new innovative varieties and their products adapted to the needs of farmers and the demands of consumers and processors requires an increasingly important research and development effort. To sustain this innovation activity, well-functioning IP rights must exist. Over the years IP legislation has been adapted to varietal creation. The needs of stakeholders to access plant genetic resources combined with the necessity to protect innovations 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, as presented briefly below.

A. Plant Breeders' Rights (PBR)

With regard to plant varieties, a specific IP right was introduced in 1961, at the initiative of France, with the creation of the International Union for the Protection of New Varieties of Plants (UPOV). 76 countries (including France) and two regional organizations (including the European Union) are signatories of this treaty. The last update of the UPOV Convention (1991)[1] was adopted by France in 2011[2]. At the European level, Regulation 2100/94/EC establishes a Community plant variety rights regime that makes it possible to obtain a PBR covering the entire territory of the EU[3]. A PBR allows a breeder to protect the variety he or she has developed and grants the breeder 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 the protected variety in their breeding programs to produce new varieties through the breeder's exemption.

It should be noted that the protection of a plant variety by a PBR should not be confused with registration of a plant variety in the French or European common catalogues of varieties of agricultural plant and vegetable species, in order to market the variety. In addition, there is often a need to obtain commercial seed certification for certain species. Only PBRs are discussed here.

A PBR can be assigned to any plant variety that meets all the eligibility criteria, namely: a **verified DUS** (Distinctness, Uniformity and Stability), **novelty** and a **validated name**. In Europe, a PBR can be requested at national level (in France, the National Plant Variety Authority – INOV) or regional level (for the EU, the Community Plant Variety Office – CPVO). The territory covered is either national (France) or regional (European Union).

The dossier is submitted to the corresponding office which examines the PBR application. The DUS study is carried out by a national examination office (GEVES in France, or a European counterpart) authorized by INOV or the CPVO. This study is based on one- or two-year trials at a minimum. If the criteria are validated, the PBR is granted for a period of 25 years (30 years for potato, vine and tree varieties) from the date of issue of the title. This is generally done between two and three years after submission of the application. The priority date is the date of filing of the dossier (see Figure 1). A PBR confers on its holder an exclusive property right, notably for commercial exploitation of his or her variety directly or through licenses to third parties. A PBR entails costs for the applicant including the preparation of the application file, payment of the examination fee and an annual fee to maintain the validity of the PBR.

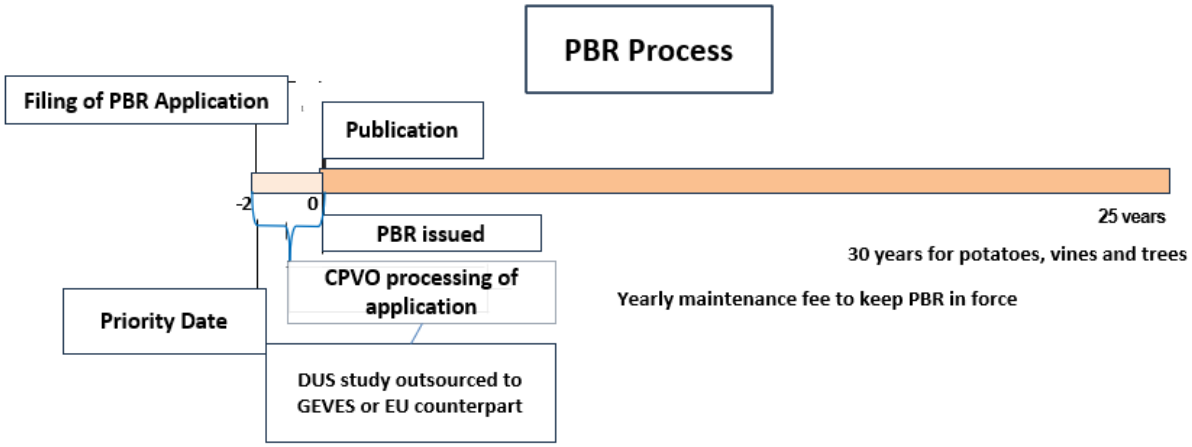

Figure 1: Key Steps in the life of a PBR

Varieties protected by a PBR can be consulted on the following databases: Bulletin Officiel de l'INOV on the GEVES website for a national PBR in France[4] and the Variety database of CPVO for a national PBR or a Community PBR for the EU[5].

Three points deserve particular attention:

- **The breeder's exemption:** in existence since UPOV was created (1961), the breeder's privilege allows third parties to freely dispose of a **protected variety** for breeding work that may lead to the creation of new varieties which can, in turn, obtain a PBR if they meet the eligibility criteria. In the event that the original variety contains a patented element, it is important to check the exact status of the patent, as certain patents are subject to the breeder's exemption (see below for details). We then have two situations:

- *The patent does not benefit from the breeder's exemption:* The protected variety containing the patented element may be used but it must be eliminated for free commercial use. If it is still present in the new variety, a license will have to be obtained from the patent holder, if the patent is still valid or if it was valid during the breeding phase. There is a compulsory licensing clause system under Directive 98/44/EC, the conditions of which are defined by a judge and for which the applicant must demonstrate the "considerable economic interest"[6] of the new variety.

- *The patent benefits from the breeder's exemption:* As will be specified in the section presenting patents, there is now a breeder's exemption for patents in some EU member states. The scope of this exemption will have to be clarified by usage. As in the previous case, it is possible to use a protected variety containing a patented element during the term of the patent to produce a new variety. This exemption allows for free marketing as soon as the patent expires. One point to be clarified is whether the steps necessary for marketing (registration of the variety, certain stages of seed production, etc.) can be carried out during the term of the patent. If the owner of the variety wishes to commercialize the new variety before the end of the patent term, he or she will need to obtain a license.

- **Farmer's privilege**: This privilege exists for PBRs and patents (see below). As a result, the farmer can reseed the product of his harvest in the following year under certain conditions: it is applicable to certain species with financial remuneration due to the breeder[3]. Provided that the conditions for using his or her crop as seedlings are respected, a farmer is not affected by a patent or a PBR.

- **The concept of essentially derived variety:** It should be noted that during the last revision of the UPOV Convention in 1991[1], the concept of essentially derived variety (EDV) was introduced in Article 14 (5). This is important for our analysis. Indeed, the Convention provides that "a variety shall be deemed to be essentially derived from another variety ("initial variety") if: **(i)** it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety, **(ii)** it is clearly distinguishable from the initial variety and **(iii)** except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety."

  This notion of derivation therefore extends the scope of a PBR beyond the protected variety. It has been clarified in an explanatory note, recently revised[7], strengthening the conditions of essential derivation with regard to targeted mutagenesis and cisgenesis techniques.

  Thus, if for example targeted mutagenesis or cisgenesis is carried out directly on a variety protected by a PBR, the progeny of the single parent is an EDV, as it differs from the initial variety only by the edition of it genome. If in a second case an NGT plant is crossed with a protected variety followed by repeated back-crossing with the protected variety, it is likely that the resulting variety will be considered essentially derived if “it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety”. Each variety considered to be EDV may be protected by a PBR if it meets PBR eligibility criteria, but its dependency will continue for the life of the PBR of the initial variety, even if it is subject to additional modifications (according to specific UPOV rules applying to EDVs). One of the consequences is that the EDV cannot be marketed without an agreement with the owner of the protected initial variety. In situations where a breeder's variety is dependent on a variety protected by another breeder, and this is the case with EDVs, Article 29(1) of Regulation 2100/94/EC[3] provides that "**compulsory exploitation rights** shall be granted to one or more persons by the Office [CPVO], on application by that person or persons, but **only on grounds of**

public interest and after consulting the Administrative Council [of the CPVO] referred to in Article 36'.

Since the breeder of the EDV does not know in advance which results are likely to satisfy this criterion, it already seems necessary for the legislator to take steps to amend or interpret the current legislation in order to clarify the circumstances giving rise to a compulsory exploitation license, which is the only real possibility for the breeder of the EDV to obtain the freedom to exploit his variety independently from the breeder of the initial protected variety.

B. Patents

The patent was introduced in 1883 with the aim of protecting the inventor and giving he or she an exclusive right to exploit the invention for 20 years in exchange for a detailed description of the invention allowing its improvement. In 1930, the U.S. Congress established the first form of IP protection for plants by adopting the Plant Patent Act (PPA): "Whoever invents or discovers and reproduces asexually any distinct and new variety of plant... can obtain a patent".[8]

The basic principles of the patent apply to NGT plants: Article 3 of Directive 98/44/EC[6] on the legal protection of biotechnological inventions, states: " inventions which are **new**, which involve an **inventive step** and which are **susceptible of industrial application** shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used".

The main steps in the most used patent pathway are as follows (see Figure 2 below):

- ***First filing:*** In most cases, the applicant makes a first filing either at the national level (in France, at the Institut National de la Propriété Industrielle - INPI) or at the regional level (for example with the European Patent Office (EPO) which has 39 members and covers 44 countries). This gives the applicant a one-year period, known as "priority", to extend the application to other countries, bearing in mind that the filing is confidential during this period. It receives a bibliographic search report and a preliminary opinion on the patentability of the invention approximately six months after filing. If interest in the patent is not confirmed, it may be withdrawn at any time during that priority year and will not be published.
- ***PCT filing:*** The first filing must be confirmed by a new filing, if a geographical extension is desired, possibly with an amended text (e.g. a reformulation of the claims or new ones; new examples, etc.). This new filing can be made under the PCT system, linked to the Patent Cooperation Treaty, which covers more than 150 countries around the world. It must take place no later than 12 months after the date of the first filing to benefit from the right of priority. One can also make a PCT filing directly. The priority date of the invention is the date of the first filing or the PCT filing if it is done directly.
- ***Publication of the patent:*** The patent application is published 18 months after the date of its filing, i.e., in practice, six months after a PCT filing following a first filing or 18 months after a PCT filing if it was made directly. It then becomes public.
- ***Examination and grant:*** If the EPO has been chosen, the EPO informs the applicant that the patent examination has begun, usually within one year of the publication of the patent. Examination may lead to the grant or refusal of the patent application depending on whether the EPO considers that the application meets the requirements for patentability. The grant of the patent, if any, takes place on average 4-5 years **after the PCT filing**. This duration may be longer in some countries. The patent is valid for 20 years from the filing date in the country concerned, which corresponds

to the PCT filing date if the country is part of the PCT. The reference text that will be used in the event of a conflict is the one published at the time of the grant of the patent. This text may be different from the filed text and may differ from one country to another, in particular at the level of claims. At the same time, and if applicable, the applicant must follow the evolution of its patent in the other countries in which it has filed its application.

- ***Extensions at national level:*** When the patent is granted by the EPO, the applicant must decide in which of the countries participating in the EPO it wishes to validate the patent and pay the corresponding fees. Since 1 June 2023, a new possibility has been offered, that of an extension under the cover of the EU Unitary Patent[9], managed by the EPO. This makes it possible to have coverage in the 17 countries having ratified the Agreement on a Unified Patent Court (UPCA) with a single validation by the EPO. A Unified Patent Court was also set up on this occasion[10]. An important feature of the treaty establishing the unified court is the creation of the breeder's exemption under patent law. As far as the farmer's privilege is concerned, it is in force in the EU through Article 11 of Directive 98/44/EC[6]. It allows the European farmer to re-sow seedlings from his or her harvest, on his or her own farm, in the following year under certain conditions (applicable to certain species with payment of a fee, except for small farmers).

In summary, the most common pattern in the EU is as follows: The applicant makes a first filing at EPO level. If it wishes to extend the application to other countries/regions, it can make a PCT filing, which must take place no later than 12 months after the first filing. The patent is published 6 months later. It is then communicated to PCT member countries. The applicant chooses in which countries it wishes to continue the examination of its application by making a request for examination and paying the corresponding fees. This request can be made at the level of the EPO, thus covering all EPO member countries. The period from examination to issuance varies from country to country; it is 4-5 years in the case of the EPO from the date of PCT filing. The patent is then granted and the corresponding text published, with content that may be different from the filed text which is binding in the event of a conflict. The patent is valid for a period of 20 years from the PCT filing date (see Figure 2). The holder then chooses from among the EPO member countries those in which it maintains its patent. It can also choose the Unitary Patent (17 member countries) plus other countries according to its protection needs.

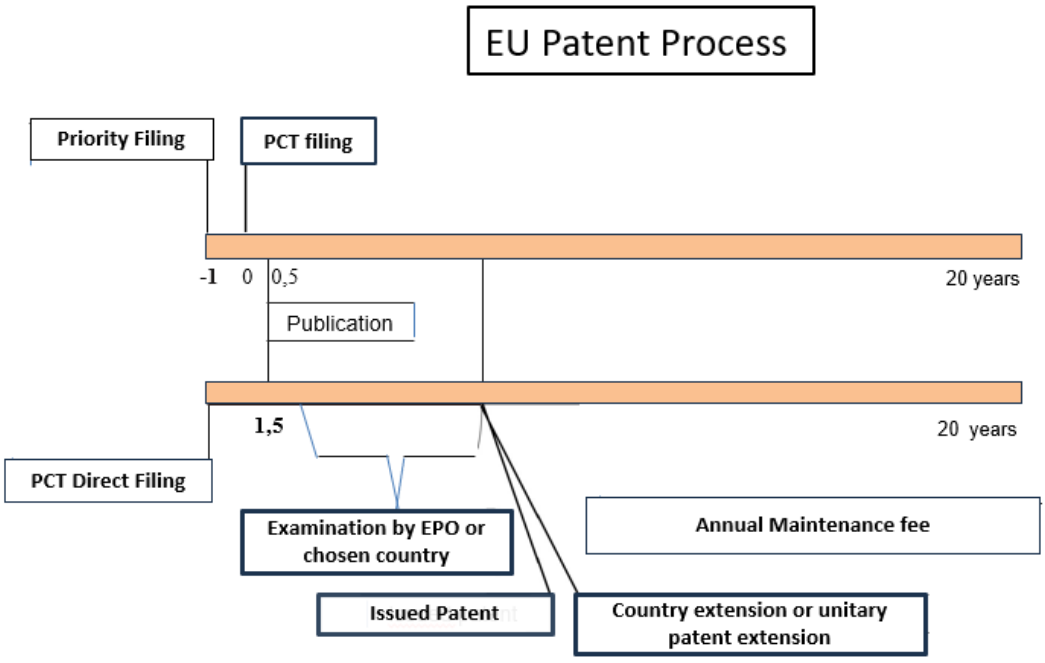

Figure 2: Key Steps in the life of a Patent

This route is the simplest to cover many countries with decisions taken as the patent progresses, which limits procedures and costs. One can also restrict oneself to filing in a single country, France for example. For non-PCT countries, the filing must be made in any selected non-PCT country at the same time as the PCT filing.

As in the case of a PBR, a patent is not for free. In addition to internal costs and fees to be paid to the law firm in charge of the file, the applicant must pay the fees charged by patent offices such as filing, extension, examination fees, renewal fees to keep the patent alive, etc. These do not include the costs of defending the patent either to ensure that it is not used by third parties or to defend it against third party oppositions or challenges.

Some important considerations to keep in mind:

- The patent gives the patent holder the right to **have third parties prohibited from exploiting its invention by court order or to authorize third parties to use the invention through licenses during a period of 20 years.** After this period, inventions can be freely used by third parties, leading, for example, to what are called "generics" in the pharmaceutical field. Taking into account the time between the PCT filing and the grant of the patent and the time related to the development of the product (in our case a plant variety), the period of protection during the commercial phase generally does not exceed 10 to 15 years.
- **A patent filed and published is not a granted patent**. Many events can occur between filing and grant such as withdrawal by the applicant, rejection by the patent office, a sharp reduction in the scope of the patent claims at the time of grant compared to the application filed. Indeed, the scope of protection is limited to what has been issued. Granted claims may be different from the claims applied for by the applicant as seen in the published application. In addition, the patent holder may decide to maintain the patent only in a limited number of countries, where the product corresponds to a market or licensing opportunities.
- **Not all filed patents are granted** for various reasons related to patentability requirements or the termination of the proceedings by the applicant. In the field of biotechnology, the EPO estimates a grant rate of around 30%.
- As with any patent, **the description must be sufficient** to allow a third party to reproduce the invention. Insufficiency of the description may result in the invalidity of the patent. In the biological field, and in regard to plants in particular, if the invention cannot be sufficiently described in words, it is possible to deposit, with a recognized depositary institution, a sample of the biological material (seeds, for example, for certain types of invention).
- **Patents can protect different aspects of a finished product** provided they meet the criteria for patentability. They may cover, for example, the techniques used, the genes that have been modified, the plants containing these genes, the products of these genes and the traits they impart, their use, or the analytical tools to identify their presence in a plant.
- Importantly, in Europe **plant varieties are not patentable --** they are only protectable by a PBR (see above). However, if a variety cannot be patented, it may contain an element or elements that can be protected by one or more patent(s). It is a misnomer in Europe to state that a variety is patented – better to state that the PBR-protected variety contains patented elements (e.g., traits). Hence the importance of the breeder's exemption for patents in the context of the UPCA[10]. Additional information regarding the breeder's exemption under patent law is provided above (pp.2-3).
- Since 1 July 2017, **plants resulting from biological processes of crossing and selection are not patentable** (EPO Rule 28(2)[11]. Patents filed before that date may still be pending and even be granted by the EPO (there are about 300 applications left), but they are scheduled to disappear

over time. Genes and plants obtained through technical processes, such as induced random mutagenesis or targeted mutagenesis, are patentable if they meet the criteria for patentability. At the same time, a disclaimer clause was introduced through an EPO guideline[12]. The disclaimer clause provides that if a person obtains a variety carrying a gene and a trait obtained by essentially biological processes, it may be used freely, even if a patent has been granted for the same gene or trait obtained by non-essentially biological means. The disclaimer must be included by the applicant in its patent application. If this clause is missing from the application for a patent on a plant containing a particular trait derived from technical intervention (such as NGTs) the patent will not be granted.

- **A granted patent is presumed to be valid.** It may, however, be cancelled at the request of third parties if the competent authority considers that the conditions for patentability are not met, either by opposition proceedings before a patent office (European Patent Office for the EP patent), or before national courts, or before the Unified Patent Court for patents with unitary effect. Because of the patent's presumption of validity, the burden of proof to obtain a declaration of invalidity is high.
- **A patent application can result in multiple patents being granted.** It is possible, from the same initial patent application, to file several so-called divisional patent applications, which may lead to the grant of several patents, each protecting a different aspect of the same invention, each of which may be enforced against a third party who reproduces the invention. This practice, which is costly for the patentee, has the advantage of increasing the risks and costs for third parties who would seek to challenge its validity.

III. Assessment of industrial property in the field of NGTs

A. Patent Review:

It is clear from the various publications on the subject that there is significant patent coverage in the areas covered below, particularly with regard to patents directed to genome-editing technologies. As we shall see, however, such an overall assessment is not easy to carry out for at least two reasons:

- *A patent is constantly evolving:* The filed text is published 18 months after filing, in most cases after the PCT filing. It is then necessary to periodically monitor the fate of this patent: examination, grant, publication phase of the granted patent, followed by extensions in the countries or regions chosen by the applicant. Finally, the applicant may decide to withdraw its patent while it is valid in some or all of the countries where it has been filed. This constant evolution leads to the need to periodically check relevant IP during the development of an NGT plant or a new NGT variety.

- *Different aspects of a given product can be covered by a patent:* the technology(s) used; the gene(s) modified or introduced; the novel trait(s) introduced and their uses.

If global data will show the dynamics of R&D activities and protection in a given field, a relevant patent analysis can only be carried out once the main parameters of the novel NGT variety to be produced and the target markets have been defined. Thus, the situation will be different if the market objective is limited to France, Europe or the World, without forgetting to take into account not only the country of sale of the seed, but also the countries where the harvest could be exported and could be covered by a patent.

At the level of global data, the publications of PCT applications give a good indication, subject to completeness, which will depend on the keywords used for querying the databases. Based on the data

available in the Lens.org database[13] (searched April 16, 2024) there are currently, in the case of published PCT patent applications for CRISPR Cas9: 12009 (6108 simple families) applications in total, including 7389 CRISPR applications claiming plants (3812 simple families) and 3016 applications claiming plant traits (**1595** for simple families). In 2023 alone, still according to Lens.org, 566 PCT applications using CRISPR and claiming plant traits (459 simple families) were published. In contrast in 2021 Michael Kock[14] counted **138** PCT applications claiming plant traits using CRISPR published between 2013 and 2020, with 30 publications published in 2020. Other databases are available to enable this type of inquiry, such as PatSnap[15] or Espacenet [16] (the EPO's database). A query with "Gene editing and plant(s)" or "CRISPR and plant(s)" brings up about 20,000 entries containing all patents on the subject, not just PCT applications. To follow the evolution of a European patent, the European Patent Register can be used[17].

It is necessary to clearly define the product (variety) that one wishes to develop as well as the target market before doing an IP analysis.

If one wishes to develop a new plant (variety) by targeted mutagenesis or cisgenesis, the first thing to do is define in as much detail as possible the plant (variety) that one wishes to obtain with information on the necessary techniques, the gene(s) to be modified or inserted to obtain the desired trait(s), in association with the target markets (cultivation and use of the crop). Once these specifications have been defined, it will be necessary to consult the databases to determine which patents exist, at what stage of the process they are (publication, under examination, granted, extension in which countries), without forgetting to check whether they are maintained. Since patents are constantly evolving, periodic checks are necessary.

Today, for a given product, there may be one or more patents covering the technology, genes, traits and sometimes applications. The more different technologies the product uses, the more genes will be modified, the more complex the IP environment will be, and greater the risk of facing what some observers call "patent tickets", with several overlapping patents for a product, resulting in the need for multiple licenses. One should try to avoid a priori concerns – all will depend on the variety one wants to develop and the market that will be targeted.

B. PBR Review:

As far as PBRs are concerned, there are currently no PBRs issued for an NGT variety or for an essentially derived variety obtained by NGTs. Given the current regulatory situation on NGT plants in Europe, it is likely that the first protected NGT varieties could begin to be introduced from 2030[18], provided that the new regulation proposed by the Commission enters into force quickly.

It should be noted that there are PBR-protected transgenic varieties. In terms of conventionally bred varieties, it is estimated that around 400 to 500 new varieties are protected in Europe every year. As of December 31, 2023, 30,939 varieties were protected by a PBR compared to 30,567 at the end of 2022[19]. The presence of new NGT varieties on EU markets will depend on the new regulations that will be put in place, the use of NGT tools by EU breeders and the public acceptance of these new varieties.

IV. Impact of IP on the Development of NGT Plants and Varieties

Complex IP situations, including patent thickets, are not new in the field of plant breeding. They already exist in the context of conventional breeding or transgenesis, although in the latter case the impact is limited for the EU given the absence of GMPs in Europe. International seed companies that develop and market GMPs are confronted with complex IP situations depending on the species they work with and the markets they cover. With the development of targeted mutagenesis and cisgenesis that could

become possible in Europe, complex IP situations will take on a new dimension, reviving debates on the patentability of biotechnological inventions.

As the draft Regulation proposed by the Commission in July 2023 cannot be adopted before June 2024[20], if a finally approved regulation were to enter into force in the years 2027-2028, the first NGT-1 varieties could be marketed in Europe in the early 2030's[18]. It can be assumed that some NGT plants are already being created at the laboratory level and that their IP environment has been evaluated by their developers. However, if the Commission's proposed regulation is adopted as it currently stands (subject to clarifications requested by several organizations), the EU will witness the development of NGT-1[21] varieties on species and traits covering smaller markets than in the case of GMOs. It is also likely that many seed companies will embark on such developments and be confronted with the analysis of the IP environment, which may be new and difficult to manage for some of them.

Faced with this complexity and the arrival of new players, is it possible to envisage adaptations of the regulations in force to facilitate the necessary assessments of freedom to operate before embarking on an NGT project and to facilitate the management of the patent thickets that affect this field?

In our analysis, we examined the impact of IP in four areas: (A) the creation of an NGT plant; (B) the creation of an NGT variety, (C) the use of a protected variety (whether or not NGT-derived) in a breeding program, and (D) the breeding of a non-NGT variety. Adaptations seem possible in each area to facilitate the identification, access and use of relevant IP. Our proposals are of two types:

i. voluntary initiatives e.g. from the breeders themselves or from the EPO in a customer-oriented approach, and
ii. actions by the European Commission, in particular to clarify or, if necessary, amend existing legislation.

Voluntary initiatives may also be discussed between the European Commission and relevant stakeholders (including the EPO) in the context of the Commission's planned study.

A. The creation of NGT-derived plants

When launching an NGT project, freedom to operate must be analyzed at two levels: at the level of the plant material used for the project and at the level of IP covering the different stages of the project -- from the production of the plant/variety to its use and that of derived products. One should inquire, for example, whether the technique used for producing targeted mutagenesis is protected, whether the gene that will be modified is patented and whether the novel trait may have already been patented.

1. Freedom of use of plant material:

Plant material to be modified needs to be free of any obligations, which is most often the case. However, it must be verified whether it contains patented elements and whether it originates from a PBR-protected variety by consulting relevant databases[4,5]. If the answer to the inquiry is positive, one can change the plant material to be modified or negotiate an agreement with the patent or PBR holder at the beginning of the work. If it is a protected variety, see section c) below (use of a protected variety containing patented elements in a breeding program).
It is also necessary to ensure that the plant material is not covered by the Nagoya Protocol,[22] which may be the case for plant species that are not native to Europe. In such case it may be necessary to contact the responsible organization under the Protocol.

2. Freedom to operate for the development of NGT plants:

As mentioned above, the first step is to define the project that one wishes to pursue with the maximum level of detail and define target markets for the NGT varieties and their derived products. Once this has been achieved, it will be necessary to launch a patent search for all steps involved in the creation of the NGT plant in relevant databases using keywords. This could prove to be challenging for companies unfamiliar with this process. They will need to do their research either in-house if the necessary skills are available or with the help of a law firm that is an expert in the field. It is necessary to look for the IP that may exist covering the techniques that will be used and the IP covering the gene(s) that will be modified and the results of the modification. In addition, given the constant evolution of a patent, periodic checks will be necessary.

Two key aspects to consider: (1) identify any patents which may relate to the development and use of a variety proposed for development and, (2) if patents are identified, define and negotiate terms of access.

a. Patent identification, analysis and follow-up:

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 is a difficult step that involves querying several databases with input keys according to the theme and/or keywords. Once patents have been identified, they must be checked to determine claim coverage and patent status. Their status will need to be checked periodically. A periodic check of the databases will need to be carried out to see if there are any new patents filed.
Identification of relevant patents is difficult 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 in EPO or PCT databases (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 1: Create specific NGT codes applied to plants in the classification of the EPO (European Patent Office) and/or PCT (Patent Cooperation Treaty) databases.

b. Improvement of patent procedures:

A filed patent application is examined by the patent office where it was filed (EPO and/or patent office of the relevant country). This examination raises many questions and comments. Two points caught our attention:

- ✓ **Reducing the delay between the publication of a patent, its examination and its grant or refusal:** We have seen that there is a significant delay between the filing of a patent and its grant or rejection. If the EPO has an examination period of 4 to 5 years from the date of the PCT filing. There may be longer delays in some cases or countries. Thus, the EPO recognizes that there are still patent applications filed before 1 January 2017 under examination. This delay leads to a period of uncertainty: whether the patent will be granted or refused and what will be its scope (claims granted). The uncertainty is compounded by the fact that with respect to biotechnology inventions, only 30% of patents filed with the EPO 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 field.

Proposal 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.

- ✓ **Examination procedure and scope of patentability:** As stated above, the grant of a patent covering a plant is based on the manner in which it was obtained (whether or not exclusively by essentially biological processes). There may be discrepancies in the interpretation of the criteria. The history of past patents makes it possible to better identify the possibilities for granting a patent. 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 for a specific 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?[23]

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.

c. Using NGT Technologies to Create a Modified Plant

- ✓ **Access to patent licenses for genome-editing technologies enabling targeted mutagenesis or targeted cisgenesis in a particular species:** It is very likely that database analysis will lead to the identification of more than one patent for the production of an NGT plant of a chosen species. In the case of a large number of patents, this is referred to as a "patent ticket". Once the patents have been identified, the developer must obtain the necessary commercial exploitation licenses) for the NGT project. To do this, the developer will have to enter into negotiations with the patent owners, a challenging prospect for SMEs.

  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, ILPV[24] and ACLP[25], 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 licences, genome editing technologies on reasonable terms.

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.

B. The production of NGT varieties

There are several possible approaches to producing NGT varieties. Examples include:

- Performing targeted mutagenesis or cisgenesis directly on an existing variety, if it is suitable for the technology. If such variety is not protected or if its PBR has expired, it can be used freely. The resulting modifed variety may be protected if it meets PBR eligibility criteria. If the variety to be modified is protected by a PBR it benefits from the breeder's exemption and targeted mutagenesis or cisgenesis can be carried out. However, as presented above, it will be considered in the majority of cases an essentially derived variety (EDV) and can only be marketed after an agreement with the PBR holder of the initial variety from which it is dependent. This agreement can be negotiated during or after the variety modification process. Direct modification of a variety, where possible, is of particular interest for long-cycle varieties, vegetatively propagated species, and traits requiring simultaneous modification of multiple alleles[26].
- The production of an NGT variety can also be achieved using an NGT plant. The latter is introduced into a conventional breeding program or used for transfer by back-crossing into existing varieties. This NGT plant may have been obtained by a seed company doing the breeding or back-crossing work. This NGT plant could have been produced by academic laboratories, genome-editing companies or seed companies wanting to expand the market for the NGT plants they produced. Potential licensees will need to verify that the licensor of the NGT plant has freedom to operate for the NGT plant proposed for licensing.

In both examples knowledge of the IP status of the plant material being used is essential, and some of the proposals presented in this note may facilitate obtaining this knowledge and use.

C. The use of a protected variety (whether NGT-derived or not) containing patented elements in a breeding program

1. Information on the patented elements present in a protected variety:

As seen previously, the use of PBR-protected varieties (whether or not NGT-derived) in a breeding program is possible, thanks to the breeder's exemption and breeders are used to availing themselves of this opportunity. With the development of patents on modified plant traits and genes, the situation becomes more complicated and it is necessary to ensure that a PBR-protected variety does not contain patented elements, which is currently not easy and could become more complicated with the development of NGT varieties which could contain additional patented elements.

To facilitate access to information related to patented elements in commercial varieties, seed companies have set up within the Euroseeds association a PINTO (Patent Database and Transparency On-line)[27] database which lists protected varieties with information on the patented elements they contain. This data base is, however, incomplete because it is limited to Euroseeds members and its updating in uncertain because it relies on the voluntary work of its members.

The Max Planck Institute recently suggested:[29]

> " EU law should provide for a duty to disclose complete and accurate information about all patent applications and patents that are relevant to a commercially available plant variety. The existing principles of forfeiture could inform such duty and the legal consequences for non-compliance. In particular, the duty could be linked to the enforceability of the patent, whereby the patent holder’s failure to disclose such information could lead to the loss of their rights to enforce the patent or seek damages for infringement. The duty of disclosure should be fulfilled

by declaring the patent status in a publicly accessible patent registry or clearinghouse. It could also be part of the EU catalogues of varieties of agricultural plant and vegetable species, which list all varieties authorised for marketing in the EU. Only patents which protect the respective variety as such and could have an impact on subsequent breeders should be declared."

For species not required to be listed in the Official Catalogues, we propose that the obligation be made at the level of the CPVO database[5]. This obligation should be applied to all varieties containing one or more patented elements, not only NGT varieties. To improve transparency, all patents attached to a variety (techniques, traits, genes, plants) owned or licensed by the variety owner should be listed. One possibility to achieve this result could be an addendum to the proposed Plant Reproductive Material (PRM) Regulation published on 5 July 2023[30], referring to the relevant articles of Regulation 2100/94/EC[3] and Council Directive 2002/53/EC of 13 June 2002[31].

Proposal 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[28], for species covered by this regulation, and/or in the CPVO database[5].

2. The use of a protected variety containing patented elements:

Knowledge of the IP status of the protected variety will allow the company wishing to use it to define the strategy it wishes to adopt at an early stage. There are at least three options available to the company when the new variety is marketed:

- If the patented elements have been eliminated during the breeding program, the new variety obtained can be marketed according to existing legislation.

- If the patented elements do not benefit from the breeder's exemption and have been retained in the new variety produced, the breeder must obtain a license from the patent(s) holder prior to marketing. It is recommended to start negotiations during the production phase of the variety. See options below for accessing licenses.

- In the event that the patented element benefits from the breeder's exemption (location in one of the 17 member countries of the UPCA[10]), it is possible to breed a new variety during the term of the patent and to keep the patented elements in the new variety. There are two possible situations to be addressed prior to marketing:

  - The patent(s) covering the patented elements is (are) still valid: the developer may launch pre-commercialization steps **(subject to needed clarifications, see below)** but will have to wait for the end of validity of the patent(s) before commercialization.

  - The patent(s) covering the patented elements are no longer valid (the patent has expired, been invalidated, or abandoned): the developer can start commercialization steps.

    The breeder's exemption for patents has been in force in France, Germany and the Netherlands for many years and has been extended to the 17 EU Member States that have ratified the UPCA, which entered into force on 1 June 2023[10]. This exemption could apply to all Member States, either by ratifying the UPCA or by incorporating this exemption into their national patent laws.

Proposal 6: Ask EU Member States to ratify the UPCA[10] or to include the breeder's exemption in their national patent legislation.

- *Clarifying the exact scope of the breeder's exemption from research to commercialization:* 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 creating or discovering and developing other plant varieties" (Art. 27(c) of the UPCA[10]). If a breeder uses a variety containing a patented trait under the breeder's exemption to create a new variety, and his or her new variety still contains that patented trait, it may not be commercialized before the expiry of the patents concerned, unless agreement is reached with the patent holder. To take full advantage of the breeder's exemption, it should be clarified that the term "biological material" includes the NGT tools used to create the NGT plant and the variety derived from such plant, and that regulatory and legal procedures for the protection and registration of varieties can be carried out under this exemption while the patents are still in force, as well as pre-market seed production.

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

3. Access to licenses:

Once all the patented elements (and corresponding patents) present in the variety have been identified, the developer must obtain the commercial exploitation licenses when necessary, before launch. These patents may relate either to the techniques used in the production of the NGT plant or to the NGT trait (gene, trait, plant). As far as genome-editing technology patents are concerned, it is possible that the company that developed the NGT plant has a right to sub-license such patents, in which case negotiations can be completed with the developer. Otherwise, it will be necessary to contact the genome-editing technology IP holders (see paragraph c above – "Using NGT Technologies to Create a Modified Plant"). With regard to the trait, if it is protected by a patent, negotiations with the patent holder should be initiated as soon as possible in order to ensure that the license is available when the product is launched.

- **Access to a license through existing platforms:** In order to facilitate information on patented elements present in a protected variety and access to licenses, two platforms have been set up by companies in the sector:

- *For vegetable crops:* The International Licensing Platform-Vegetables (ILPV)[24], set up in 2014, currently has 17 members. Members provide information on the patents they hold in the field. The geographical scope is the world. Licence terms and conditions are provided on their website.

- *For field crops:* The Agricultural Crop Licensing Platform (ACLP)[25], set up in 2023 by nine founding members. The terms and conditions are similar to those of the ILPV. It covers Europe only and includes NGT traits.

  These platforms operate according to the following principles: They are open to all interested parties, whether they are patent holders or not. Patent holders waive the exclusivity provided by their title and undertake to grant a non-exclusive commercial license to any member of the platform who has developed a variety containing a patented element who requests it. The

proposed license is the simplest possible standard patent license, the text of which is available online. In addition, they also undertake to provide a breeder's exemption to any member who requests it, especially in EU states that do not have one in their national law. The only element left to be negotiated is the royalty rate in return for the license. However, in order to avoid any unreasonable royalty rate, in either direction, a mechanism called "baseball arbitration" is put in place in the event of difficulty for the parties to reach an agreement. This mechanism, inspired by salary negotiations in baseball, requires the parties to each make a reasoned proposal of the royalty rate they consider fair to three independent arbitrators selected by the parties. The arbitrators then choose, not an intermediate proposition, but the one of the two propositions closest to the market value of the patented trait. A proposal that is too far from market value will then be rejected, and the other proposal will be binding on both parties. Due to its potentially risky effect, this mechanism has never been used in the ILPV platform, which has been in existence for ten years.

Warning: these licensing platforms are not exhaustive and an off-platform patent analysis is essential to ensure that the freedom to operate analysis is complete.

Proposal 8: Encourage all companies developing NGT plants to become members of existing licensing platforms. Encourage the creation of licensing platforms for plant species not covered by existing (trees, fruit trees, ornamentals, "orphan" species).

- **Compulsory licenses in case of dependency:**

  Currently, a compulsory license is included in Directive 98/44/EC[6]. 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 clause 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 fee[32]. 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.[3]

  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 9: **Remove 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.**

D. Breeding a non-NGT variety

A breeder carries out a continuous production of new varieties using the genetic background at his disposal. The breeder may be faced with a difficult situation if he or she is working on a trait found in this background that could be dependent on a patent on the same trait obtained using NGTs. We have seen above that a disclaimer clause has been introduced through an EPO guideline[11]. 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.

Proposal 10: **Supplement the current disclaimer clause introduced by the EPO in the context of the application of EPO Rule 28(2) with an additional disclaimer covering claims to native traits or to genes corresponding to such native traits.**

V. Impact of IP on the use of NGT varieties by farmers

As noted above, the farmer's privilege allows the farmer to use part of his or her crop for next year's planting under certain conditions. However, the farmer's privilege is limited in Europe to 21 species (eight species of fodder plants, nine species of cereals, potatoes and three species of oilseed and fiber plants[3]). It does not extend to hybrid and synthetic varieties. As vegetable species are currently excluded from the privilege, the Commission could investigate the current relevance of this exclusion, given that in 2018 around 40% of the vegetable varieties in the Catalogue were open-pollinated[33]. To extend the privilege at the European level, it may be necessary to amend Article 14 of Regulation 2100/94/EC[3] and to use the current draft PRM Regulation to effectuate such amendment[30].
In addition, 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.
With regard to the collection of remuneration due on a variety, the Max Planck Institute has made the following recommendation[34]:

> " The Commission should clarify that there is only one compensation for FSS [farm-saved seed], irrespective of the number of plant breeders' rights and patents that cover a variety. This compensation should be paid only once to the owner of the respective variety (usually the holder of the PBR) and then allocated to the different rights owners. The holder of the PBR should be entitled to the collection but is also responsible for the distribution of royalties among different IP holders. Patent holders should only have subsidiary rights, including to collect royalties, in situations where the PBR owner might fail to do so."

Proposal 11: Investigate the scope of the farmer's privilege, consider its extension to new species such as vegetable crops, and clarify that the farmer must only remunerate the holder of the cultivated variety, and that it is the holder who redistributes this remuneration if the variety is covered by one or several patents.

Conclusion

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 NGT IP. We remain at the disposal of the Commission and any other stakeholders for any further information.

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