

Position

Brussels, 4 June 2024

Euroseeds View on Intellectual Property

1. Introduction

Reconciling agricultural productivity with sustainability relies strongly on the development of stable, high-yielding crops of superior nutritional value that can be grown more resource efficiently. Therefore, innovation in plant breeding has gained unprecedented importance. But it is a time-consuming and costly endeavour. Plant breeders are investing up to 20 % of their annual turnover into research and the development of new varieties, which is considerably higher than in most other industries.

The European plant breeding and seed sector is firmly of the view that an effective protection and practical enforcement possibilities of intellectual property (IP) rights are a precondition for the continuous innovation in plant breeding, particularly because the results of plant breeding are biological material, which is easy to copy being generally self-reproducing. Therefore, plant breeders require an intellectual property protection system which effectively generates a fair return on its exceptionally high level of research and development investments.

At the same time, access to all forms of plant material, specifically including all commercially available plant varieties, for the breeding of new varieties is indispensable for a successful plant breeding sector based on as much genetic diversity as possible.

Given the specific nature of the sector, the breeding innovations used, and the products derived therefrom, it must be acknowledged that no single IP system is capable of covering all the relevant innovations and needs [from breeding technologies over trait development to final plant varieties].



For decades, European plant breeders have mainly relied on the specific *sui generis* IP system of plant breeders' rights (PBR) based on the UPOV Convention which provides effective IP protection for new plant varieties. Euroseeds confirms its view that the 1991 Act of the UPOV Convention is the most suitable existing *sui generis* IP system for the protection of plant varieties as such.

Within the UPOV PBR system, the breeder's exemption is a key cornerstone. This compulsory exemption provides an "open source system" that assures that all varieties protected by PBR can be used freely for further research and breeding and that resulting new varieties can be commercialized without any obligations towards the PBR holder.

Next to the PBR system, specific other forms of IP protection related to plants exist, such as e.g. patents for biotechnological inventions. In the EU, this form of IP is provided for by the European Patent Convention (to which all EU Member States are Contracting States) and EU Directive 98/44. The system does not provide for a similar breeders exemption but requires a formal consent by the patent holder for the marketing of new varieties that contain the patented element.

Over the past two decades, the interaction between these two IP systems has continuously evolved. Addressing this interaction, a number of legislative measures as well as private management tools have been introduced such as e.g.

- (i) specific decisions adapting the legal framework such as the adoption of Rule 28(2)¹ by the European Patent Office or the introduction of the limited breeder's exemption in some national patent laws and through Article 27(c) of the Unified Patent Court Agreement;
- (ii) <u>PINTO</u>, an industry-led database for creating transparency with regard to patented traits in marketed plant varieties;
- (iii) and company-led initiatives such as the <u>International Licensing Platform</u>

 <u>Vegetable</u> and the <u>Agricultural Crop Licensing Platform</u>, aimed at making patented traits broadly accessible.

All these elements have in common that they address challenges resulting from the parallel existence of the two, independent yet overlapping IP systems related to plants. They have been designed with the intention to facilitate the management of this situation

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¹ https://eurosee<u>ds.eu/news/euroseeds-welcomes-limitation-of-patentability-by-european-patent-office/</u>



and contribute to a better balancing of broad access to and use of genetic variability on the one hand and return on investment on the other. This also included the objective to maintain fair competition and freedom of choice for both breeders and farmers and the wish to speed up the deployment of scientific and technical progress across the sector and entire agri-food chain.

2. New discussions due to an increasing diversity of innovative breeding methods and business models

The most recent scientific progress in plant breeding methods such as gene editing is leading to the development of more and more diverse business models within the plant breeding sector. Additionally, and despite the concrete measures described above, there is continuous criticism of the filing and granting practice for plant-related patents. Together, and given the current legislative framework, it can be expected that the number of plant-related patents and thus the overlap of the existing two IP systems will rather increase. This has re-triggered the discussion if (and how) a functional balance between the two IP protection systems is achievable, or whether reinforced or new regulatory or legislative measures are required. Fundamentally, this discussion comes down to the principal question whether the plant breeding sector could work solely with a PBR system when it comes to the IP protection for plant material.

Euroseeds acknowledges this discussion which is also very much present within the EU plant breeding and seed production sector itself.

Some breeding companies are specifically concerned about a restriction of the breeders' exemption as granted by the UPOV system due to an increased patent protection of germplasm. This could lead to higher transaction costs to achieve freedom to operate (patent searches, freedom to operate analysis and license negotiations) and legal uncertainty due to a lack of transparency about patent protected germplasm. The freedom to operate in plant breeding might also be restricted by patent holders who either deny a license to patent protected germplasm or may impose conditions that are perceived unfair. Specifically small and medium sized breeders with a clear focus on variety development as their main business model consider all this to negatively impact their innovative capacity and future competitiveness.

Other operators in the sector (many start-up companies but also larger players) either solely or partly focus on technology and/or trait development. These companies are of



the opinion that the possibility to protect their innovations by patents is the only available option and essential to assure return on investment for their business models. Such operators are sometimes not directly involved in further variety development but provide either services for breeding companies by applying their technologies to breeders' germplasm or out-license their patent-protected traits.

Due to these different business models, respective needs, and preferences for the one or other IP system (or a combination thereof), there is no consensus within the breeding sector whether, or to what extent, the patentability of plant material resulting from biotechnological inventions must be maintained, or if patentability of plants should either be abolished or a full breeders' exemption also for patented material should be introduced.

Euroseeds represents companies and national or regional professional seed associations which contribute by their research, production and/or marketing to the seed sector. Consequently, its membership encompasses a broad range of companies, diverse in size and focus, and with partly similar and partly highly differentiated business models. This broad diversity reflects on companies' preferences for either the one or other plant-related IP protection system or for different levels of use of both.

While these preferences are logical and very present in the principal debate about the sufficiency of the PBR system as single form of IP related to plant material, or the necessity of a combination of both, the PBR and the patent system, the European plant breeding sector is united in a set of concrete objectives and demands in relation to IP protection and management.

These demands do not aim at or claim to resolving the principal concerns or difference of preferences of all companies; some consider them, individually and/or jointly, as fully sufficient to successfully improve and manage the situation while others see them as temporary measures that mitigate principal challenges as long as patents exist.

But Euroseeds stresses that all the concrete elements individually and jointly are useful measures to improve the protection of IP for the plant breeding sector and to manage the situation of the parallel existence and partial overlap of the two IP systems of PBR and patents for plant innovations.



3. Euroseeds demands to improve IP protection and support the management of the different IP systems related to plants

Euroseeds points out that it is essential to promote efficient protection of plant related innovations, without obstructing access to progress. One of the prerequisites for maintaining this dynamic is the continuous adaptation and improvement of management of rights and obligations as provided by the currently existing systems of intellectual property rights, adapted to each type of innovation: Plant Breeders' Rights (PBR) to protect a plant variety, and patents to protect technologies and traits obtained through biotechnological processes.

To improve and support this management of the overlapping IP systems and to promote plant breeding innovation while acknowledging diverse and competitive business models and consequent preferences for specific IP systems, Euroseeds underscores the importance of its following requests:

The PBR system must be strengthened and improved

Euroseeds considers the 1991 Act of the UPOV Convention to be the most suitable existing *sui generis* IP system for the protection of plant varieties as such. Euroseeds nevertheless sees room for the improvement of the enforceability of the farm saved seed (FSS) exemption. This exemption allows farmers to use, on their own holding, the product of their harvest while obliging those farmers to inform the PBR holder comprehensively about the use of the exemption and to pay an equitable remuneration for the use of the protected variety. Today, plant breeders all over Europe increasingly face severe difficulties in enforcing their rights on the use of farm saved seed by farmers (see Euroseeds Position on Farm Saved Seeds).

Euroseeds also considers the enforceability of the PBR system to require improvement (see Euroseeds view of the Enforcement of Plant Breeders Rights).

Strengthening of the initial breeder

Specifically in the light of modern breeding techniques, it becomes much more likely that a new variety bred from an existing ("initial") variety may still conform to this initial variety in its essential characteristics. Euroseeds supports the concept of Essentially Derived



Varieties (EDV) as an important tool for ensuring an effective protection of the plant variety right of the initial breeder. The strengthening of the edv concept becomes specifically relevant with the evolvement of new breeding innovations that allow new forms of mono-parental derivation².

Extending the implementation of the limited breeder's exemption

Access to the genetic composition, including to patented traits, of a plant variety for breeding purposes is guaranteed by the so-called limited breeder's exemption in the national patent law of some EU Member States (like France, Germany and the Netherlands) and by the Unitary Patent Court Agreement (UPCA). This requires further legal implementation in each Member State of the European Union and those of the European Patent Convention – EPC (39 countries).

Euroseeds calls upon all countries where such limited breeders' exemption is not yet enshrined in national patent law to proceed with the necessary legislative initiatives as soon as possible.

Furthermore, Euroseeds advocates that this limited breeders' exemption shall also extend to the use of molecular and sequence-based markers covered by patent protection.

Confirming and extending the restriction to patentability

For a long time, European patent laws have excluded essentially biological breeding methods from the scope of patentability. Euroseeds has always supported the patent exclusion of products and traits resulting from spontaneous natural variability. This exclusion has now been enshrined in European law, excluding the results of conventional methods of crossing and selection from patentability.

Patents need to provide a technical teaching that can be repeated by a person skilled in the art achieving the same results with a high degree of probability. Euroseeds therefore considers the extension of exclusion from patentability to all breeding methods yielding non-repeatable results (such as random mutagenesis based on chemicals or irradiation and protoplast fusion) as well as the resulting products as a logical consequence. Such

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² https://www.upov.int/edocs/mdocs/upov/en/wg edv 2/wg edv 2 2.pdf



clarifying and limiting extension must be implemented in relevant EU legislation and the EPC as soon as possible.

Limiting and clarifying the scope of patents

Obtaining a patent is subject to fulfilment of the principle patent criteria of novelty and inventiveness. Since New Genomic Techniques (NGTs) and other technical breeding methods can create mutations that might also occur spontaneously or result from random mutation breeding, it is important that the effect of a product patent on biological material must not extend to any biological material which has the same properties but has occurred naturally or results from undirected and thus not repeatable processes like random mutagenesis and protoplast fusion.

Euroseeds considers the inclusion of respective disclaimers to be an essential provision for limiting and clarifying the scope of a patent, thereby facilitating breeders' access to work with plant genetic resources.

Raising the bar

Euroseeds underlines the need to apply strict quality/novelty criteria in the assessment of plant-related patent claims. To support this, Euroseeds commits to continue to engage in regular exchanges with patent examiners at national and European Patent Office level.

Supporting transparent information on patented traits

Patent protection covering plant varieties must be completely transparent to ensure that seed companies and farmers are properly informed about the presence of a patented trait in marketed varieties. Euroseeds already today supports such widespread distribution of information by means of its private database PINTO.

To assure completeness of information, Euroseeds advocates for mandatory transparency through public databases like the European Common Catalogue of Varieties³ which should be extended to include up to date information about the patent status of any variety.

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³https://food.ec.europa.eu/plants/plant-reproductive-material/plant-variety-catalogues-databases-information-systems en



Facilitating access by mandatory licensing on fair, reasonable and nondiscriminatory (FRAND) terms

Patents must be tools that encourage and protect investment in research, while at the same time fostering dissemination of innovation. Licensing platforms are useful tools to support a facilitated and standardized management of access where patents exist. They do not constitute and therefore should not be advocated as stand-alone solution(s) to achieve a balanced overall IP system.

Euroseeds therefore advocates for the introduction of a mandatory licensing obligation to provide access for all relevant stakeholders on FRAND conditions. Euroseeds also advocates to develop special, most-favourable terms for small companies as to the EU definition⁴.

As the voice of Europe's entire plant breeding and seed sector, Euroseeds remains committed to contribute to and to advocate for a system of intellectual property rights that takes the needs of all its members involved in the development of innovative technologies and products into account.

Any such system needs to successfully balance deserved, effective protection, and fair, broad access, to the benefit of Europe's agri-food sector and society at large.



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#EmbracingNature









⁴ https://single-market-economy.ec.europa.eu/smes/sme-definition_en

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