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Supporting innovation in the EU bioeconomy through intellectual property protection

Challenges and opportunities for agricultural biotechnology
Final Report

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Abbreviations

Abbreviation	Full title
AI	Artificial Intelligence
CJEU	Court of Justice of the European Union
CMO	Collective Management Organisation
CPVO	Community Plant Variety Office
CRISPR Cas	Clustered Regularly Interspaced Short Palindromic Repeats – CRISPR-associated protein
CVC	University of California and the University of Vienna
DG GROW	Directorate General for Internal Market, Industry, Entrepreneurship and SMEs
DUS	Distinctness, Uniformity, and Stability (test for plant variety protection)
EC	European Commission
EDV	Essentially Derived Variety
EP	European Parliament
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
EUIPO	European Union Intellectual Property Office
FRAND	Fair, Reasonable and Non-Discriminatory terms
FSS	Farm-Saved-Seed
FTO	Freedom-to-operate
GDPR	General Data Protection Regulation
GMO	Genetically Modified Organism
IP	Intellectual Property
IPR	Intellectual Property Rights
IPRED	Intellectual Property Rights Enforcement Directive
LMO	Living Modified Organism

Abbreviation	Full title
MARA	Ministry of Agriculture and Rural Affairs (China)
MS	Member States
NGO	Non-Governmental Organisation
NGT	New Genomic Techniques
PBR	Plant Breeder's Rights
PVP	Plant Variety Protection
PVPA	Plant Variety Protection Act (United States)
PVR	Plant Variety Rights
R&D	Research and Development
SDN	Site-Directed Nuclease
SEP	Standard-Essential Patent
SME	Small and medium-sized enterprises
TRIPS	(WTO Agreement on) Trade-Related Aspects of Intellectual Property Rights
U.S.	United States of America
UK	United Kingdom
UK IPO	United Kingdom Intellectual Property Office
UP	Unitary Patent
UPC	Unified Patent Court
UPOV	International Union for the Protection of New Varieties of Plants
USPTO	United States Patent and Trademark Office
VCU	Value for Cultivation and Use (test for seed market authorization)
WIPO	World Intellectual Property Organization

VII

Abstract

This study examines how the current intellectual property (IP) framework affects breeders, farmers, and plant biotechnology actors, with a particular focus on the use of new genomic techniques (NGTs) in developing new plants.

The analysis combines legal, economic, and market perspectives using a multi-method approach, allowing the study to offer both quantitative indicators and qualitative insights reflecting stakeholders' practical experiences. The report emphasises the interplay between IP rules and market realities, and highlights how this interaction shapes opportunities and constraints in the sector.

The European plant breeding sector is technologically sophisticated yet structurally diverse, with many SMEs operating alongside a small number of large international firms. Breeding is highly research-intensive.

The study identifies potential legal and economic impacts arising from patents on NGT plants. The increasing complexity of the patent landscape may pose challenges for smaller breeders to access plant genetic material in terms of licensing costs and freedom-to-operate constraints. The study highlights multiple opportunities to strengthen transparency, support SMEs, and facilitate licensing. Overall, the study concludes that a balanced, coherent, and transparent IP system remains essential for ensuring that the benefits of NGTs are realised across Europe's plant breeding and farming sectors while maintaining diversity, competition, and long-term resilience.

Executive summary

Purpose and scope of the study

The European seed and plant breeding sector is facing a period of profound transformation. Driven by technological progress, climate change, and evolving regulatory expectations, the sector now combines traditional breeding methods with powerful biotechnological tools such as genome editing and data-based trait analysis. Against this backdrop, the European Commission tasked this study to analyse how the current intellectual property (IP) framework impacts the plant breeding, farming and plant biotechnology sectors, particularly in the context of the use of new genomic techniques (NGTs) for the development of new plants .

To that end, the study responds to a request for an evidence-based analysis of how patents on NGT plants, traits, and processes affect breeders' access to genetic material and availability of seeds to farmers. It aims to clarify the potential economic and legal impacts of IP protection, including its implications on market concentration, innovation incentives, transparency and overall EU competitveness.

The findings of this study show that **a balanced and coherent IP system is a key driver to innovation** in the the plant breeding and plant biotechnology sectors. Patents reward research and attract private investment; Plant Variety Rights (PVRs) safeguard accessibility and diversity. The real challenge lies in maintaining this equilibrium in a changing technological and economic landscape.

Methodological Approach

The analysis combined legal, economic, and market perspectives through a multi-method approach. It draws on:

- **Extensive desk research** on legislation, academic and policy publications as well as previous studies on plant breeding, IP, and biotechnology in Europe and globally;
- **29 targeted interviews** with breeders, farmer organisations, sectoral associations, civil society representatives, research institutes, national authorities, and international organisations (including the EPO, CPVO, and UPOV);
- **Two expert panels** – one focusing on legal aspects and one on policy measures – and a validation workshop to test and refine findings;
- **Empirical evidence** from patent databases (PATSTAT, Patentscope, Orbis IP), company data (Crunchbase), and the EU-SAGE database on NGT plant research.

This evidence base allows the report to provide both **quantitative insights** – such as the number of patent filings or the concentration of breeders – and **qualitative assessments** of stakeholder perceptions and practical challenges. The synthesis emphasises the interaction between legal design and market realities rather than treating them as separate dimensions.

Main findings

Market insights on plant breeding and PRM markets

Europe's plant breeding industry is both technologically advanced and structurally diverse. The majority of breeders remain **small or medium-sized, family-owned, or cooperative firms**, often specialised in a limited range of plants, or operating in niche markets. There are also a range of European champions such as KWS, Limagrain, DLF, and Rijk Zwaan, which remain internationally highly competitive while four multinational companies dominate the global crop market.

The plant breeding sector is highly research-intensive, with **R&D expenditure averaging 16% of turnover**. Modern breeding integrates a growing range of techniques, from traditional crossing to marker-assisted selection, tissue culture and gene editing tools such as CRISPR/Cas. NGT-based research is expanding rapidly: globally, studies on NGT traits increased from around 550 in 2022 to over 1,000 by 2025. **EU research represents about 12% of global activity**, while the largest number of studies can be found in China and the United States.

The EU is the second-largest seed market in the world, valued at roughly €7 billion in 2024, representing around **20% of global trade**. European plant breeders show a great variety in their breeding focus and possess outstanding technical expertise. Yet, scale remains crucial for achieving global leadership, which is why consolidation and acquisitions are increasingly seen across the sector.

European market leaders remain highly specialised: for example, KWS is world leader in sugar beet, DLF in forage grasses, and HZPC in seed potatoes. Geographic and crop specialisation provide resilience and diversity but limit economies of scale for smaller players.

Seed costs represent a modest share of total farm expenses (5–6% on average), yet they are a decisive input for productivity and sustainability. Quality seeds incorporating disease resistance or stress-tolerance traits reduce – for example – pesticide and water use, contributing to the Green Deal's environmental goals. Farmers depend on steady innovation in plant breeding to maintain competitiveness and adapt to climate change.

Patent landscape: NGTs and NGT plants

From 1982 to July 2025 the number of European patent applications in the area of genetically modified plants, including patents on breeding tools, amounted to 9 580. More than half were either withdrawn or refused and around one third were granted. The number of patent applications on conventional plants is much lower with about 1 290 (1995 - July 2025). About 38% cases were refused or withdrawn, 25% were granted and the remaining cases are still pending.

Plant related patenting is subject to careful examination: since 2018, the granting rate in the field of biotechnology - in which plant breeding patents largely fall - fell from 58.3 % to 21.8 % in 2024, making it the technology field with the lowest granting rate at EPO.

Regulatory and IP mechanisms

Europe's IP architecture offers a broad toolbox for breeders and innovators:

- **Plant Variety Rights (PVRs)** provide tailored protection for new plant varieties through[3] the Community Plant Variety Office (CPVO). Since 1995, over 65,000 rights have been granted, with more than 31,000 still in force.
- **Patents**, governed by the Biotechnology Directive (98/44/EC) and the European Patent Convention (EPC), protect technical inventions such as traits, genes, or processes.
- **Other IP tools** – including trade secrets, trade marks, and contractual agreements – allow companies to manage knowledge and branding effectively.

This dual system of patent and plant variety protection ensures both incentives for innovation and access for follow-on breeding through the breeders' exemption in the PVR regime. However, the coexistence of national and EU-level patent laws, the Biotechnology Directive, and EPC provisions creates a complex system requiring specialised knowledge to navigate. Furthermore, the complex patent situation surrounding foundational process patents is a key impeding factor that all types of companies struggle with.

Regulatory and public mechanisms in place to facilitate access to IP information and to patented genetic material include:

- **Patentability exclusions and EPO disclaimer practice**: Plants obtained exclusively by essentially biological processes are excluded from patent protection. The EPO requires disclaimers in claims on NGT-derived plants which could also be obtained by essential biological processes.
- **Limited breeder's exemption**: The limited breeder's exemption set out in the Unified Patent Court Agreement and some national laws of EU Member States allows the use of protected varieties for further breeding, while commercialisation requires obtaining a license.
- **Farmer's privilege**: The use of farm-saved seed is allowed under specific conditions for certain crops, but only when propagating material was sold by the patent holder or with their consent.
- **Compulsory cross-licensing**: This mechanism,set out in the Biotechnology Directive, provides for the possibility of compulsory licenses granted by competent authorities in specific cases. This mechanism does not appear to have been applied in practice.
- **SME support measures**: SMEs benefit from advisory services and fee reductions for patents and PVRs. In addition, SMEs can obtain support for protecting and enforcing their IP rights though the SME Fund, which provides financial support for activities such as IP registration and enforcement. Support for patent-related tasks and costs - especially for FTO analyses - remains limited. Many SMEs therefore operate without adequate legal certainty in fields where NGT-related patents may apply.

Furthermore, a number of mechanisms exist in the private sector to overcome shortcomings in terms of access and reduction of costs:

- **Voluntary licensing platforms**, such as the International Licensing Platform Vegetable and the Agricultural Crop Licensing Platform, facilitate access to patented traits under standardised, fair and reasonable terms. They reduce transaction costs, provide arbitration mechanisms and enhance trust among competitors. Although voluntary, these platforms indicate that private-sector collaboration can address access barriers effectively.
- **Transparency initiatives**: the European seeds sector has set up a database (PINTO - Patent Information and Transparency On-line) to provide information on plant varieties that might fall under the scope of patents or patent applications.

IP challenges and awareness gaps for NGTs and NGT-derived plants

While, overall, the current EU seed market is a vibrant market with a strong export base and a diverse corporate landscape, the need to continue advancing in yield, quality and resilience traits remains challenging but can also bring opportunities.

The expansion of NGT use raises a series of potential IP challenges for breeders, particularly SMEs. Under current EPO practice, NGTs are considered technical processes and therefore patentable, and - if meeting novelty, inventiveness and industrial applicability criteria - so are the resulting plants. This has generated substantial patenting of enabling tools such as CRISPR/Cas, while patents on NGT-derived plants remain limited. As NGTs enter commercial breeding pipelines, the combination of complex patent landscapes and low IP literacy among SMEs increases their concerns as to access to genetic material for further breeding.

Takeaways on the potential legal and economic impacts, and opportunities for improvement

Expected impacts

The potential **economic effects** of NGT patents and NGT-derived plants are significant and unevenly felt across the sector. For many breeders - especially SMEs - the growing complexity of patent landscapes raises the cost of freedom-to-operate analyses and may prevent them from using certain genetic material to avoid patent infringement risks. **Licensing is essential** for facilitating access to patented traits and technologies. Yet, it is resource-intensive and could potentially even become prohibitive when a variety contains multiple stacked patents. Typically, larger firms can manage these costs better, while smaller breeders risk exclusion. Over time, such a scenario could lead to an accelerated market concentration. For farmers, these developments could translate in higher seed prices. Over time, there is a possible narrowing of organic and GM-free seed options as well as patent-free plant reproductive material, which leads to higher search costs for those breeders. Although NGTs promise shorter breeding cycles and improved traits that can enhance productivity and reduce input needs, the overall economic benefits may also depend on transparent, fair, and accessible IP rights.

Opportunities

The majority of stakeholders emphasise that transparency and facilitating licensing, not the abolition of patents, is the key to fair and efficient innovation. The study identifies several promising approaches:

Integration of patent and variety databases would allow users to identify patents linked to registered plant varieties. Including **relevant patent data** in the EU Common Catalogue database, for example, would simplify freedom-to-operate assessments for breeders.

SMEs frequently lack dedicated legal units and have limited awareness of patent options and obligations, and require support in obtaining transparency. **Expanding SME support** - such as legal advisory services, IP training, or further use of the SME Fund voucher schemes - could reduce the risk of SMEs being excluded from NGT innovation.

Public-private partnerships remain a cornerstone of Europe's innovation ecosystem. Many foundational technologies, including CRISPR/Cas systems, originated in public research institutions. Ensuring that patents resulting from public funding are **licensed on non-exclusive or fair, reasonable and non-discriminatory (FRAND) terms** can promote wider diffusion while maintaining incentives for spin-outs and technology transfer. 5

Mechanisms such as the **licensing platforms** ILP Vegetables and ACLP, and patent databases (PINTO) already help breeders identify patented traits and negotiate licences. Strengthening these systems - particularly by broadening participation or linking patent and variety data - can reduce transaction costs and improve access to patented material.

As NGTs become more common, **fair and predictable licensing** will be essential. Opportunities include promoting FRAND-style licences, clearer articulation of royalty structures, or standardised licensing templates that reduce transaction costs for all actors.

Not only organic and GMO-free, but also most of the conventional breeders rely on diverse, accessible PRM pools. **Monitoring market developments** and ensuring continued availability - particularly if NGT-based varieties expand - supports market diversity and safeguards choice for farmers and breeders.

By **improving transparency**, **strengthening SME support** and **reinforcing access to genetic resources**, policymakers can ensure that both PVRs and patents continue to work together to encourage innovation while preserving diversity and accessibility in the plant breeding sector.

1. Introduction

1.1. Background and purpose of the study

On 5 July 2023, the European Commission (EC) issued its proposal for a regulation on plants obtained by new genomic techniques (NGTs) (COM(2023) 411 final). The scope of this proposal is plants produced by targeted mutagenesis, which comprises a set of techniques that allow modifications of the genome without the insertion of foreign DNA, and cisgenesis (including intragenesis), which result in the insertion in the genome of an organism of genetic material already present in the breeders' gene pool. The proposal does not include plants obtained by NGTs that introduce genetic material from a non-crossable species (transgenesis). Plants obtained with such techniques would remain subject to the existing GMO legislation. The proposal also regulates food and feed containing, consisting or produced from such plants and other products containing or consisting of such plants.

The EC proposal distinguishes two types of plants:

- Category 1 NGT plants – in essence plants which are considered to be equivalent to conventional plants either because they could also occur naturally or they could be bred by classical breeding techniques. The proposal includes a set of specific molecular characterisation criteria of equivalence.
- Category 2 NGT plants, by default, are all other plant varieties obtained by NGTs. These plants would be subject to specific risk assessment, monitoring and detection method rules compared to other GMOs.

For the organic sector, both categories are excluded.

In the context of the preparation of the Commission proposal, a number of stakeholders, in particular in the plant breeding and farming sectors, raised concerns about the potential impact of the patenting of NGT plants on breeders' access to breeding material and on the price and diversity of seeds. As a result, when the Commission adopted its proposal, it announced that it would carry out an assessment of the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to genetic material and techniques and on availability of seeds to farmers[1]. This study is intended as an input into that assessment.

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1.2. Study scope

The title of the report already indicates that the scope of the study goes beyond analysing the impacts of patents on access to plant reproductive material (PRM).

Innovation in plant breeding is closely linked to a range of intellectual property rights (IPR). While patents may be the most publicly known form, the dedicated plant variety right (PVR) is equally significant and merits particular attention. The study therefore addresses mainly **patents and PVRs**, while also touching upon neighbouring rights where relevant.

[1] Commission Communication of 5 July 2023 on Ensuring resilient and sustainable use of EU's natural resources (COM(2023) 410).

The plant breeding sector is undergoing a profound transformation driven by rapid scientific advances in biotechnology and related technologies. Like other structural shifts, this transformation affects sectoral structures, business models, and production processes. At the same time, it opens opportunities: for new players to enter the market, for new approaches to emerge, and for efficiency gains to be realised. The study therefore extends its analysis beyond IPRs to examine **market dynamics** and the challenges that patents pose for different actors.

Unlike innovation based on non-living material, plant breeding deals with living material in open environments. This creates unique challenges for innovation and IP protection: plant breeding is an iterative process and new plant varieties are often improving existing commercial varieties while keeping the previously beneficial characteristics ('stacking'). Furthermore, the constant threat of spontaneous viral mutations or new pests requires breeders to develop resistant varieties on an ongoing basis. In order to keep a wide variety and gene pool, a reliable access to plant genetic resources is key.

The PVR system provides a framework that ensures such access and enables traditional crossing and selection methods for the development of new varieties. Technological change, however, has introduced novel approaches alongside a broader uptake of patent rights, many of which originate from public research organisations, science-based start-ups, and spin-outs.

Finally, plant breeding is a highly international activity. A range of European breeders operate across global markets, where diverse intellectual property regimes apply. The study also considers **international perspectives** in order to place developments in the EU within a broader global context.

2. Approach and Methodology

2.1. Research questions

The request to the study included a range of tasks and related questions (see Table 1). The study team approached them with extensive desk research, data analysis, interviews, focus groups. The following table provides also a reading guide in which sections evidence is provided. The summaries and answers to the Tasks is included in Chapter 9.

Table 1 Research questions

Tasks	Related research questions	Section
Task 1 – Assessing the potential impacts of the IP system on uptake and availability of NGT plants, and PRM for farmers & genetic diversity	Q1: What are the likely economic impacts on plant breeders and farmers (conventional/organic/GM-free) of an increase of/in: • NGT patents • NGT-based plant varieties • licences • litigation costs	5
	Q2. What are the likely impacts on availability and access to PRM for breeders (conventional/organic/GM-free)? • availability of conventional PRM • availability on organic/GM-free PRM • access to conventional PRM • access to organic/GM-free PRM	8.3

	Q3. What are the likely impacts of a higher concentration of the seed market in terms of: • costs • diversity of varieties • overall competitiveness of the market	3.3 3.4 8.2.4
	Q4. What are the likely risks associated with introgression of NGTs on organic and GMO-free farmers	Not addressed in study. See EC (2022) NGT Support study
Task 2 – Mapping the EU and selected third countries' plant breeding and PRM markets	Q5. How does the IP system affect the market structure of seed markets in EU and third countries?	7.
	Q6. What is the ownership structure of patents and PVRs?	4.5
	Q7. What is the share of patent citations (prior art) in plant patents	
	Q8. How does the IP system affect the innovation patterns in the EU and third countries?	7. 9.
Task 3 - Mapping the patent landscape	Q9 What is the situation of patent applications/patents granted in the EU	6.2
Task 4 – Assessment of possible IP issues relating to NGT plant' patents	Q10. What is the rate of legal disputes on NGT plants	8.3.2.8
	Q11. What are the likely impacts of (voluntary) transparency initiatives on access and costs of information	8.3.3
	Q12. What is the level of complementarity between IP and PBR and effects for different stakeholders?	4 4.1 4.2 4.5
Task 5 – Assessment of possible awareness issues relating to NGT plants	Q13 Which awareness issues about the IP framework and relevant practise prevail by SMEs?	8.6
Task 6 – Assessment of possible IP issues relating to NGT plant' patents	Q14. How effective are identified regulatory mechanisms on facilitating transparency and availability on: • patented PRM • non-patented PRM • the evolution of patent disputes	8.3.3 8.4
Task 7 – Assessment of existing voluntary measures	Q15. What are the impacts on effectiveness of transparency initiatives on SMEs in terms of • access of breeders and farmers on PGM • on PRM diversity • PRM affordability • competitiveness of the European agritech sector • ease of use • usefulness, in particular for SME breeders	8.3.3 9
Task 8 – Considerations on potential new measures	Q16. What are considerations, favouring alternative measures in terms of effects on innovation and economic effects on breeders and farmers?	8.4 8.5 8.6

2.2. Data and evidence gathering

2.2.1. Desk research

The desk research formed an essential foundation of the study and was initiated already during the proposal stage, where key sources were mapped in advance.

This first step concentrated on **legislation, policy reports, and academic papers** that directly informed the legal and regulatory framework relevant to the topic. As the study also required a market-oriented perspective and a longitudinal analysis of developments over the past decade, the scope of research was expanded to include empirical studies offering quantitative evidence.

To obtain a more granular picture of company-level and sector-specific dynamics, several **specialised databases** were consulted, among them PATSTAT, Patentscope, Crunchbase, and Orbis IP, each providing complementary insights into intellectual property trends, business activities, and innovation pathways. The material identified through these databases was then triangulated with annual company reports, as well as broader policy and scholarly sources to ensure consistency and reliability.

Importantly, the desk research process was iterative: many of the reports identified contained extensive bibliographies, which in turn served as a valuable "snowball" mechanism, leading to identifying additional, relevant publications and data sources.

This cumulative approach allowed the research team to build a comprehensive knowledge base that combined regulatory analysis with empirical evidence and market intelligence.

2.2.2. Targeted interviews

29 interviews were conducted between March and April 2025, with two exceptions, which were carried out in May. Several interviews were with more than one person of a given organisation and in two interviews, more than one organisation was present.

The typical interview partners within the **private sector and sectoral associations** were legal experts – heads of the legal departments, legal counsels, or advisors with detailed experience in Intellectual Property Rights (IPR), technology licensing, and equally with substantial knowledge about the specificities of plant breeding. These interviews reflected the full range of actors, including large corporations with breeding but also other commercial interests, dedicated European-based plant breeders, as well as smaller NGT related research performing or research services providing firms. The larger breeding operators are members of the two existing licensing platforms.

Interviews with **sectoral associations** at national and EU-level included typically more than one person with at least one legal expert. Given the stakeholders' advocacy role, they often added a policy angle.

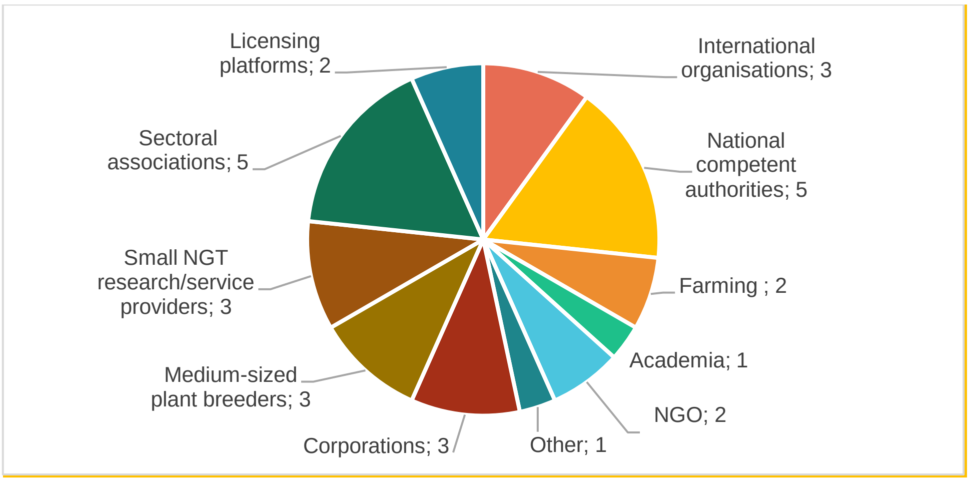
Interview partners representing **farmers and consumer rights** contributed *i.a.* by pointing out a number of expected impacts of IPR, in particular patents, on small and medium-sized breeders and farmers and thus adding economic and societal aspects.

Interviews with **academia and academic spin-outs** were conducted with scientific experts in the area, which were equally involved in science/technology transfer.

In terms of **international organisations**, interviews with EPO, CPVO and UPOV provided substantial details on definitions, guidelines and review processes.

Finally, interviews with **national authorities** were conducted with five Member States (MS) – typically with Ministries or national IP offices responsible for patent and PVR legislation.

Figure 1 Overview of interview programme



2.2.3. Expert panels

The approach included two expert panels which were organised in July 2025. The two online panels were structured around two broad axes: one legal panel and one policy panel. Both addressed questions on access to material and transparency measures from their respective perspectives.

2.2.4. Validation workshop

An online validation workshop took place in October 2025. The participants obtained an overview of the study and a synthesis of challenges and opportunities. There was broad agreement with the findings and suggestions made.

SECTION 1

MARKET OUTLOOK AND R&D TRENDS IN PLANT BREEDING

3. Overview of the seed market

3.1. Information sources

The plant breeding sector is not well covered through business statistics. At the EU-level, Eurostat does not provide statistics for the Sector A (Agriculture). In the absence of official statistics, a comprehensive sector analysis already lacks key information on the number of companies by size class per Member State, turnover, R&D budgets, and other valuable indicators.

Estimates about the sector thus come either from national statistical offices, private information sources, or information the sector is willing to share, for example, through plant breeder's associations. Derived information, for example, from patent applications or filed plant varieties help to identify individual breeders and to calculate proxies at national level. An important source are the national plant breeding associations which (may) collect data or survey their members.

In the absence of official statistics and, therefore, also the absence of time series, a transparent overview of "the sector" in Europe is practically impossible to establish with official, public data sources.

For the following analysis, the market was approximated using a range of data sources and available indicators. This includes publicly available trade data and memberships in national seed associations. At the firm level, company information was retrieved using annual reports as well as data from the Crunchbase database.

3.2. Approximation of the EU market

The study task on market analysis asked that developments over the last 10 years be taken into account. In the absence of time series and statistical data collected by Eurostat, previous studies are based on a market report published by the European Parliament (EP) in 2013.[2] The data used in that EP report was provided by Euroseeds and other sources, and related to the year 2010[3]. Based on these data, the European seed market was characterised as large and diverse, with an estimated total number of around 7 000 breeders (see Table 2).

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[2] European Parliament. (2013), The EU seed and plant reproductive material market in perspective. Focus on companies and market shares. DG for Internal Policies. Policy department B: Structural and Cohesion policies. Agriculture and Rural Development. Available at: https://www.europarl.europa.eu/RegData/etudes/note/join/2013/513994/IPOL-AGRI_NT(2013)513994_EN.pdf

[3] EUROSEEDS, then European Seed Association. Clear references and information on the year of the data are not included in the report. However, Wesseler et al (2015) refers equally to the data and indicates 2010 as reference year. The data was equally included in the OECD market study (2018).

The wide differences in the number of seed companies by country in 2010 can be attributed to differing statistical demarcations and structural factors: the estimates may include agricultural and horticultural breeding firms, propagation organisations, seed multipliers, as well as trading companies – as detailed below.

Table 2 Estimated numbers of seed breeding companies in key seed producing European countries (2010 and 2025)

Country	Estimated number of seed companies	
	2010	2025
Poland	~2 000	76
Romania	~2 000	40
Hungary	~800	n.a
United Kingdom	~600	
France	~120–350	118
Italy	~120–350	173
Germany	~120–350	59
Netherlands	~120–350	250
Slovakia	~120–350	80
Czechia		65
Spain		56
Belgium		23
Denmark		21
Austria		13
Other EU Member States	<60	

Note: Selection of countries and order following Royal Swedish Academy of Agriculture and Forestry (2024), Plant variety rights and patents on plants – their application on NGT plants and plant varieties in the EU, based on: European Parliament (2013): Report on the EU seed and plant reproductive material market. The 2013 publication only contained the first nine countries listed. The numbers were elaborated internally by the EP, based on SWD(2013)162 (see footnote 9. The data did not distinguish between plant breeding and seed multiplication activities, 2025 data collected by Technopolis Group – see sources in footnotes 7-28. The 2025 data excludes the UK and includes those EU-MS with significant trade volumes and market value as detailed in the Annex, Table 15.

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The value for Europe was estimated at €7 billion in 2012, with a global market share of 20 %, following the USA (27 %) and China (22 %). According to the EP study, the ten globally leading companies held a cumulated market share of 62 % in 2012.

Wesseler et al. (2015)[4] referred to the cited EP data collection and based their calculations on the 6,974 European seed companies recorded in 2010[5]. These firms were active across various stages, including plant breeding, seed production, seed conditioning, and distribution[6]. The figures included the United Kingdom (UK), which was estimated to have around 600 seed companies. For 2012, the Wesseler et al (2015) estimated a slightly higher market

[4] Wesseler, J (et al) (20215), Overview of the agricultural inputs sector in the EU, available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2015/563385/IPOL_STU(2015)563385_EN.pdf

[5] OECD (2018), concentration in seed markets. Potential effects and policy responses. Paris: OECD

[6] Ragonnaud (2013), cited in OECD (2018), p. 48

concentration among the then ten leading companies, at 68 % compared to 62% that was calculated for 2012 in the EP study[7]. In terms of commercial seed market concentration, the study concluded that the European market was less concentrated than the global market.[8]

To focus specifically on plant breeders and exclude growers – who can easily number in the thousands, as seen by the 2010 data in Table 2 above – the 2025 data is based on data from the national seed associations and the literature, as detailed in the following regional breakdown. The number identified for 2025 is with roughly 1,000 companies, just about 15 % of the estimates of 2010.

Is it realistic to assume such a sharp decline, or is the main explanation the different collection method? In 2010, only two countries – Poland and Romania – accounted for more than 50 % of the total number of companies. Yet, these figures, as detailed below, appear to be vastly overestimated, as they did not cover only breeders but also propagators, growers, and traders. Furthermore, the 2013 assessment wrote that more than 90 % of the Polish, Romanian and Hungarian companies were small. Aready then, a consolidation of the market had happened since the 1980s in EU-15 MS. The assessment concluded that in the new MS, the share of SMEs in PRM markets would be decreasing in the future.[9]

A caveat regarding membership as an indicator concerns internationally active breeders. Larger firms are typically members of several national plant breeder's associations. As a result, when using membership numbers by country, there is likely an inherent double-counting of internationally active plant breeders. Public information about the members, such as size or research intensity, differs among the national associations. This is reflected in the level of detail provided below.

Western and central Europe

The **French** plant breeders' association counts 118 companies involved in plant breeding, seed production and marketing[10].

The **German**[11] plant breeders' association counts 130 breeders and seed traders employing roughly 5,200 people. 59 companies maintain their own breeding programmes, covering a total of 115 plant species. R&D investment is high at 16 %.

The **Netherlands**[12] counts 250 specialist breeding and propagation companies. They breed, produce and trade vegetative starter material such as seeds, bulbs, tubers, cuttings and young plants for agriculture, food horticulture and ornamental plant cultivation.

[7] The EP (2013) study indicates ten companies but only lists and bases the concentration calculates on nine companies. The effect is likely marginal since the company listed 9th came to a share of 1%.

[8] The method to calculate global market shares has its counterarguments: the global values tend to be estimates that vary by author and due to the underlying indicator 'sales' which reflects values of seed prices. Deconinck (2020) argued that "Higher prices for GM seed imply that a higher weight is assigned to firms active in corn and soybean in North and South America. This overestimates the shares of those large companies which are active in GM seeds in the U.S.." see: Deconinck, K (2020), Concentration in Seed and Biotech Markets: Extent, Causes, and Impacts, *Annual Review of Resource Economics*, 12. Available at: https://www.annualreviews.org/content/journals/10.1146/annurev-resource-102319-100751

[9] EC (2013): Commission Staff Working Document. Impact assessment. Accompanying the document Proposal for a Regulation of the European Parliament and the Council on the production and making available on the market of plant reproductive material (plant reproductive material law). SWD(2013)162 final. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0162:FIN:EN:PDF

[10] https://www.ufs-semenciers.org/accueil-2/who-we-are/

[11] https://www.bdp-online.de/de/Branche/Kennzahlen/

[12] https://www.plantum.nl/wp-content/uploads/2024/03/2024_FS-Onderzoek_EN.pdf

The **Spanish**[13] plant breeders' association (ANOVE) counts 56 private companies and 5 public research centres. In total, the Spanish sector employs 2,500 people of which 38 % are in R&D functions.

The **Italian**[14] plant breeding association includes 173 plant breeders and 45 nurseries. The seed companies are classified by the sections they are active. For example, 67 seed companies are involved in the vegetable section, 46 in cereals, 8 in rice and so on. 32 companies are either also, or exclusively, involved in the section of companies working on genetic improvements.

Similarly, the **Belgian**[15] seed breeders' association is organised by section. It includes 23 private companies, one trader, and two regional research centres.

Austria's[16] association counts 25 companies, 3 public research institutes, and 10 individuals as members. Among them, 13 are indicated as having breeding activities within Austria.

Nordic countries

Sweden[17] and **Finland**[18] 1have 19 and 17 members respectively. With one international exception, the members in both countries are local firms only. **Denmark**[19] lists 21 members.

Eastern Europe

The large differences in particular for Poland and Romania between 2010 and 2025 data in Table 2 reflect both structural factors and variation in the data collection methodology, in particular for the 2010 figures. [20]

In Eastern Member States, state-owned breeding companies were the norm after World War II. The pace of privatisation developed differently. Furthermore, public plant breeding and research institutes continue to play a major role in plant breeding. Research and innovation are primarily carried out in public or national research institutions. For example, in **Estonia**, **Bulgaria**, and **Latvia**, national crop research or plant breeding institutes provide basic seeds to farmers, who then multiply them. There can be a contractual arrangement whereby the national institute repurchases the propagated material for further distribution[21]. Based on the number of seed companies, the private seed market in these countries is very limited.

In **Poland**, formerly private breeding companies were nationalised in the 1950s. Today, public breeding programmes continue in institutions and state-owned agencies, with only a small

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[13] https://www.anove.es/wp-content/uploads/2025/06/2025-Listado-socios-1.pdf

[14] https://www.sementi.it/dati-generali/

[15] https://www.seedabel.be/leden/

[16] http://www.saatgut-austria.at/MEDIA/Factsheet %20Saatgut %20Austria.pdf

[17] https://www.svuf.se/medlemmar.aspx

[18] https://www.siemenkauppiaat.fi/pa-svenska/foreningen/medlemsforetag/

[19] https://www.sortsejere.dk/om-os/medlemmer/

[20] The origin of the 2010 data cannot be traced back. The source indicated in the EP study does not include these estimates. Literature analysis and desk research about the developments in Poland and Romania support the study authors conclusion, that for these countries, a wider population if growers and farmers were counted. During the cold war, most of plant breeding was concentrated in state-owned companies (Poland) state research institutes (Romania). It is therefore unlikely that within 10-12 years, about 2,000 breeders started a company both in Poland and in Romania.

[21] LIVESEED (2019), Report on national visits (D1.7) available at: https://www.liveseed.eu/wp-content/uploads/2019/12/LIVESEED_D1.7-Report-on-the-National-Visits.pdf LIVESEED was a project funded under Horizon 2020. It aimed to understand the situation on organic seeds but also included general structural information

number of small privately-owned breeding companies operating[22]. The Polish seed association counts 76 members, including more than 20 branches of international firms.[23] This discrepancy between the 2010 figure of Polish breeders and the current number of members of seed association members suggests that the earlier figure likely included growers and propagators under the term 'plant breeder's. A similar situation appears in **Romania,** where the association ANSEM counts 45 members[24], including breeding stations affiliated with national research institutes.

In **Slovakia,** three national plant breeding institutions remain, while all others have been privatised. About 80 companies and organisations are active in plant breeding and seed production. The **Czech Republic** maintains nine public research institutes and 11 private ones. The Czech seed association counts 65 members[25].

Hungary's[26] seed association includes a large number of members, as membership is mandatory for anyone intending to sell seeds in the country[27]. In 2025, it counted 1 205 members, including international companies, large-scale agricultural firms, specialised research organisations, and private farms[28]. The Hungarian seed production has largely evolved through foreign-owned breeding stations. According to LIVESEED[29], there were around 400 seed companies among the members in 2019. The association reports 600 persons working in R&D[30]. The breeders mainly produce seeds for the domestic market[31]. In the CPVO's Variety finder, 18 Hungarian breeding firms can be identified as well as individual breeders.Some may be linked to the public research institutes and university departments.

3.3. Specialisation pattern

3.3.1. Specialisation across Member States

Among the 250 000 known plant species, around 30 000 are edible and 7,000 are cultivated. Yet, for the human food chain, only 150 play a more significant role. 30 plant species provide more than 90 % of the needed calorie intake worldwide; the four plant species wheat, rice, maize, and potatoes alone cumulate 60 %[32].

Yet, even if 'only' 150 plant species are grown, no breeder – not even the largest company – addresses them all. Due to the varying geographic and environmental requirements in Europe

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[22] Podlaski, S., 2018, Small breeding companies are important in the seed market [Małe firmy hodowlane mają duże znaczenie na rynku nasiennym], see: https://www.agrofakt.pl/male-firmy-hodowlane/

[23] https://pin.org.pl/en/pin-psta-members/

[24] ANSEM Membership database, available at: https://www.amsem.ro/baza_date_membri.aspx

[25] https://www.cmssa.cz/o-cmssa/clenove/

[26] https://vszt.hu/about-us/

[27] LIVESEED (2019), Report on national visits (D1.7) available at: https://www.liveseed.eu/wp-content/uploads/2019/12/LIVESEED_D1.7-Report-on-the-National-Visits.pdf LIVESEED was a project funded under Horizon 2020. It aimed to understand the situation on organic seeds but also included general structural information

[28] Hungarian Seed Association, Membership, https://vszt.hu/about-us/

[29] Cf fn 27

[30] https://vszt.hu/vetomagszektor/

[31] Cf fn 27

[32] Nationales Fachprogramm pflanzengenetische Ressourcen, see: https://www.ble.de/DE/Themen/Landwirtschaft/Biologische-Vielfalt/Nationales-Fachprogramm-Pflanzen/nationales-fachprogramm-pflanzen_node.html

and beyond, breeders may focus on one production area and develop the needed reproductive material, or they may focus on one species, e.g. potatoes or beans, but develop various varieties adapted to different geographic markets and uses.

Specialisation can be seen at **national level** as well as at company level. France, for example, leads in the production of maize, oilseeds, fibre crops, and pulses. Spain holds the lead in straw cereals. Denmark is a major producer of forage grasses and supplies about 75 % of the world's spinach seeds[33]. Italy is a dominant force in small-seeded legumes and produces 60 % of Europe's durum wheat. It also holds strong positions in rice (77 %), alfalfa (53 %), and soybeans (27 %)[34].

According to Wesseler et al (2015), Europe is the largest producer of seed potatoes, with 95 % of potato breeding companies located in the EU. With 37 %, the Netherlands is the largest seed potato producer, followed by France[35] and Germany[36]. Additionally, the EU is the global leader in sugar beet seed production, accounting for 50 % of global output. Germany, France, and Poland are key producers, contributing 29 %, 28 %, and 15 % respectively[37].

3.3.2. Specialisation at company level

Each and every plant species is unique and requires specialised breeder's knowledge. There are a range of 'divisions' among the breeders, which makes plant breeding a **highly segmented** sector:

- By **type of plant:** there are crop oriented companies which specialise, for example, in wheat or maize, others specialise in potatoes, broccoli, onions, tomatoes, or fruits.
- By **size**: there are large multinational companies – corporations - such as Bayer, Corteva, and Syngenta with a large breeding section and with a focus on field crops such as maize or soybeans. While larger breeders may also opt for a mix in type of plants, there are a range of breeders entirely focusing on one species within field crops, vegetables, or ornamentals.
- By **geographical focus**. As can be seen with export data, breeding can be envisaged as an international activity, but it can also be an activity entirely for local/national markets without an international aspect. As indicated in several interviews with breeders and breeder's associations, many breeders are active on a regional or even local level; they are typically small with no ambition to go beyond their niche. Others have a dedicated international outreach. The Danish DLF for example, a world leader in forage and grasses "provide[s] locally adjusted products to more than 100 countries"[38]. 17

Another important selling point is **high-tech** versus **conventional breeding**. There is no clear definition of 'high-tech breeding', yet several interviewees linked the term to greenhouse production culture, which allows for controlled production conditions in terms of light,

[33] DCA, Case: Danish seed production at the forefront, available at: https://dca.au.dk/en/sector-collaboration/cases/case-danish-seed-production-at-the-forefront

[34] Assosementi, Il settore sementiero italiana, available at: https://www.sementi.it/dati-generali/

[35] ESCAA, Seed production in the EU- 2024, available at: https://www.escaa.org/index/action/page/id/7/title/seed-production-in-eu---2023

[36] ibid

[37] Eurostat, Agricultural production – crops, available from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Agricultural_production_-_crops

[38] https://dlf.com/about-us

temperature, and nutrient solutions. Greenhouse cultivation is typically used for more ‘fragile’ plants such as lettuce or tomatoes. For example, a newly developed variety of cherry tomatoes, which has attractive characteristics, requires a controlled maintenance for optimal yield. It can be marketed wherever greenhouse cultivation is maintained. More robust crops such as *Brassica* are typically cultivated on farmland.

Other factors like soil properties, climate conditions, the availability of skilled personnel and individual business aims and opportunities may equally play a role in the decision-making of individual plant breeders. Together with the dividing factors, this provides for an almost endless mix of options and business models for European breeders.

When the data of the largest European companies are taken into account (see section 4.2) specialisation by type of plant seems to be a decisive factor. KWS for example is specialised in sugar beets and has an estimated global market share of 55 %[39]. DLF is a world leader in forage and grasses while HZPC is a leader in seed potatoes.

3.3.3. The market by trade volumes

Trade data enables the analysis of the flow and value of crop seeds by exporting country. This allows to calculate export and import shares by country and crop type. The International Seed Federation provides such data annually[40].

Based on 2022 estimates, the global value of sowing seed exports was US$ 16.2 billion (€ 13.7 billion). Approximately 20 % of this was attributed to the Netherlands, largely due to its significant share in vegetable and flower sowing seeds, France followed with 16 %, and the USA with 12 %.

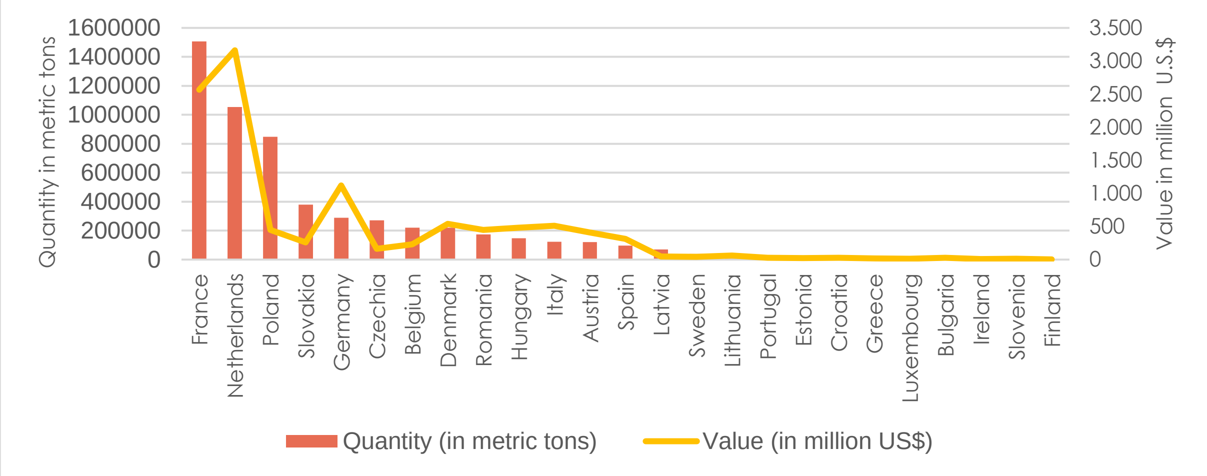
Although vegetable sowing seeds account for only a small share of total export volumes compared to field crop sowing seeds, they have a much higher value per tonne. In this respect, the Netherlands is by far the leading exporter (see Figure 2 and Annex Table 15).

Among EU member states, France, the Netherlands, and Poland lead in export volumes by metric tonnage (see Figure 2). However, high export figures do not necessarily reflect the strength of a country’s breeding sector. Large breeding firms often operate internationally, making use of favourable conditions abroad, such as available land, suitable climate, or lower labour costs for seed propagation.

[39] OECD (2018), p. 57

[40] https://worldseed.org/document/seed-export-2022/ Data published 19.02.2025

Figure 2 EU-MS by export volumes and value in total seeds (2023)



Data: Wordseed Org, see Annex Table 15 for detailed data. Treatment: Technopolis Group. Note: Malta and Cyprus are not covered in the original data

Poland, for example, hosts a range of foreign breeding firms that use its land for propagation, making it a key exporter in terms of volumes. Still, a comparison of export volumes and values reveals significant variation by crop type and country.

A case from the flower segment illustrates the international nature of seed propagation and production: *Dümmen Orange*, a world-leading Dutch breeder and propagator of ornamental flowers and plants, has its main high-tech breeding technology centre in the Netherlands. Yet, for propagation and production purposes, the company operates more than 260 hectares abroad, notably in East Africa, and Central and South America[41].

Combined with the 2010 ‘number of breeder’s’ data from Table 2, this suggests that in a range of EU-MS, the limited plant breeding activities within the country are focused on national demand. These countries are by and large sowing seeds net importing countries.

3.4. Seed prices

For European growers, the **seed price is a relatively small cost item** among the total farm costs. Between 1989 and 2009, the share of seed prices in total farming costs rose slightly from 5.2 % to 6.3 %; between 2004 and 2012[42] and within the EU-15 Member States, it declined slightly. National differences also exist. For example, in the Netherlands, seed costs made up 15 % of total farm costs, compared to just 2 % in Ireland (2004–2012)[43], This correlates with the Dutch specialisation in onions, tomatoes, and greenhouse production of vegetables.

Given the wide variety of plant species and traits, **seed prices** are extremely differentiated. Prices vary largely between open-field and greenhouse cultivation, and by factors such as standard or speciality, form, size, or colour.

[41] See https://emea.dummenorange.com/site/en/about-us/what-we-do

[42] OECD (2018), concentration in seed markets. Potential effects and policy responses. Paris: OECD

[43] ibid

For example, 1,000 cherry tomato seeds for greenhouse cultivation can cost between €114 and €283, whereas for open field use, the price range from €88 to €148. Field crops such as cabbage, onions, potatoes etc. are less costly: 2,500 seeds of cabbage seeds cost between €20 and €57, and 10 000 onion seeds range from €11 to €15[44]. Price differences within an individual plant species are typically due to the traits they contain. According to interviews with breeders, these are the 'selling points' for a given variety and their 'quality characteristics' for which growers – and in the end also consumers – pay a premium. In this category, one seed may cost one euro.

The purchase of quality seeds may be driven by consumer demand, but often it is essential for improving yields or managing stress conditions. According to breeders, the higher prices of such seeds reflect the R&D investment required to develop improved plant varieties, while growers see advantages be it in yield, or colour, nutritious value etc. which the grower can pass on to the retail chain.

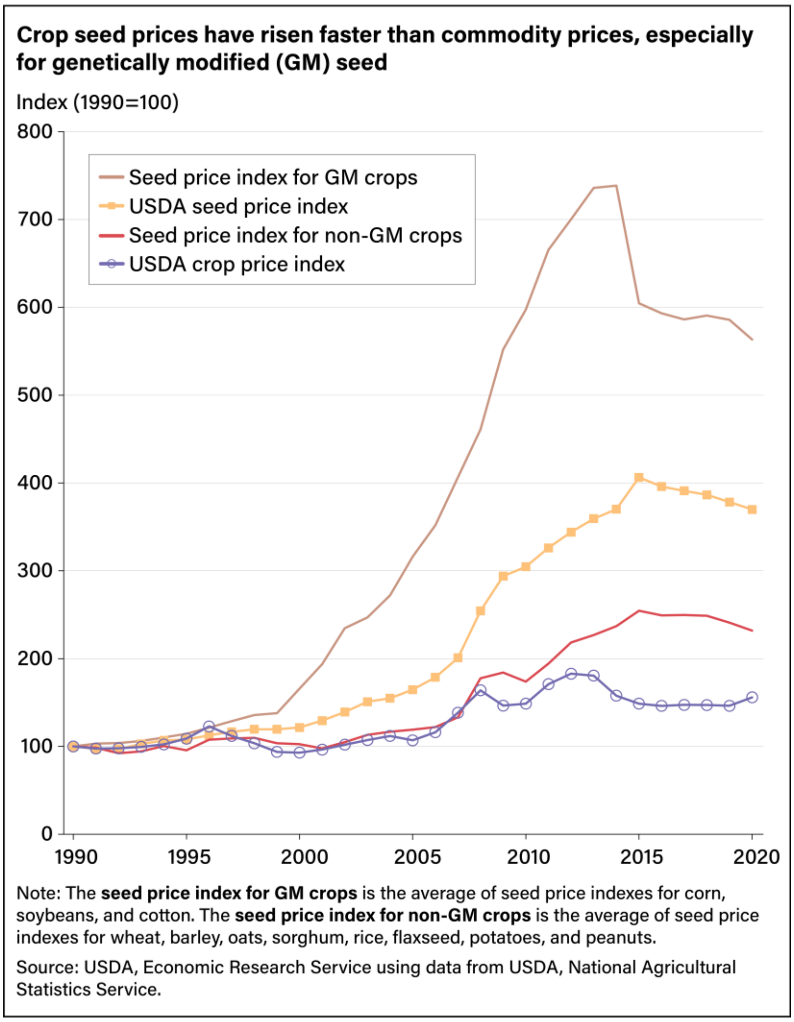
Breeders can obtain higher prices for greenhouse seeds, as these usually produce higher yields and quality. Open-field tomato plants, for example, may not grow as high as in a greenhouse and may have more limited yield. Ultimately, farmers choose varieties that best suit their growing conditions and market opportunities. Interviews confirmed that, compared to fertiliser costs, **seeds remain a relative "low input cost" for farmers** (ID_3).

The situation is different in the U.S. Since 1990, the increase in crop seed prices - for both conventional and genetically modified varieties – has been attributed to two factors: the greater concentration in the U.S. seed industry, and the market power of firms to set seed prices, particularly for improved varieties[45] (see Figure 3).

[44] The prices were taken from https://www.seednet.eu.com/index.php (prices April 2025). This trader offers vegetable and flower seeds from numerous breeding firms.

[45] MacDonald, J. et al (2023), *Concentration and competition in U.S. agribusiness*, U.S. Dept. of Agriculture, Economic Research Service, EIB-256. Available at: https://www.ers.usda.gov/data-products/chart-gallery/chart-detail?chartId=107195

Figure 3 Crop seed price developments in the U.S. (1990-2020)



3.5. Market value and global estimates

The global seed market is highly dynamic and developed rapidly over the last decades. 21

The OECD (2018) market report, based mainly on company estimates, valued the global seed market at U.S.$ 52 billion in 2014. Maize accounted for 40 % and soybean seeds for 14 %[46]. The leading trading countries were the U.S., Brazil, and Argentina, all of them also dominant in genetically modified (GM) varieties. In fact, nearly 80 % of soybean seeds in the Americas were genetically modified, which contributed to the higher market value, as "*typically higher prices for GM seed automatically lead to a larger estimate of market sizes in terms of value".*[47] Beyond maize and soybean, the main crops by market value were rice, vegetables, cereals, cotton, rapeseed, sugar beet, and sunflower.

A decade later (2023), private sector estimates placed the global seed market at U.S.$ 60 billion. The shares of maize and soybean seeds had risen to 48 % and 22 %

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[46] OECD (2018), p. 27

[47] ibid

respectively, together representing U.S.$ 42 billion of the total market[48]. Latin America has been a key driver of growth since 2021, expanding seed production and consequently reducing the U.S. share of the global seed market from 35 % in 2021 to 30 % in 2023[49]. The increase of Latin America is partly due to a permissive regulation in Argentina and rapid adoption of herbicide-tolerant soybean traits since 1996.[50]

4. Business models and market consolidation

4.1. Traditional plant breeder's business model

The need to develop new plant varieties is driven by the inherent unpredictability of nature and the continual emergence of **biotic stresses** – such as fungi, viruses, phytoplasma, nematodes, insects, and parasites. Of increased urgency is also the need to adapt plants to **abiotic stress,** especially climate-related. As these factors may be local or widespread, and may affect one or multiple plant species, breeders face a broad spectrum of potential markets for individual plant products. In addition to managing stress factors, there are other areas to innovate such as yield, colour, taste, or nutritional value.

For the breeding success, access to a wide range of breeding material – a broad genetic variation - is key. This principle is the reason for collaboration even under competitors: the **need to access any plant material, including competitors' plant material** for crossing and selecting for the development of better varieties is a deeply embedded, accepted, and appreciated principle of traditional plant breeders. According to interviews, large companies are often less dependent on the exchange than smaller ones since they often own larger collections of germplasm[51].

One of the key characteristics of European breeders today is their size and ownership structure. They tend to be small and medium sized enterprises and are typically **independent, cooperatives, or family owned**. Breeders such as KWS, Lemaire Deffontaines, BelOrta, or Rijk Zwaan were founded more than 100 years ago and still maintain their independence from capital markets. While this is a characteristic that often limits the growth of an enterprise regardless of the sector, it also provides for long-term perspectives and independence from investors' requirements.[52]

Any plant is easy to reproduce and the costs for reproduction are low. To protect and reward the investments made, the U.S. protected vegetatively propagated plant varieties already in

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48 Kynetec https://www.kynetec.com/seeds-of-opportunity-ag-market-research-explains-global-growth

49 Ibid. The available ISF data cannot corroborate the trends. 2021 data is lacking – presumably due to the low exports during the Covid-19 pandemic, and 2022 data is the latest available data.

50 US Dept. of Agriculture (2024), Agricultural Biotechnology Annual – Argentina. Available at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Buenos%20Aires_Argentina_AR2024-0018

51 Germplasm refers to seeds, plants, or plant parts that are maintained for their genetic information and used in crop breeding, research, and conservation. It encompasses living material—such as seeds, pollen, or tissues—that carries the hereditary traits of a species. Germplasm serves as a vital genetic resource, enabling scientists and breeders to study, preserve, and utilise genetic diversity for developing new crop varieties, safeguarding biodiversity, and maintaining valuable traits for future agricultural improvement. See: Managing Global Genetic Resources: The U.S. National Plant Germplasm System. https://www.ncbi.nlm.nih.gov/books/NBK235638/

52 See for example KMU Forschung Austria (2008), Overview of family business relevant issues. Report of the expert group, see: https://ec.europa.eu/docsroom/documents/10388/attachments/1/translations

the 1930s with the Plant Variety Act. Since the early 1960s, the UPOV Convention[53] provides for a *sui generis* right with **plant variety protection** (PVP).[54] This right is still the core right within the European breeding sector.

4.2. Consolidation and concentration

Following World War II, agricultural practices underwent significant changes. The urgent need to produce food in sufficient quantities brought the chemical industry and synthetic fertilisers to the forefront. [55] Agricultural chemical companies - then as now - operated under a shareholder-based corporate governance model. These companies displayed several characteristics that stood in stark contrast to those of the traditional plant breeding sector, such as company size, the approach to innovation, or intellectual property rights.

The largest actors in the plant breeding sector today are corporations stemming from the agro-chemical industry but which developed or acquired substantial plant breeding capacities (see Table 3).

The consolidation of the seed market has occurred in waves, as observed by Schenkelaars (2011)[56]. These waves were driven by either technological advances or regulatory developments:

- A first wave in the 1930s occurred when hybrid seeds were introduced. This led to spin outs of public research organisations and the creation of commercial, private seed companies (such as Pioneer Hi-Bred in the USA)
- The second wave is linked to the introduction of the plant breeder's rights and patents in the 1970s. It spurred mergers and acquisitions of pharmaceutical, petrochemical, and agrochemical firms in the U.S. and Europe.
- The third wave started in the 1980s with the emergence of biotechnology. Large agrochemical companies in the U.S. began investing in genetically modified organisms (GMOs), acquiring smaller players and increasing in-house R&D capacities.

In the U.S., a key regulatory development during this period was the **Bayh-Dole Act** (1980), which enabled public research institutions and small businesses to own and commercialise intellectual property generated from federally funded research. This significantly stimulated innovation, particularly in biotechnology[57].

Over the past four decades, the seed market has become increasingly concentrated. In 1985, the top ten seed companies globally held a combined market share of approximately 13 %. By

[53] Available at: https://upovlex.upov.int/en/convention

[54] Italy and Portugal joined in the first wave 1978, many EU member states joined in 1991. The European Union became a member in 2005.

[55] The introduction of the Haber-Bosch process at the beginning of the 20th century enabled the synthesis of ammonia for fertiliser production on a large scale. The availability and use of fertilisers increased enormously, and the yields of agricultural land increased extraordinarily.

[56] Schenkelaars et al 2011 as cited in OECD 2018, p. 58

[57] https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35-partII-chap18.htm

2005, this had increased to 45 %, and by 2012 to 61 %[58]. This trend was driven by mergers, acquisitions and divestments by large U.S. and European chemical companies.

As indicated above, these companies were originally focused on plant protection products (pesticides) and fertilisers. In the 1990s, U.S. chemical firms began to embrace biotechnology. For example, **Monsanto** was already experimenting with GMO technologies in the 1980s. It subsequently divested its non-agricultural businesses and began acquiring established U.S. seed breeders, leading to further consolidation across the pharmaceutical, chemical, and agricultural sectors[59].

In contrast, the EU's biotechnology wave primarily affected the pharmaceutical industry, leaving much of the traditional plant breeding structure intact.

The most significant agrochemical mergers and acquisitions that contributed to today's largest seed firms include:

- DuPont acquired the previously largest U.S. agrochemical firm Pioneer in 1999.
- Syngenta was formed from the 2000 merger of the agrochemical divisions of **Novartis** and **AstraZeneca**.
- Bayer acquired Monsanto in 2018. As part of this acquisition, Bayer divested its seed business to BASF.
- Corteva was established in 2019 as the agricultural division spun off from the 2017 merger of Dow and DuPont.

These mergers significantly reduced the number of very large agrochemical and seed firms to four by 2019. According to the OECD (2018) study, BASF, Syngenta, and Bayer earned the majority of their revenues from agrochemicals, while Corteva and Monsanto generated more from seeds and biotech.

The mergers and acquisitions increased both turnover and market share. For example, Bayer Crop Science grew from a turnover of approximately €5.2 billion in 2005 to €22.3 billion in 2024.[60] By 2020, these four firms held around 70 % of the global pesticide market and 60 % of the seed market, highlighting the oligopolistic structure of the sector.[61]

The primary drivers of mergers and acquisitions in the seed and agrochemical sectors include[62][63]:

- Increasing R&D costs associated with plant breeding
- Economies of scale and scope arising from patent rights and regulatory costs

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[58] Podlaski, S., 2018 Development of the seed industry – what determines it? [Ewolucja przemysłu nasiennego – co o niej decyduje?], see: https://www.agrofakt.pl/jak-sie-zmienia-rynek-nasienny/

[59] See for example OECD (2018) pp. 49ff on the M&A that led to the establishment of the key agrochemical companies which are equally the largest in the seed markets. For a more detailed overview of the U.S. developments in the 1990s see: Fulton, M., Giannakis, K. (2001), fn 62

[60] Statista, see: https://de.statista.com/statistik/daten/studie/20046/umfrage/umsatz-von-bayer-cropscience-seit-2005/

[61] L'olipole de l'agrochemie, Statista, 15.09.2023, see: https://fr.statista.com/infographie/30834/agrochimie-oligopole-parts-de-marche-des-quatre-plus-grands-groupes-de-semences-et-pesticides/

[62] Fulton, M., Giannakis, K. (2001), Agricultural biotechnology and industry structure, AgBioForum, Vol 4/2, pp137-151. Available at: https://mospace.umsystem.edu/xmlui/bitstream/handle/10355/340/Agricultural %20biotechnology %20and %20industry %20structure.pdf?sequence=1

[63] Schenkelaars (2011) as cited in OECD 2018, p. 61

- Product complementarity (e.g., combining seeds and crop protection solutions)
- Overcoming challenges in enforcing certain intellectual property rights

With the advances of new technologies not only inter-dependencies change, but also new opportunities arise. With gene-editing techniques, contracted service providers, research institutes and in-house R&D labs can create a diverse genetic pool without having to rely on competitors' material (ID_16). Furthermore, the use of public gene-banks and their screening with AI tools is expected to be "transformational".[64]

Acquisitions can be seen as an ultimate form of control and ownership. Yet, the broader plant breeder sector knows also a number of time-bound alliances and equity investments – which in many observed cases have ultimately led to a so-called vertical acquisition of a company that complements with additional characteristics.

For example, Pairwise, the U.S.-based start-up company that developed one of the first patent protected NGT based plants -leafy greens-, entered into a licence agreement with Bayer in May 2024. The licence allows Bayer to develop and sell CRISPR-edited leavy greens at commercial scale. The two companies already have a five-year collaboration for gene edited maize. Corteva equally invested in Pairwise in a Series C funding round of U.S.$ 40 million in 2024, including a U.S.$ 25 million equity investment to form a joint venture on maize.[65] Pairwise developed a technology platform which is secured through access to the CRISPR-Cas complex; F. Zhang as holder of the foundational patents is listed as a co-founder. The developed platform enables Pairwise to licence its patent-protected knowledge base and collaborate with agricultural companies focussing on crops (such as Corteva and Bayer), and the same time to develop its own NGT-based vegetables (seedless berries, mustard greens etc.).

The traditional European breeding sector has also seen acquisitions. Those between Limagrain and Vilmorin &Cie in 2023 and between RAGT and Delaplanque Group (2025) are horizontal acquisitions, providing the acquiring company with a larger portfolio and higher sales (thus with a scale focus).

Since 2019, KWS is actively expanding its scope – from agricultural crops to develop also vegetables. The company bought two vegetable seed growers in the Netherlands and opened a new R&D centre for vegetables in the Netherlands.

4.1. Platforms, research services: the new kids on the block

The technological developments and analytical methods available today typically stem from academic research. But not only that academic research generates the foundational knowledge – it is also mainly scientists and academic researchers which are trained in the use of these technologies. Practically all new methods used in modern plant breeding (see also Box 1) were developed in universities and dedicated public research institutes.

Given that many universities (and other public research institutes) in EU-MS, the U.S., and China are entitled to file patent applications, and many individual scientists are not only the legitimate inventors but possibly also included in revenue-sharing agreements, this is one of

[64] Doudna, J, (2024), Combining AI and CRISPR will be transformational, *WIRED*, 28.11.2024, see: https://www.wired.com/story/combining-ai-and-crispr-will-be-transformational/

[65] Bayer 2024 Annual report, Crunchbase,

the pillars to develop a start-up. This has happened in the first biotechnology wave of the 1980s and 1990s; today, history is repeating.[66]

4.2. Largest seed companies

The following table provides an overview of the largest breeders by revenues of seeds in 2024 (or latest available year stated). With Corteva and Syngenta, two non-EU companies are among the top three companies. Yet, the remainder is from the EU, indicating not only the international orientation of European breeders, but also their overall competitiveness.

The overview also includes selected acquisitions. Mergers are much less seen but two of these top firms resulted from mergers with (1) Limagrain and Vilmorin and (2) HZPC (merger of Hettema and ZPO.

The largest seed breeding companies are listed in Table 3. Beside Corteva and Syngenta, the remaining 12 companies are all European. Dutch, French, and German companies dominate.

[66] The biotech companies of the first wave such as Genentech, Cetus, Amgen were co-founded by scientists, relying mainly on their intellectual capital such as rDNA sequencing, cloning, or PCR. Cohen and Boyer as inventors of the rDNA patent (applied for by the University of California System) was the basis for Genentech. The PCR method and granted patent was the backbone of Cetus. Today, the foundational CRISPR-Cas patent of inventor Feng Zhang is the basis for his co-investments in several biotech firms such as Editas Medicine, Beam Therapeutics, Sherlock Biosciences, as well as Pairwise Plants and Conscious Foods - the two latter key for NGT plant development. J. Doudna and her patent estate on CRISPR is key for the start-ups Mammoth Biosciences, Caribou Biosciences, Intellia Therapeutics, and Tempus AI, E. Charpentier co-founded CRISPR Therapeutics and licenses her patent via 'ers genomics' – about 150 licence agreements worldwide have been concluded so far.

See for example Zucker, L. G., & Darby, M. R. (1996). Star scientists and institutional transformation: Patterns of invention and innovation in the formation of the biotechnology industry. Proceedings of the National Academy of Sciences, 93(23), 12709-12716.

Table 3 Largest seed breeding companies

#	Company	Country	Revenue Seeds	Plant focus	Selected M&A or main funding rounds	Notes
1	Bayer Crop Science	DE	€22.bn[67] (2024)	Maize, soybean, cotton, oilseed raps, rice, wheat, vegetables	• Covercress (A) 2022 • Prophyte (A) 2013 • Athenix (A) 2009	Publicly traded corporation;
2	Corteva	U.S.	$9.5 bn[68] (2024)	Maize, sunflower, soybean, rapeseed, other agricultural crops	• Symborg (A) 2023 • The Stoller Group (A) 2022 • IBI-Ag (Series A) 2025 • Solasta Bio (Series A) 2024 • Pairwise (Series C) 2024 • Micropep Technologies (Series B) (2024)	Publicly traded corporation
3	Syngenta	CH	$3.8 bn (2024)[69]	Vegetables, agricultural crops	• Produtécnica Nordeste Comércio de Insumos Agrícolas Ltda (A), 2024 • Intrinsyx Bio Inc (A), 2024 • Macspred Pty Ltd. (A), 2023 • Agrocerrado Produtos Agricolas E Assistencia Tecnica Ltda. (A), 2023 • Kubix AgroIndustrial Ltda. (A), 2023 • Feltrin Sementes Ltda. (A), 2023	Owned by ChemChina since 2017
4	Limagrain/Vilmorin	FR	€2.5 bn (2023/24)[70]	Maize, rapeseed, vegetables	• Vilmorin & Cie in 2023	Cooperatively owned
5	BASF	DE	€2.2 bn (2024)[71]	Rapeseed, cotton, soybean, wheat	• Crop Design (A) 2006	Publicly traded corporation

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[67] https://www.statista.com/statistics/263782/revenue-of-bayer-cropscience-since-2005/

[68] https://investors.corteva.com/static-files/e5d99b14-6fc1-40c0-9a88-f04c39b4c81b

[69] https://www.syngenta.com/sites/default/files/2025-03/Financial %20Report %202024.pdf

[70] https://www.limagrain.com/en/news/key-figures-for-limagrain-s-2023-2024-financial-year-and-our-businesses

[71] https://report.basf.com/2024/en/combined-managements-report/fundamentals-of-the-group/basf-groups-business-year/segments/agricultural-solutions.html

#	Company	Country	Revenue Seeds	Plant focus	Selected M&A or main funding rounds	Notes
			(seeds & traits)		• Acquisition of selected Bayer seed segments following the Monsanto acquisition of Bayer (2017)[72]	According to Future Farming, BASF is spinning-out its agricultural activities by 2027[73]
6	KWS	DE	€1.67 bn (2023)[74]	Sugar beet, maize, cereals	• Geneplanta (A) 2021 • Pop Friend Seeds (A) 2019	Independent private company
7	DLF	DK	€1.1 bn (2023)[75]	Forage seed	• JV (United Beet Seeds) with Florimond Desprez (2025) on sugar beets • Corteva Agriscience Alfalfa Breeding programme (A) 2023 • Hilleshog (A) 2019 • Syngenta sugar beet seeds business (A) (2017) • Florimond Desprez Alfalfa seed business (2016) • Pickseed Group (2013) • Various forage and crop seeds companies	Owned by farmers
8	Rijk Zwaan	NL	€627 mn (2023) [76]	Vegetables		Independent private company
9	HZPC	NL	€500 mn (2024)[77]	Seed potatoes	TLC Potatoes (A) 2023 Sadoka Seed Potato (A), 2016 Hettema – ZPO (M), 1998	

[72] See https://www.basf.com/global/en/media/news-releases/2017/10/p-17-336

[73] https://www.futurefarming.com/crop-solutions/basf-to-divest-agricultural-activities/

[74] https://reports.kws.com/2024/de/geschaeftsjahr.html

[75] https://dlf.com/about-us/annual-report-governance

[76] https://igrownews.com/rijk-zwaan-financial-growth-amidst-expansion/

[77] https://www.hzpc.com/hzpc-news/royal-hzpc-group-expects-strong-result

#	Company	Country	Revenue Seeds	Plant focus	Selected M&A or main funding rounds	Notes
10	RAGT	FR	Estimated €475 mn	Agricultural crops	• Delaplanque Group (A), 2025 • Serasern (A) 2010 • PBIC (Plant Breeding International Cambridge) (A) 2004	R&D expenditure: 18 % of turnover
11	Enza Zaden	NL	€440 mn (2023)[78]	Vegetables	Carosem's carrot breeding programme (A),	Independent family business
12	Agrico	NL	€400 mn (2023)[79]	Seed potatoes	Wolf & Wolf (M) 1993	Organised as cooperative
13	Bejo Zaden	NL	estimated €270 mn (2017)[80]	Vegetables, focus on onions, carrots, brassica	• Nuvance (A) 2020 (SA distributor) • Agrisemen, (A), 2015	
14	Florimond Desprez	FR	€250 mn[81]	Agricultural crops, mainly sugar beet and industrial chicories	• Endotar (A), 2018 • Germicopa (A), 2014 • Seedexseed (A), 2000	Independent family-owned Patents mainly on chicories 17 % R&D expenditure

Data: Annual reports; Crunchbase. Compilation: Technopolis Group.

[78] https://www.agf.nl/article/9541433/minder-winst-meer-omzet-voor-enza-zaden-in-2022/

[79] https://www.agricopotatoes.com/news/press-release-agrico-passes-the-400-million-mark-in-sales

[80] https://www.accesstoseeds.org/app/uploads/2018/11/bejo-scorecard-global-seed-companies-index-2019.pdf Note that the company does not publish Annual Reports nor is it listed in Crunchbase.

[81] https://www.florimond-desprez.com/ctc/en/kr/groupe-florimond-desprez-2/chiffres-cles.html

5. Innovation in plant breeding

5.1. Plant breeding innovation over time

Since the end of World War II, agricultural production in Europe and beyond has almost tripled. Production increases were made possible due to improved technologies, fertilisers, plant protection products and new improved plant varieties. This has been achieved since "*Agricultural history is filled with moments of transformative technology adoption. […] Emerging biotechnologies present similar opportunities for agriculture*."[82]

New plant varieties with traits such as higher yields, superior quality, and resistance to pests and diseases play a crucial role in enhancing productivity and product standards in agriculture, horticulture, and forestry. To fully unlock their potential, these varieties must be supported by a range of complementary inputs. The significant advances in agricultural productivity seen in many regions across the globe are largely attributable to the development of improved plant varieties.[83] Some of the breeding programmes provided 'revolutionary' breeding improvements not only in Europe or the U.S.; the first "green revolution" in the 1960s[84] helped in particular developing countries to fight hunger. Today, **available farmland, labour input[85] and soil quality declines. To breeders, this poses a constant quest to obtain higher yield per planted hectare and to improve the resistance against constantly new biotic and abiotic stress**. While the latter is linked to external factors such as drought or floods, biotic stress originates within the plant kingdom through naturally occurring fungi, bacteria, or viruses. Plant breeders are thus faced with two types of challenges: to biotic stress, they *respond* with the development of traits coping with the particular stress factor such as a fungi. Given climate change and growing abiotic stress, they develop traits responding to current weather events, and/or they develop *traits envisaged to be* needed in the (near) future (such as drought, heat wave or frost tolerance).

Innovation brough measured yield growth - by declining capital and labour inputs. Based on a literature review and data analysis, Noleppa and Cartsburg (2021) concluded that "*plant breeding across all arable crops in the EU and its member states has a tremendous impact on innovation-induced yield growth in arable farming. In the past two decades, genetic crop improvements have been responsible for the (vast) majority of innovation-driven progress.*"[86] The opposite effects can be seen in countries that rely or relied predominantly on non-certified quality seeds: Poland, as one of the largest agricultural plant producers in Europe, was also among the three largest grain producers in the EU in the early 2010s. Yet, the avoidance of the use of certified quality seeds brought less effective results and high consumption of planting

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[82] NSF (2025) "There's a real urgency to be ready when that bioconvergence happens". Interview with T. Young in *Issues in Science and Technology*, Vol XLI, 4. available at: https://issues.org/interview-senator-young-bioconvergence/

[83] See https://www.upov.int/overview/en/improvement.html

[84] See Norman Borlaug, winner of the Peace Nobel Prize in 1970– termed father of the 'green revolution' in developing countries with his development of disease-resistant, high-yielding wheat and rice in the 1950s and 1960s. The downside of the high-performance crops was the high need of pesticides and fertilizers. See: https://www.britannica.com/biography/Norman-Borlaug

[85] Over the past 20 years, the labour input of managing farms has decreased. An average annual growth of -2.3 % was calculated by Noleppa and Cartsburg (2021). They equally calculated the declining farmland and concluded that the growth intensity is due to breeding effort.

[86] Noleppa, S., Cartsburg, M. (2021), *The socio-economic and environmental values of plant breeding in the EU and for selected EU member states. Hffa Research*

seed. Polish farmers used twice the volume of seeds than the EU-average, indicating the low yield of non-certified seed sowing material.[87]

Box 1 Key developments of breeding tools and techniques over time

In order to develop new varieties which for example respond to changing biotic and abiotic pressures, or have a commercial value such as improved nutritious values or new colours, the tools breeders use developed over time:

- Traditionally, breeding is based on the principle of **crossing and selecting** the naturally existing diversity of plants. Since the rediscovery of Mendel's rules around 1900, breeders experimented with intentional crossing between selected parent plants to obtain desirable traits. If offspring had a highly beneficial trait, it was preserved and propagated for further breeding over generations.

- **Tissue culture** is among the earliest techniques used for growing plant cells (Haberlandt 1902). Further developments led to the application of tissue culture to five broad areas, namely, cell behaviour, plant modification and improvement, pathogen-free plants angermplasm storage, clonal propagation, and product formation, starting in the mid-1960s.[88]

- In the mid 20th century, the development of **hybrid varieties** led to dramatic increases in yield in maize, followed by a range of crops. A hybrid variety is comprised of a population originating from a cross and is directly used as the commercial variety to be cultivated. Hybrids present enhanced performance and uniformity compared to either parent. Due to their hybrid nature, their offspring will segregate and result in a heterogenous population that will not perform as well as the hybrid parents. [89]

- Internationally coordinated **mutation breeding** became popular in the 1960s, mainly radiation and the use of chemicals created genetic variation. It led to numerous new cultivated varieties of many species such as broccoli, nectarines, or rapeseed. [90]

- The discovery of **molecular markers** since the early 1980s enabled breeders to track traits at the genetic level without waiting for the plant to mature. This **marker assisted selection (MAS)** technique made selection faster, cheaper and more precise.

- **Genetic engineering** tools were developed in the 1980s and 1990s. The decision in the U.S. to allow patents on genetically modified microorganisms (Chakrabarty vs Diamond 1980) and the patent on the rDNA technology (Stanford University and the University of California System) led to an uptake of genetic engineering. The available technique allows introducing transgenes into crops to obtain traits such as herbicide tolerance or insect resistance. Bt maize and Bt cotton, which are resistant to certain pests, are primary examples. In 1987, the

[87] USDA Foreign Agricultural Service (2015), Planting seed market in Poland – Outlook 2015, see: https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Planting %20Seed %20Market %20in %20Poland %20- %20Outlook %202015_Warsaw_Poland_7-30-2015.pdf Changes in seed regulation in 2016 in Poland led to an increase in production of certified seeds with the effect that the volume of required seeds has halved for example for buckwheat. See Kwiatkowsky, J., 2023, Buckwheat breeding and seed production in Poland, *Fagopyrum* 40 (2): 29-40. https://doi.org/10.3986/fag0032

[88] Thorpe, T. (2006), History of plant tissue culture, Methods Mol Biol, 318:9-32. doi: 10.1385/1-59259-959-1:009. PMID: 16673902.

[89] Ayiecho, P.O., Nyabundi, J.O. (2025). Hybrid Varieties. In: Conventional and Contemporary Practices of Plant Breeding. Springer, Cham. https://doi.org/10.1007/978-3-031-74998-8_10

[90] FAO (2011), Plant mutation breeding and biotechnology, Available at: https://openknowledge.fao.org/server/api/core/bitstreams/a25f529d-592b-4368-9965-6c77696f00f1/content

U.S. start-up Calgene obtained a patent in the U.S. on a tomato with a trait for longer shelf life.[91]

- The **genomic sequencing** of crop genomes provides understanding complex traits. The first full genome sequencing of the model plant *Arabidopsis thaliana* in the year 2000, is hailed as the turning point for the modern plant breeding research. Since then, hundreds of plant species, including all major agronomically relevant crops (such as rice (2002/2005), maize (2009), soybean (2010), millet (2017), wheat (2018), and oat (2022)), root crops (potato (2011)), vegetables (chickpea (2013), brassica (2014), cassava (2016), pea (2019)), or fruits (papaya (2005), apple (2010), peach (2013)), have been sequenced.[92]
- Since around 2010, **CRISPR/Cas** and other **genome editing technologies** allow breeders to target modifications without introducing foreign genes. In particular CRISPR/Cas9 has been in the focus and is a key patented technology (see section 5.4.2) with applications in plants since 2014. The system has been continuously developed since its discovery and a broader range of tools are available such as **base editing** or **prime editing**. These use different tools such as Cpf1 (now called Cas12a).[93]
- **Speed breeding** – combination of techniques used under controlled environments to accelerate the plant growth cycle while **machine learning** and **genomic data analysis** provides breeders with tools to optimise breeding decisions (**precision breeding**). Various companies – in particular in the U.S. - offer platforms to develop the envisaged plant as service providers (e.g. GreenVenus, Pairwise).
- **Integrated approaches** for 'next-generation plant breeding' – increasingly breeders can use integrated pipelines (platforms) that offer convergence of multiple advanced methods to optimise the development of improved plant varieties. Genomic selection, speed breeding, genome editing and pangenomics, high-throughput phenotyping are combined with machine learning and the integration of -omics – to name currently available tools.
- Other tools including high-throughput phenotyping and genotyping expanded the array of tools and enabled the rapid analysis of large numbers of plants and their genomes.[94]

5.2. Length of the innovation process

The innovation process of new varieties involves five stages: discovery, proof of concept, early development, advanced development and pre-launch[95]. According to interviews, the development of a variety from discovery to pre-launch takes on average 10 to 15 years. This range varies, however, by type of species[96] and necessary market authorisation trials. In the EU the latter takes two to three years. It is the **official variety testing phase** for the stability

[91] Under the name 'Flavr Savr', the tomato became the first gene edited food on the U.S. market, available between 1994-1997. Calgene was acquired by Monsanto in 1997

[92] Purugganan, M., Jackson, S. (2021), Advancing crop genomics from lab to field, *nature genetics.* Available at: https://purugganan lab.org/Papers/2021/Advancing %20crop %20genomics %20from %20lab %20to %20field.pdf

[93] For a short introduction and the legal situation about Cpf1 (Now Cas 12a) see : https://www.juve-patent.com/cases/epo-upholds-three-broad-institute-patents-for-next-generation-crispr-cas12a/

[94] An overview of applied research tools in dedicated studies is included in Ricroch, A. et al (eds) (2024), *A roadmap for plant genome editing*. Springer. Available at: https://link.springer.com/book/10.1007/978-3-031-46150-7

[95] Jewell, C. (2015), Who benefits from IP rights in agricultural innovation? WIPO Magazine, 21. 08.2015, available at: https://www.wipo.int/en/web/wipo-magazine/articles/who-benefits-from-ip-rights-in-agricultural-innovation-39238

[96] See https://www.plantetp.eu/wp-content/uploads/2024/10/pd-the-process-of-bringing-new-plant-varieties-to-the-market.pdf

of the traits, before a variety can be commercialised. Breeders can try to plan the seed propagation periods with the required testing phase simultaneously.

Within the average of 10-12 years, the discovery, or **research phase,** offers the largest degree of freedom: Depending on the plant species, the breeder can choose a mix of tools. Through the use of new genomic techniques as well as data-based prediction tools, breeders are able to reduce the research phase significantly.

The **biological phase**, namely the processes from seed to harvesting the next seeds, depends on the biological cycles of perennial or non-perennial plant species (one or two years), and the propagation to large quantities, which takes some more plant generations. Interviews with plant breeders indicated that these periods from the development onwards cannot be shortened since they are essentially biologically rooted (ID_3, 5).

5.3. Key actors and the development of traits

Plant breeding is one part of the wider agricultural value chain. Everything considered part of the initial stages before the harvest of the seeds or other plant reproductive material is considered part of the **upstream sector**. It includes the research and development phase of seeds as well as production of plant reproductive material. The downstream sector covers the farmers, processors, distribution, packaging, and trading actors. While some of the harvested plants is intended for foodstuff, the majority are further processed in industry as feedstuff but it can also be treated as bio-based material or used for biofuels.

Beside direct economic, social, and health benefits for actors across the value chain, **environmental benefits** play an increasingly important role in driving trait development to reduce the use of pesticides, or fertiliser; improve soil structure, extended shelf life, and help to reduce food waste.

Yet, the successful development of – for example - a variety tolerant to diseases or abiotic stress today does not mean that the variety will remain tolerant in five years' time since other stress factors may develop in the meantime for which new solutions are needed. Thus, breeders constantly need to improve plant properties. According to interviews with breeders, a new trait may have a commercial value for about 20 years while a variety stays on the market for 4-6 years.

With the advent of the new genomic techniques, a range of new actors emerged, which are in particular relevant for the research and development phase. One can identify academic **spin-offs and start-ups** that base their businesses on commercialising a newly developed trait. Others offer specific services based on a platform that operates thanks to licenses of the foundational technical innovations through which genetic modifications are enabled. Such a business model is based on patents and licenses.

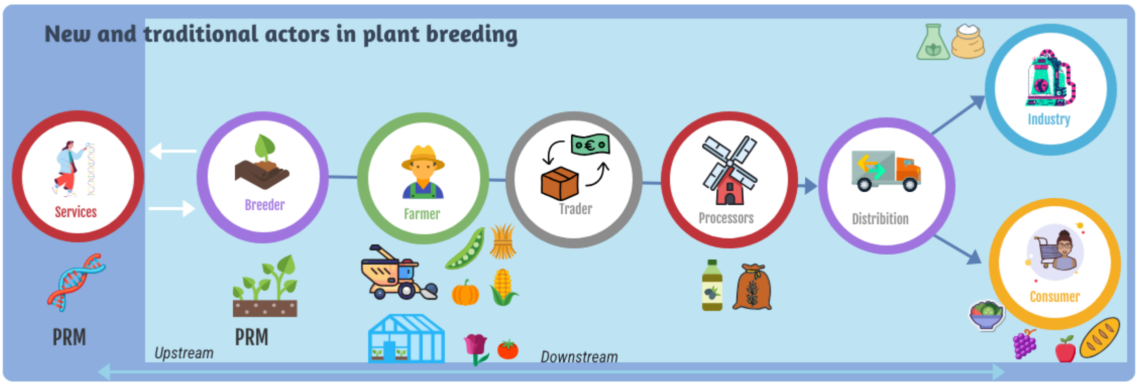
Individual start-ups are currently testing a range of NGT based traits for sustainability in agriculture, such as the Korean ToolGene's drought-resistant bell pepper or the Spanish Grupo Lucas testing of a gene edited broccoli that can grow even in salty or dry soil. The Italian research Institute Edmund Mach has developed a grapevine variety through point mutations that is resistance to downy mildew, while the Norwegian Institute of Bioeconomy Research developed the first a gene-edited iceberg lettuce resistant to white mould.[97][98]

[97] See https://www.plantetp.eu/information-hub/ - Factsheets NGT crops for… series

[98] See https://www.nibio.no/en/news/the-worlds-first-crispr-lettuce-with-increased-resistance-to-fungal-disease

With the development of the platforms and individual technologies, the offerings of the service providers expand.

Figure 4 Key actors in the plant breeding value chain



Source: Technopolis Group

Breeders

Breeders have the choice to develop traits based on traditional cross-breeding, invest in their own R&D research infrastructure, or make use of specialised service providers. This latter option is particularly interesting when breeders lack access to the necessary research laboratory, equipment, and skilled personnel – which seems to be the standard condition for small and medium-sized breeders.

In case a **trait developed by a breeder** is also patented, the breeder has two options: they can **license the trait** or decide **not to grant licenses**. Interviews with breeders suggest that traditionally, breeders develop their own plant varieties and market them, but they also license their developed trait to competitors. This has a) **economic benefits** of licence income (~5 % of the revenue on net sales from every licensee, and b) potentially wider **societal benefits** if a trait resolves biotic or abiotic stresses or increases the yield. Furthermore, not offering a license may be **reputation damaging**: 'Nobody in the breeding sector wants to be known as not sharing an innovation' and keeping the trait exclusively. (ID_5, 20, 22)

Yet, an interviewee indicated that it is less of a level playing field than often portrayed: in some cases, it is not in the interest of a breeder to grant licenses. Depending on the attractiveness of a trait, keeping exclusivity excludes other market actors and can lead to market concentration (ID_22).

Research organisations

There are equally **research institutions** (universities or dedicated plant breeding institutes) developing technologies and/or traits. To them, patents have various functions. Having a patent on certain aspects of a technology provides the organisation with a **stronger position in negotiating** partnerships for a commercial R&D collaboration.

Equally important is the **signalling function** for external private funding. It allows research organisations to foster spin-offs by attracting venture capital (VC). To venture capitalists, patents have a value. Thus, growing an IP portfolio can be a goal of a public research organisation. Developing a technology may result in numerous patents. If such a technology is benefitting various players, interviewed breeders associations prefer non-exclusive licenses.

In collaborative research projects, academic institutions may prefer to provide exclusive licenses to their commercial partners or own spin-offs. Exclusive licenses can be limited to a certain use of a certain area, thus providing the opportunity to set up a broader range of exclusive licenses. Yet, to several interviewees and experts, exclusive licenses based on public research should be avoided. Instead, patent pools and non-exclusive licenses under FRAND terms would provide greater societal benefits (see also section 8.4.1.3.) (ID_2, 4, 7, 10, 21).

Farmers

Farmers require seeds adapted to open-field or glasshouse cultivation. In terms of traits, farmers are interested in biotic or abiotic stress tolerances throughout the growing cycle, from germination to harvest. Furthermore, they seek traits on food or feed quality, increased plant yield, industrial utilisation, resistance to pest and diseases, or tolerance to abiotic stress[99]. Some traits may have little or no commercial value but are important to farmers because they make cultivation and harvesting easier and potentailly less costly – such as thornless berries or dwarf tree varieties.

Seeds with improved, patented traits are usually more expensive than those without. However, if a trait provides benefits such as pest or disease resistance, the farmer may have better yield or reduced production costs and they reduce the use of pesticides. A trait such as drought resistance is key where water is scarce and costly. The higher seed cost may be offset by reduced irrigation needs. As a result, farmers can lower their input costs and lessen environmental impact.

Food processors and wider industry

Food processors also benefit from plant varieties with specific traits, such as improved nutritious value[100] or traits that reduce energy or chemical inputs during the processing – e.g., for producing flour, starch, or sugar.

Similar to food processors, specific traits can benefit a wide array of industry sectors which use plant-based components. Industrial starch for example is used as a component in textiles, pharmaceuticals, bioplastics, paper and packaging, painting and coating, etc.

For animal feed quality, improved digestibility and processing traits are key. Research into lignocellulosic fibres, such as altering the lignin composition is an area where plant breeders have various opportunities to adapt various plants and processors differing demand.

5.4. Research and development trends

The plant breeding sector spends heavily in R&D with around 16 %[101] of its turnover. This is comparable to the research-intensive pharmaceutical sector. The German plant breeder association indicates an R&D intensity of 16 % of annual turnover[102], some larger breeders indicated an even higher share of up to 30 %. 35

[99] These categories are used by the EU-SAGE network and its database. See: https://www.eu-sage.eu/genome-search

[100] Known as biofortification, conventional and GMO methods are used to increase staple crops as well as fruit crops to provide otherwise deficient elements such as proteins, essential amino acids, vitamins or minerals to plants. The development of ('golden rice' for example addressed the vitamin A deficiency in various Asian countries. See for example Naik et al (2025), Biofortification as a solution for addressing nutrient deficiencies and malnutrition, Heliyon, Vol. 20/9.: https://doi.org/10.1016/j.heliyon.2024.e30595

[101] Interview ID_19, contribution of Limagrain to 'Have your say' on Plant variety rights – evaluation of EU legislation, see: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14037-Plant-variety-rights-evaluation-of-EU-legislation/feedback_en?p_id=35249177&page=1

[102] https://www.bdp-online.de/de/Branche/Kennzahlen/

Even before new breeding techniques became more widely available, the R&D intensity of crops and GM was estimated with 10 %.[103] Yet, the larger shares are mainly seen with medium and larger breeders. Small breeders, which employ often less than 10 people, have much lower R&D costs.

The **costs for developing a new plant variety vary**. The literature mentions an average of €360 000. However, the effort varies significantly depending on the type of plant. For arable crops such as potatoes, cereals, maize, oilseeds, protein crops, sugar beets, etc., the cost ranges from €210 000 to €525 000. For perennial crops like fruit or vines, the cost per variety can be as high as €1.2 to €1.7 million.[104] Interviews indicated similar ranges of €220 000 to €1 million.

A large company such as Bayer Crop Science released over 490 new hybrid and varietal seeds worldwide in 2024[105]. Depending on the segment (i.e., agricultural crops, vegetables, ornamentals, etc.), international breeding firms typically release between 150 to 180 new varieties a year. Large breeders often maintain (i.e., continue paying the annual fees for) hundreds of protected varieties. In contrast, smaller breeders may only maintain a handful or a few dozen, as reflected in the data from the CPVO database[106]. On average, a variety remains on the market for less than ten years.[107] (ID_1, 5, 20, 21, 22)

The development of traits happens at much lower levels. For example, Bayer Crop Science – as globally the largest seed company – has "*12 next-generation traits in development*"[108]. Expected to be launched in 2027 are two 'biotechnology traits' in maize on crop efficiency and soybeans on weed management.

5.4.1. NGT-based plant research

While not many NGT plants are on the market – so far none within the EU – some expect that this is a matter of time. Interviews with breeders confirm that different genomic techniques are applied in the R&D process, yet, the extent can only be proxied through patent disclosure. Another indication is provided with the EU-Sage database which includes academic publications relevant for plant breeding.[109]

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103 See Fuglie et al (2011), as cited in OECD (2018), Concentration in seed markets. Potential effects and policy response. OECD, Paris, p. 18.

104 Eidgenössisches Justiz- und Polizeidepartment EJPO (2024), Vorentwurf der Revision des Bundesgesetzes über die Erfindungspatente. Erläuternder Bericht zur Eröffnung des Vernehmlassungsverfahrens.

105 As mentioned in the Bayer Annual Report 2024, p. 39, available from: https://www.bayer.com/sites/default/files/2025-03/bayer-annual-report-2024.pdf

106 See https://online.plantvarieties.eu/publicSearch

107 Contribution of Dachverband Kulturpflanzen- und Nutztiervielfalt e.V. on Plant variety rights – evaluation of EU legislation, see: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14037-Plant-variety-rights-evaluation-of-EU-legislation/feedback_en?p_id=35249177&page=1

108 Bayer Annual report 2024, p39, available from: https://www.bayer.com/sites/default/files/2025-03/bayer-annual-report-2024.pdf

109 Only English-language scientific publications are covered. They are selected based on several pre-defined criteria, the main being "*the research article should describe a research study of any crop plant in which a trait has been introduced that is relevant from an agricultural and/or food/feed perspective*". The database does not provide information about the development stage nor if the crop plants are to be marketed. See: https://www.eu-sage.eu/

Research on traits for plant innovation is an early indication of what could emerge in the innovation pipeline. A comparison between August 2022[110] and April 2025, offers a snapshot of the dynamics in this area.

In August 2022, research activities covered roughly 550 traits. Two and a half years later, this number had almost doubled to 1,000. Most of this growth occurred outside the EU, mainly in China. The EU's figures rose from 77 to 125, research in the rest of the world expanded from 469 to 875. This corresponds to an average annual growth rate of about 37 % outside the EU, compared with 27 % within the EU.

The traits are researched and disclosed in 1 250 relevant studies in which one or more research teams are involved; this is a higher number than the number of traits researched (see Figure 5). The vast majority of the research projects are located in China (560, 46 %), followed by the U.S. (187, 15 %), Korea (46, 3.7 %), and Japan (44, 3.5 %). The first EU-MS is France with 2.7 % (34 studies). The EU as a whole has a share of 11.8 % (147). For the EU, 14 countries are involved. Beside France, Germany (31), Italy (21), the Netherlands (14), Belgium (12), and Spain (11) which are in the range of two-digit figures while the remaining countries Sweden, the Czechia, Hungary, Portugal, Poland, Denmark, Greece, and Austria, range from seven down to one study.

Another noticeable indicator is the **number of plant species researched**. Worldwide, 79 species are researched, ranging from rice (with more than 300 studies), and tomato (140) down to 37 individual plant species with only one or two studies. These include rare plants such as water spinach, flax, or chicory. One can note that there are by far more studies on plants whose entire genome was mapped early on such as rice, tomato, or soybean but research has expanded. European research teams focus on tomatoes (29 studies), followed by rice (16), potatoes (12), and barley (9). Altogether, 29 plant species are focused in Europe.

Finally, when it comes to the technology used, there is a significant **increase of CRISPR/Cas** studies. Whereas the share of Talen (30), BE (27) ZFN (7), and ODM (6) techniques was 12 % in 2022, they decreased to 7 % in 2025. Talen and BE are mainly used in research on rice in China and the US. CRISPR/Cas based studies almost doubled in these 2.5 years from 480 to 925 (93 %). Yet, the average annual growth in the EU is seven percentage points lower than in the rest of the world.

In terms of research on traits and their destination, one can observe that European research in NGTs is to a large part directed to biotic stress tolerance. Worldwide, abiotic stress tolerance is by 2025 the single most relevant research purpose, overtaking 'improved food/feed quality' and 'increased plant yield/growth', which dominated in 2023. The highest growth worldwide can be observed in 'biotic stress tolerance' with an impressive growth due to international research projects.

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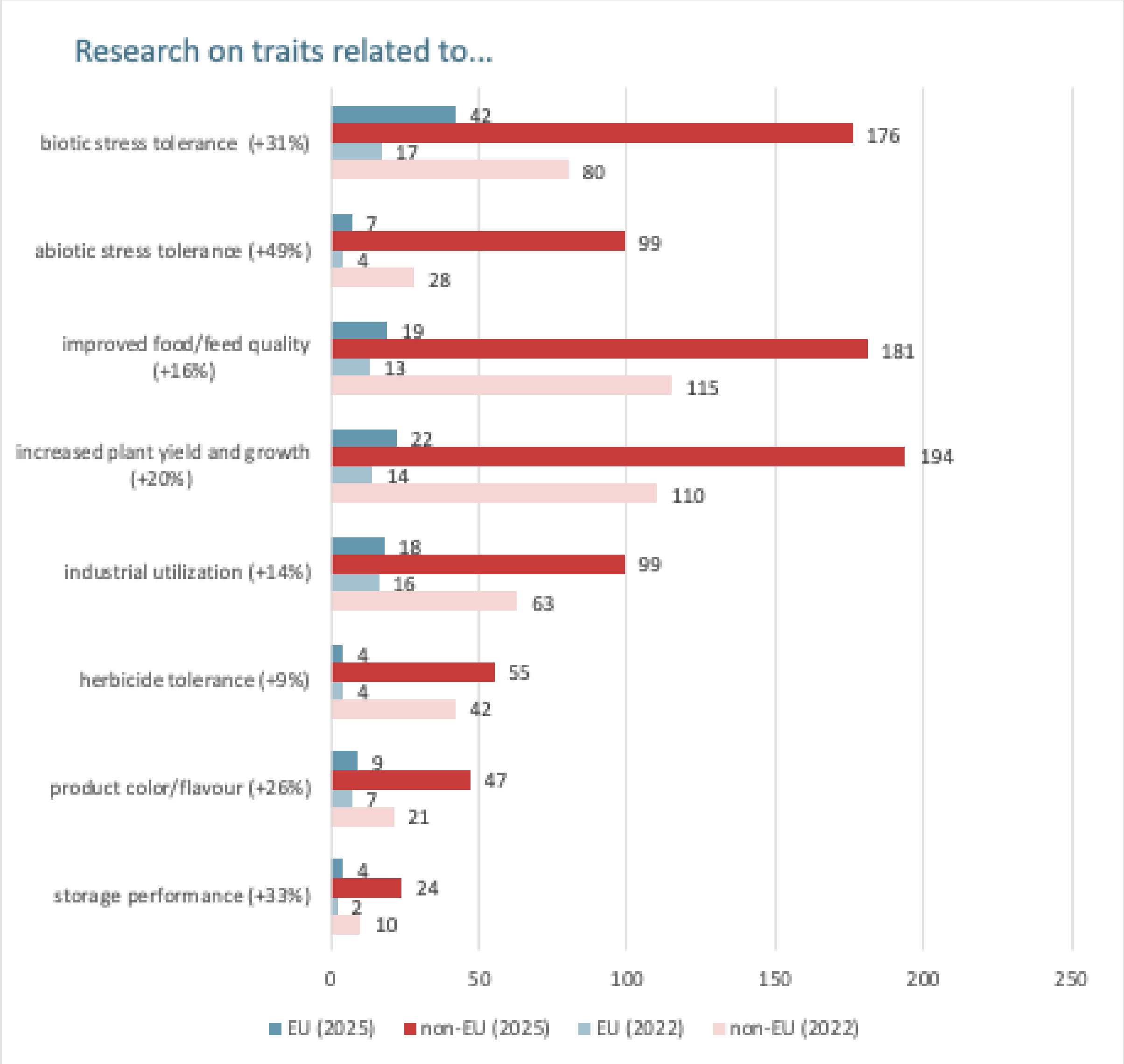
[110] The data for Augst 2022 was used for the support study on the legislative proposal on NGTs by Technopolis Group. See: EC (2023) Study to support the impact assessment of legislation for plants produced by certain new genomic techniques. Final report. Available at: https://op.europa.eu/s/z4N4

Figure 5 Research on traits by categories, EU vs rest of the world, totals, average annual growth by trait category (in brackets)



Source: EU-SAGE, analysis: Technopolis Group. Database accessed 22.8.2022 and 3.4.2025. 88 % (93 %) of the projects in 2022 (2025) are based on CRISPR/Cas

From NGT research to uptake and commercialisation

Yet, this growth in studies using CRISPR/Cas – and thus, a technique that allows the development of NGT plants, was not unanimously seen as a key indicator for the uptake of NGTs. To some breeders portraying NGTs as 'the' solution was overestimated, others indicate that it adds a very useful tool in the already broad toolbox of breeders. In particular small organic breeders and civil society groups expect that in the longer run, NGTs will dominate the markets. Various intervieweeswith breeders and R&D service providers indicated that already now, a range of techniques are used that render the search and research phases more efficiently (see Box 1 above); if NGTs can be added to the toolbox and shorten the processes further by 20-30 %, this will be key in developing solutions for farmers in a shorter time. (ID_5, 8, 20, 22)

Interviewees pointed out that the current cost of the technology license is only one aspect to consider. Much higher would be the **investments needed to transform a business** based on (conventional) greenhouse skills and educated personnel, to a business based on a lab and the skills of more costly research personnel. An alternative avenue could be provided by specialised service-providers; companies, that could provide the necessary specialised research skills to those companies lacking the technical expertise. This would add costs to the conventional breeders (for the 'outsourced' research) but opens up commercial gains as well. It is an economic calculation if those necessary investments are more beneficial to breeders than conventional breeding.

In the public consultation on NGTs (2023)[111] various citizens, academic, and private sector stakeholders indicated that **access to the patented technology** is also key for SMEs.[112] This may offer a range of opportunities to small breeders to develop varieties for a regional demand and offer farmers a wider choice of suppliers and less dependence on large corporations.

In this study, interviews with breeders and also academic researchers indicated that in the area of genome-edited plants, not everything will be patented. There are various reasons for patenting or not patenting plants obtained by NGTs: Interviews with breeders pointed to licensing aspects of the process technology: the use of the technology (such as CRISPR/Cas) for the development of traits is based on a license. Not only are licensing procedures lenghty, but **licensing conditions** typically foresee milestone payments for the technology providers for out-licensing such developed traits to third parties.The sub-licensee will therefore take into account potential (or likely) payments in his or her calculation.

Parallel to the licensing costs, the licensee takes into account the patenting procedure: Since a patent is typically applied very early in the innovation process – but the development of a new variety with an attractive new (patented) trait takes between 8-15 years[113], the actual time left to license the trait (and recover part or all of the process technology license costs) is about 5-12 years before the patent expires.

If the remaining (commercially viable) period is short – such as the indicated five years, breeders indicated that this is sufficiently long to gain **market shares from being the first on the market**. Due to the needed time to propagate sufficiently large volumes by competitors, the first to market will likely have this competitive advantage for the time a patent would provide protection. In such a case, again, patent protection may not be envisaged as it could be a sunk cost factor.Thus, the decision to patent or not, takes into account the costs for potential technology licences and the patenting process.

In one focus group, additional factors were pointed out with product cycles and regulation. In the case of horticulture, NGT use is expected to be very limited due to the (still) high costs and very short product cycles. For fruit and vegetables, regulation was mentioned. If product labelling should be mandatory for NGT developed fruits and vegetables, growers and retailers could be reluctant to introduce those, fearing a negative consumer choice. The most promising area for NGTs – and patents - are crops such as maize where traits can rather easily be developed and the commercialisation can be broad.

[111] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

[112] Question 17. Do you think any regulatory measures should be included in new legislation to facilitate the uptake of these technologies by small and medium-sized enterprises?

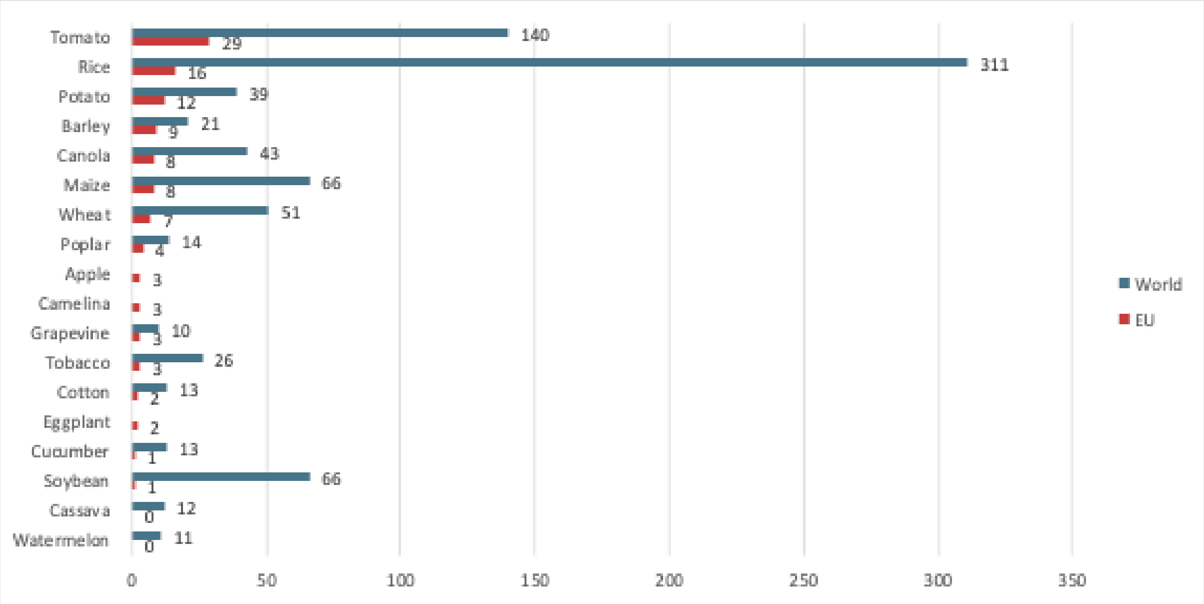
[113] Without the use of NGTs

The literature equally suggests opportunities for forest tree breeding.[114]

Beside the decision to patent or not, interviewees pointed out that patents on traits need to fulfil the regular patentability criteria of novelty, inventive step, and industrial application. This provides for quality in patents but also makes it difficult to patent "me-too" traits. Not every change introduced by a NGT will lead to a new invention and therefore a patentable trait. Also, the increase of academic literature and thus a wide disclosure will affect the application of the patentability criteria.

Today, only a few NGT plants are available worldwide, and those are rather niche plants. If and which ones may be the first on the market in Europe is not clear. Some interviewees expected that the first to be on the European market would be those where commercial expectations can be met such as tomatoes, broccoli – in essence greenhouse crops. Figure 6 shows that in particular tomatoes, and field crops such as rice and potatoes are the more frequently studied plants in European research while vegetables and fruits are rarer. (ID_1, 2, 5, 22)

Figure 6 Most frequently studied plants



Source: EU-SAGE, analysis: Technopolis Group. Database accessed 3.4.2025

Despite the various advances in genetic techniques, their use and effects vary by plant species. "*The genetic architecture of crop traits (…) remains incomplete*".[115] The complexity of crops complicates the identification of polygenic traits. This has been indicated as a hampering factor for why there have been no significant improvements in complex plant species such as wheat, and to some interviewees, this is also a reason why they would not see '*all kinds of plant species produced with NGTs'*. At least from today's perspective, the use of NGTs is primarily thought for greenhouse culture, which, compared to field cultivation, requires 'high-tech, high-performance' seeds which guarantee high yield.

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[114] Chenglin, L. et al (2025), Forest tree breeding under the global environmental change: Challenges and opportunities, *Trees, Forests and People,* Vol 20, 100867. Available at: https://www.sciencedirect.com/science/article/pii/S2666719325000937

[115] Cf fn 92

To several interviewees, **legal certainty** was the key factor that will trigger the development of NGT products. Whether plants made with technical means can be patented, was – for several – of lower importance. Given the number of studies as indicated through the EU-SAGE database, several expect that NGT plant varieties will be developed in Europe, once their legislative framework is provided.[116] Interviews confirmed that it will be a matter of time, when Europe may see the first commercialised plants. At present, many European breeders are hesitant given the burdensome existing and lacking enabling legal framework. (ID_1, 2, 5).

5.4.2. Patented foundational technologies: CRISPR/Cas

Based on the EU-SAGE database of relevant studies as well as interviews, CRISPR/Cas is the dominant technology used within plant breeding. It provides the highest potential to shorten the research phase, as indicated by several interviewees. Its relatively wide use in research – as measured by the EU-SAGE documented research projects – suggests that there is a growing skilled researcher base and a relevant knowledge base. While some may remain in academic research, others may move and serve as a basis for future service-oriented research firms or researchers in private sector breeding firms.

Box 2 Basics on CRISPR technology IP & licensing

With the Broad Institute, MIT, and Harvard (“*Broad*”) on the one hand, and the University of California and the University of Vienna (“*CVC*”) on the other hand, two groups hold foundational CRISPR/Cas patents. With Toolgen and Sigma Aldrich, there are two more players with (internationally) pending successor patent applications covering usage in eukaryotes.[117]

Patents were first filed in the U.S.

- CVC filed the first provisional patent application in the U.S. 25 May 2012 targeting human cells.
- Broad published results on experiments with mice 5 October 2012 and filed a series of provisional patent applications in a fast track procedure in October 2012 and January 2013 on eukaryotic cells.
- In March 2013 the U.S. changed from a first-to-invent to the first-to-file system.
- Broad’s patent application was granted in April 2014 (US patent 8697359). CVC has challenged the decision unsuccessfully. A second patent interference dispute followed in 2019. In 2022 the USPTO Patent Trial and Appeal Board (PTAB) decided that Broad were the first to invent the single guide RNA version of the CRISPR-Cas9 system to edit genes in eukaryotic cells. The decision was again opposed by CVC. In May 2025, the U.S. Court of Appeals for the Federal Circuit agreed in part and has sent back the case to the PTAB for reconsideration.
- In 2019, CVC obtained its third foundational patent in the U.S. protecting claims to the use of CRISPR-Cas9 in any cell. This requires users to obtain licences from both parties.

At EPO:

[116] There is a legislative framework with the Biotech Directive, but interviewees generally referred to a new legislation for NGTs that would provide the legal framework for NGTs.

[117] For a short overview of the four main patenting entities and their claims, see for example: Genomics Series: CRISPR/Cas patent disputes - the position in Australia https://www.lexology.com/library/detail.aspx?g=1042234f-22ef-4292-8a18-adbde34387cd, BROAD Institute: Statements and background on the CRISPR patent process, available at: https://www.broadinstitute.org/crispr/journalists-statement-and-background-crispr-patent-process; JUVE Patent: EPO upholds three Broad Institute patents for next generation CRISP-Cas12a, available at: https://www.juve-patent.com/cases/epo-upholds-three-broad-institute-patents-for-next-generation-crispr-cas12a/

- CVC applied its first patents in March 2013. EPO granted CVC patent EP2800811 in March 2017, EP340140081 in February 2019 and EP3597749 in May 2023. The first two applications were withdrawn in September 2024. All three faced opposition, the currently still valid patent faced an opposition filed in April 2024 and had its oral proceeding set for November 2025.
- Broad has filed 29 CRISPR-Cas9 patents at EPO. EPO revoked several (including EP2771468 due to lack of right to claim priority in 2019). In March 2023, EPO's Opposition Division upheld three Broad patents for the next generation CRSPR-Cas12a (EP 3 502 253, EP 3 310 917, EP 3 470 519).
- For plant breeding and the European territory, the **foundational patents of the Broad Institute** are key. CVC group still holds one foundational patent on the use of Cas9. In Europe, Broad's foundational patents were revoked in 2018, two foundational CRISPR patents of CVC were equally revoked in October 2024, followed by Sigma-Aldrich in December 2024. "*This not only creates uncertainty in the CRISPR field but also an inefficient use of EPO resources*".[118]
- Given that the **foundational patents** were all applied in 2013, they **will expire** (in all main geographies) **in 2033**.
- Today, there are **more than 11,000 CRISPR-related patent families filed** worldwide.[119]
- The technology modularity of the CRISPR/Cas system provides that its elements can be modified or substituted. They may result in 'follow-on' patentable modifications or improvements of the basic technology and its specific applications.[120]
- In the U.S. and other jurisdictions, **legal battles around and about the foundational patents and their claims are ongoing**. This has however not stopped CVC and Broad to issue a number of exclusive/ non-exclusive licences: in the field of agriculture, CVC has granted exclusive licenses to Corteva while Broad issued non-exclusive licenses in the field of agriculture, among others, to Corteva.
- There are several systems similar to CRISPR and alternatives to CRISPR/Cas9 available.

Since the U.S. patent filings on CRISPR/Cas9 in 2012, a "burgeoning CRISPR/Cas patent complex" has built up.[121] WIPO points out that the **determination of ownership** plays a crucial role in driving innovation. Without clear ownership, as is the case in the CRISPR technology, "*it becomes difficult to identify who holds the rights to license a technology, creating uncertainty that can hinder further development and investment*." In this sense, litigations that clarify or resolve disputes over ownership are essential while revocations – as seen with several foundational CRISPR patents – do not provide this clarity.[122]

Interviews confirm the dilemma: In particular the revocation of the CVC patents at EPO 2024 leave companies with the question if they still require a CRISPR/Cas9 licence in Europe. Since most foundational patents for enabling technologies are held by U.S.-based academic institutions or, as in the case of CVC, by its exclusive U.S.-based licence holder, European breeders need to negotiate with new business partners. These may not fully understand the

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[118] *Troubling Trend of "Self" Revocation in the CRISPR Space Continues in Europe,* see: https://www.proskauer.com/blog/troubling-trend-of-self-revocation-in-the-crispr-space-continues-in-europe

[119] CRISPR-Cas: *Navigating the Patent Landscape to Explore Boundless Applications*, see: https://www.wipo.int/en/web/global-health/w/news/2024/crispr-cas-navigating-the-patent-landscape-to-explore-boundless-applications

[120] Schweizerische Eidgenossenschaft (2024), Vorentwurf der Revision des Bundesgesetzes über die Erfindungspatente,

[121] Kim, D. et al (2024), CRISPR/Cas technology and innovation: mapping patent law issue, Max Planck Institute for Innovation and Competition Research Paper Nr. 22-06

[122] Cf fn 119

European breeding model, while European breeders themselves are not necessarily experienced in dealing with large U.S. private and public patent holders. (ID_8, 11, 16, 22).

Given the large number of technology patents, the view has been voiced that "*any commercial action [will need] to obtain licenses for multiple patents from multiple groups. There is no true patent pool to simplify the process of licensing*".[123] The current landscape of licensing arrangements in agriculture reflects this complexity. Broad has non-exclusive licenses with the large agrochemical companies Bayer (through Monsanto), BASF, Corteva, and Syngenta, but also Vilmorin & Cie, Pairwise, etc. CVC has given non-exclusive licenses (e.g. Cas9 to Vilmorin & Cie), as well as an exclusive license to Corteva.[124] Corteva's patent portfolio makes it a very strong player in providing the necessary sub-licenses within Europe. The company decides to whom and under which conditions it is sub-licensing.

In practice, licensing requirements depend on the type of user. Research institutes benefit from non-assert provisions and do not require licenses for a use of Cas9 from Broad or CVC.[125] Commercial companies by contrast, require a license.

Information about licence costs is not publicly available. Interviewees did not reveal details but shared "what they heard". Obtaining a technology license is a time-consuming and costly endeavour. Breeding firms need in-house or hired legal experts to be able to negotiate. The licensing costs can vary according to size of the company. What has been observed is that licensors use their bargaining power to obtain royalty payments beyond the time when the foundational patents will expire in 2033.

[123] Swiss Federal Institute of Intellectual Property (2024), CRISPR technology: patent and license landscape. Report prepared by SCBT-Centredoc, version 05.02.2024., p. 34.

[124] ibid p. 37.

[125] The situation about potential licensing from Sigma and Toolgene is not yet clear.

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6. Intellectual property tools in plant breeding

6.1. Patents and other intellectual property tools

A primary purpose of intellectual property rights is to provide incentives and rewards for inventions. Key functions include:

- Enabling a return on R&D investment
- Motivating further development of new and improved plants
- Granting temporary exclusive control over an innovation and its use
- Providing enforcement against infringement
- Disclosure of the invention allowing others to build upon or design around

The effectiveness of the different IPR tools, in particular patents and their use, depends on a range of aspects:

- **Sectoral differences**: Patents are highly significant in fields of regulated technologies with long innovation lifecycles and significant investments (e.g., pharmaceuticals, crop protection, GM plants). In sectors with fast innovation cycles and lower investments (e.g., food products) other forms of protection (e.g., trade secrets) dominate. [126]
- **Firm size**: For start-ups and SMEs, patents are often essential to attract investment and enable partnerships. For large firms, they serve to protect R&D investments and market position.
- **IPR strength**: The relation between strength of protection and incentive for innovation is a matter of balance: If protection is too weak, there is less incentive for primary innovation. If protection is too strong, there might be less space for follow-on innovation.
- **Strategic behaviour**: Patents can be combined with other measures such as trade secrets, which may create barriers to entry for third parties.[127] Patent thickets with overlapping rights may further hinder follow-up innovation.
- **Competition**: Patents shape competitive dynamics. As a temporary monopoly, patent holders can prevent competitors from the use of the patent. Yet, the disclosure may also incentivise competitors to reverse engineering and innovation. Often, the patent holder aims to recoup investments made through licensing. Licensing restrictions, exclusivity clauses, or cross-licensing may structure competition.[128] While patent pools may mitigate some economic inefficiencies, they may create antitrust concerns.

Overall, patents and other IPRs play an important role in incentivising and protecting innovation. They provide legal certainty for innovators, attract investments, and help secure retuns on longterm R&D investment. At the same time they generate costs for application,

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[126] Kim, D., Kock, M. et al. (2024). New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector, GRUR Int. 2024, 323, 335

[127] Gallini, N, (2002), The Economics of Patents: Lessons from Recent U.S. Patent Reform, Journal of Economic Perspectives—16/2, pp. 131–154 . see: https://pubs.aeaweb.org/doi/pdf/10.1257/0895330027292

[128] From an economic theory point of view, patents are a second-best solution to overcome market inefficiencies in knowledge markets because they create inefficient temporary monopolies. See Thumm, N., Blind, K (2025), Introduction to A Modern Guide to Patents, in: A modern guide to patents. E. Elgar. Available at: https://www.elgaronline.com/edcollchap/book/9781035308606/chapter0.xml

protection and enforcement,[129] create legal complexities for competitors, and have other unintended effects on market dynamics.[130] Their effectiveness is sector-specific, context-dependent, and subject to strategic behaviours in the market.[131] ,For example, biotechnology is the most IP-intensive sector in the EU, with nearly half of start-ups using patents or registered trademarks.[132] There is also a positive correlation between IPR use and firm performance, yet, while almost 50% of large firms in the EU own IPR, the share of SMEs is lower with 10%.[133]

The effects of patents on innovation are not uniform but vary depending on sector, firm size, and the wider regulatory framework. Especially, when both IP and regulatory entry barriers exists, it is inherently difficult to distinguish whether the entry effect is based on IPR, regulations, or an antagonist interaction of IPRs and regulation.

In plant breeding, the empirical evidence base is thin. Overlapping rights, unclear patent scopes, and weak breeder's exemptions have been argued to deter new entrants and slow cumulative innovation.[134] Large patent portfolios, combined with regulatory hurdles and technological developments, are seen as a driver of consolidation in the sector by raising barriers to entry.[135]

Table 4 provides an overview of the most common IP tools, which vary in scope, but generally provide breeders with legal frameworks to safeguard their investments in developing new varieties.

[129] Moir (2008), 'What are the costs and benefits of patent systems'

[130] Such as excessive monopoly power that may impede further innovation, as well as excessive propertisation (too many patents)

[132] EUIPO/EPO (2023), *Patents, trade marks and startup finance: funding and exit performance of European startups.* Available at:https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2023_Patents_trade_marks_and_startup_finance/2023_Patents_trade_marks_and_startup_finance_FullR_en.pdf

[133] EUIPO (2025), *Intellectual property rights and firm performance in the European Union*. Available at: https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2025_IPRs_firm_performance_in_the_EU/IPRs_firm_performance_in_the_EU_FullR_en.pdf

[134] Kim et al., (2024), CRISPR/Cas technology and innovation: mapping patent law issues

[135] Louwaars et al., (2009), The future of plant breeding in light of developments in patent rights and plant breeder's rights

Table 4 Overview of available IP protection tools for plant breeders

	Plant Variety Rights	Patents	Trademarks	Trade Secrets	Contracts
Scope	Protects new varieties of plants.	Protects inventions: products and processes.	Protects brand names and logos on goods and services. Distinguishes goods and services of one enterprise from another.	Protects devices, strategies or other information that is not public, valuable, and kept confidential with reasonable efforts.	Protects secrets, processes, and information. Used for seed multiplication, production, commercialisation, licencing and Farm Saved Seeds.
Agent of Protection	PVP offices at the national/ regional level. Enforcement at the national level.	Patent offices at national level or regional level.	TM offices at national, regional, regional, or international level.	Protected without registration or procedural formalities.	Contracts place legal obligation on employees or any party to keep data and procedures secret.
Criteria	Novelty, Distinctness, Uniformity, Stability, Suitable Variety denomination	Novelty. Inventive step. Industrial applicability. Enabling disclosure.	Distinctiveness in the respective class.	Must be commercially valuable and known only to a limited number of people. Rightful holder takes reasonable steps to keep the information secret.	A contract's basic elements are: mutual assent, expressed by a valid offer and acceptance, adequate consideration, capacity, and legality.
Access by Third Parties	Breeder's exemption, research exemption, exemption for farm-saved-seed.	Research exemption and other exemptions vary country-by-country.	N.A.	N.A.	N.A.
Protection Period	Protection generally lasts 20–25 years.	Protection lasts for up to 20 years.	Protection can be endless but needs to be renewed every 10 years.	Unlimited in time provided secrecy remains.	Specified in the contract.
Costs	Moderate	High.	Moderate	No registration costs, but associated precautions and security may be costly.	No registration costs, but transactional/lawyer cost can be high.

Adapted from "ISF: A guide to intellectual property"

6.2. Legal framework for plant-related innovation

6.2.1. International level

At the international level, the **TRIPS Agreement** (Trade-Related Aspects of Intellectual Property Rights) under the WTO sets the fundamental principles for intellectual property protection, including patents on biotechnological inventions. This agreement mandates that patents be granted for inventions in all fields of technology, provided they are new, involve an inventive step, and are capable of industrial application.

Article 27(3)(b) allows the Parties to exclude plants, animals, and essentially biological processes from patentability. As the roots of this permitted exception are found in the "double-protection prohibition" of the UPOV 1978 Convention, which for plant varieties only allowed a single IPR – either patents or PVRs – it is argued that the exception can be interpreted broadly to also allow for limitations to patent rights covering plants.[136] If countries make use of the permitted limitation under Art.27(3)(b) they have to provide for an effective sui generis system, such as PVRs under the UPOV Convention.

Article 28 TRIPS establishes the rights of patent holders, while Article 30 permits limited exceptions to patent rights. Article 31 outlines the conditions for, enabling governments to grant licences to third parties without the consent of patent owners in specific cases. Enforcement of patent rights is governed by Articles 34 and 41-48 TRIPS Parties.

With the establishment of a professional breeding industry, a robust testing of new improved plant varieties was a core driver to introduce the variety rights system. Although new varieties take several years to develop, once on the market, they are – unless they are hybrid varieties - easy to copy and reproduce.

Discussions how to establish adequate protection for plants varieties started in the 1950s. While industry associations such as AIPPI favoured a development of the patent system to cover plant varieties, the International Association of Plant Breeders (ASSINSEL) argued for an independent *sui generis* system. The Lisbon Diplomatic Conference on the Revision of the Paris Convention in 1958 did not pave to way for patents on plant as there was a growing consensus that a “special law” was needed for IP on new plant varieties.[137] The considerations were that plants are less "technical", not independently reproducible, and often being rather incremental improvements do not meet the common requirement of inventiveness. It also as to be noted that the instrument of a deposit of biological material under the Budapest Treaty to replace or supplement a written description was not yet developed.

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To promote plant breeding, the International Union for the Protection of New Varieties of Plants (UPOV) and its convention from 1961 established a sui generis system of **plant variety protection**. It privileges breeders and their protected varieties from unauthorised commercialisation by third parties, but it equally allows breeders to use the genetic material of protected varieties to include in their breeding programmes and to develop and commercialise new varieties without having to pay a fee or licence to the variety rights holder. Protection applies only to a single variety and does not extend to other varieties developed later, unless they are essentially derived varieties. The requirements for a PBR are distinctness, uniformity,

[136] Metzger A (2024) Rechtliche Möglichkeiten zur Änderung des Patentschutzes von Pflanzen in Deutschland, Europa und im internationalen Recht Gutachten im Auftrag der Bundestagsfraktion Bündnis 90. At: https://www.martin-haeusling.eu/images/Gutachten_Biopatente_METZGER.pdf

[137] Greengrass B (1989) UPOV and the Protection of Plant Breeders—Past Development, Future Perspectives. IIC 20(5):622–636, at p. 623

stability (DUS), and novelty (see section 6.4.1). These requirements are adapted to the realities of plant breeding and are considered less stringent than the requirements for patentability.

The UPOV Convention is agnostic regarding the breeding process. New varieties can obtain a PBR if they meet the DUS requirement irrespective whether they are made by crossing and selection or mutagenesis breeding. PBRs only provide rights to propagation material. No protection is provided to specific gene sequences, processes, or biotech tools. PBRs under the UPOV convention are limited by a mandatory breeder's exemption, which allows plant breeders to freely use protected plant varieties to breed and develop new plant varieties, and in general to commercialise those varieties without the consent of the PBR owner. Additionally, countries may provide for a "farmers privilege" to enable farmers to save and replant seeds.

6.2.2. EU level

The framework for plant related innovation in the EU is established by several instruments on EU and national level, which relate to IPR as following:

Table 5 EU plant-related innovation framework

Type	Legislation	Scope	Notes
	Biotechnology Directive 98/44/EC	• Provides rules on patentability, patentability exclusions, scope of patent rights, and their limitations. • Transposed into national patent laws of EU Member States.	
	European Patent Convention (EPC)	• Enables obtaining patent protection in up to 39 EPC Contracting States based on a single patent application subject to harmonised examination by the European Patent Office. • Does not address rights conferred by European patents or their limitations. • Requires post-grant validation in individual EPC Contracting States.	• Separate legal system not subject to EU legal and institutional framework • Key provisions of the Biotechnology Directive incorporated in the EPC.
IPR	Unitary Patent Regulations / Unified Patent Court Agreement (UPCA)	• Enables unitary effect to be attributed to a European patent granted by the EPO • Enables uniform protection and enforcement in (currently) 18 EU Member States.	• Provides a limited breeders exemption • Provides for a general research exemption
	National Patents	• Main requirements harmonised by the Biotechnology Directive	Several countries have specific provisions for plant related patents which go beyond the Biotech Directive, including limited breeder's exemption.
	Community Plant Variety Rights (CPVR)	Provides a uniform PVR for all EU countries (community right).	See 6.4
	National Plant Variety Rights	Provides national PVRs.	Is inactive in case there is a parallel CPVR

Type	Legislation	Scope	Notes
Other	Trade secrets	(EU) 2016/943 provides EU-wide protection against unlawful acquisition, disclosure, and use of trade secrets	See 6.5.1
	Trademarks	Provides enforceable brand protection and higher consumer awareness in the EU (Dir. 2025/2436)	See 6.5.2
	Seed Market legislation	Mandatory for marketing of plant varieties in the EU.	Requires DUS and for some species VCU.
		Multiple pieces of legislation for different classes of plant species.	Pending proposal to consolidate >10 Directives into a single uniform legislation.
	GMO legislation	Key laws: Dir. 2001/18/EC for environmental release, Reg. (EC) 1829/2003 for GM food and feed, and Reg. (EC) 1830/2003 for traceability and labelling.	Pending proposal on plants obtained by certain NGTs and their food and feed.

6.2.2.1. Biotechnology Directive 98/44/EC

The **Biotechnology Directive**[138] governs the patentability of biotechnological inventions and establishes, inter alia, the legal conditions within which patents may be granted for biological material. It further sets out exceptions from patentability, defines the scope of protection of patents involving biological material and the applicable limitations to such protection such as – for example – the farmers' privilege. It also establishes a mechanism for compulsory cross-licensing in case of dependencies between patents and plant variety rights.

The Directive excludes certain narrowly defined subject matter from patentability (Articles 4 and 6), taking a more generous approach on patentability than the EPC historically[139], which holds every claim covering a plant variety non-patentable. For instance, plant and animal varieties are not patentable under the Directive unless technical feasibility of the invention is not confined to a specific variety (Article 4(2)). Similarly, the Directive excludes essentially biological processes for the production of plants or animals which are entirely based on natural phenomena such as crossing or selection. While the European Commission in its 2016 Notice[140] held that the exception for essentially biological processes extends to products exclusively made thereby, the Directive does not include such extension *explicitly* and a final interpretation would be for the CJEU as recognised by the Commission.

Directive 98/44/EC establishes several important exceptions and limitations to patent rights in order to strike a balance between encouraging innovation and protecting public interest, particularly in the field of plant and animal biotechnology.

[138] Directive 98/44/EC.

[139] i.e. prior to the incorporation of the provisions of the Directive into the EPC

[140] Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03), online available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003

6.2.2.2. European Patent Convention (EPC)

The **European Patent Convention** (EPC) governs the activities of the European Patent Office (EPO) and its examination of European patent applications.[141] Article 52 EPC defines patentable subject matter. Article 53(a) EPC excludes inventions contrary to public order or morality, while Article 53(b) EPC explicitly excludes plant varieties and essentially biological processes from patent protection. Rules 26 to 34 of the EPC's Implementing Regulations lay down more specific provisions relating to biotechnological inventions, which are in line and reflect the provisions of the Biotech Directive 98/44/EC.

Following the publication of the *Commission Notice*[142] of 2016 interpreting the exclusions from patentability defined in Directive 98/44/EC, the Administrative Council of the European Patent Organisation and subsequently the EPO's Enlarged Board of Appeal further clarified patentability exclusions in the area of plants.[143] Due to new Rule 28(2), the EPO no longer grants patents on plants or plant parts which are obtained exclusively by means of essentially biological processes if they have a first filing date (i.e., priority date) of July 1, 2017 or later.[144] In consequence, plant-related inventions are only patentable as long as they:

(i) are not limited to a single variety (see G1/98[145]),

(ii) do not relate to essentially biological processes (G 2/07-G01/08[146]), and

(iii) do not relate to a plant which is exclusively obtained by an essentially biological process (G 3/19[147]).

As NGT-based processes are – in general[148] – not considered "essentially biological processes", both these processes and the resulting plants are deemed patentable under the EPC if they meet the general requirements of patentability and the as long as the invention is not limited to a single variety (see 8.2.1).

The European Patent Convention (EPC) allows patents on plants obtained by technical processes such as genetic modifications or a technically created mutation. According to the EPO, this has led to about 9 100 patent applications and 3 300 granted patents since 1995.[149]

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[141] EPO (2024), What is patentable? See: https://www.epo.org/en/news-events/in-focus/biotechnology-patents/what-is-patentable

[142] Commission Notice (Fn. 140)

[143] Based on the Biotech Directive (98/44/EC), including the Commission notice (2016), Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003

[144] In 2020, the EPO's highest judicial authority on the uniform application of the EPC, the Enlarged Board of Appeal, confirmed the validity of Rule 28(2) but stated that it cannot have a retroactive effect for applications filed before it entered into force, i.e., 1 July 2017. Following case number G 0003/19 'Pepper", see: https://www.epo.org/en/boards-of-appeal/decisions/g190003ex1

[145] EPO – Enlarged Board of Appeal (2000) Decision G 1/98 "Transgenic plant/ NOVARTIS II." OJ EPO 3/2000, 111. Available at https://www.epo.org/law-practice/case-law-appeals/recent/g980001ep1.html.

[146] Processes comprising steps of crossing and selection are not patentable. A narrow exception is provided if there is a step between crossing and selection which introduces a genetic change by technical means. See Enlarged Board of Appeal (EBA), Decision G 2/07 – G 1/08 "Broccoli & Tomato I" (December 9, 2010); OJ EPO 2012, 130, 206. Available at https://www.epo.org/law-practice/case-law-appeals/recent/g070002ex1.html.

[147] Enlarged Board of Appeal (EBA), Decision G 3/19 "Pepper" (May 14, 2020); OJ EPO 2019, A34. Available under http://documents.epo.org/projects/babylon/eponet.nsf/0/44CCAF7944B9BF42C12585680031505A/$File/G_3-19_opinion_EBoA_20200514_en.pdf. However, non-propagatable plants materials (e.g., silage) or technically treated parts (e.g. seeds with seed coating) might be patentable).

[148] Rare exceptions are NGT processes which depend on sexual crossing e.g., EP3316676 - HAPLOID INDUCER LINE FOR ACCELERATED GENOME EDITING (UNIV MINNESOTA; see Office Action dated 16.11.2023); EP3547825 - SIMULTANEOUS GENE EDITING AND HAPLOID INDUCTION (Syngenta; see Office Action dated 10.06.2022)

[149] Cf fn 20

6.2.2.3. Unitary Patent / Agreement on a Unified Patent Court

The Unitary Patent system comprising the Unitary Patent regulations and the Unified Patent Court Agreement (UPCA) was launched on 1 June 2023.

The **Unitary Patent regulation (Regulation (EU) 1257/2012)** establish a single patent right, namely a European patent with unitary effect ('Unitary Patent'), providing uniform protection across the participating EU Member States. Unitary Patent protection currently applies in the following 18 participating Member States that have ratified the Agreement on a Unified Patent Court (UPCA): Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, Sweden and Romania.

The **UPCA** establishes the Unified Patent Court (UPC) as a centralised jurisdiction for patent disputes. The UPC ensures uniform interpretation and application of patent law across the participating Member States. Articles 24, 25, and 26 establish the legal framework for the protection and enforcement of patents, while Article 27(c) introduces limitations on patent rights, specifically exemptions for research, plant breeding, and farm-saved-seed (the so-called farmers' privilege).

Articles 55, 58, 59, 63, and 68 regulate aspects such as infringement claims, damages, and licensing agreements. Although national courts retain jurisdiction over UPOV plant variety protections, over national patents and over certain (i.e., opted-out) European patents having no unitary effect, the UPC is exclusively competent – as regards the participating Member States – for handling disputes relating to unitary patents and to non-opted-out European patents, including those related to biotechnological inventions.

6.2.2.4. IPR Enforcement Directive

The **IPR Enforcement Directive**[150] harmonises enforcement measures for patents and other IPRs. It ensures that patent holders have effective legal mechanisms to defend their rights, while ensuring that such measures remain proportionate and fair. Article 13(2) addresses unintentional IP infringement in providing that in such cases *"Member States may lay down that the judicial authorities may order the recovery of profits or the payment of damages, which may be pre-established"*.[151]

6.3. Patenting activities

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Plants can be protected through "composition of matter" claims on the plant as such, plant materials or parts, DNA sequences incorporated into the plant, or as product of a patented manufacturing process. Process patents may include patents on transformation, Cas-systems, or gene editing.[152]

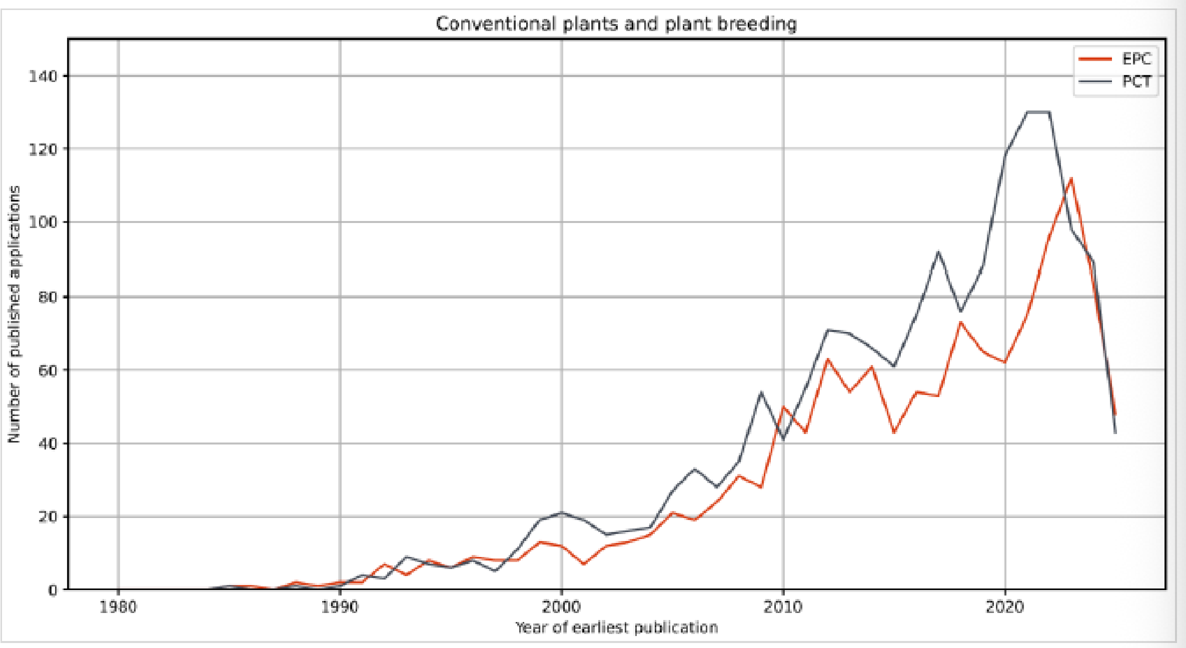
[150] Directive 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights. At: https://eur-lex.europa.eu/eli/dir/2004/48/oj/eng.

[151] Germany and Austra provide an exception for unintentional infringement by farmers (see Table 11)

[152] However, with respect to process patents the interpretation of the "specific characteristics as a result of the invention" required under Art. 8(2) Dir. 98/44 is debated. It is argued that only processes which specifically disclose a characteristic as an relevant part of the invention should be entitled to such extension.

From 1982 to July 2025 the number of European patent applications in the area of genetically modified plants, including patents on breeding tools, amounted to 9 580. Over this period, 51 % were either withdrawn or refused, 36.4 % were granted. Among the remaining share that needs to be processed, there are about 1.2 % which were applied before 2017, do not fall under the disclaimer solution and are still pending.[153] The number of patent applications on conventional plants is much lower with about 1 290 (1995- July 2025). About 490 cases were refused or withdrawn. About 330 patents were granted while about 470 are still pending.[154]

Figure 7 Evolution of genetically modified plants and plant breeding patent applications (process and product) by earliest publication year, EPO, 1982-2025



Source: EPO (2025) Search: A01H5+ and A01H7+/CCI. The "drop" in 2024 is due to the fact that not all applications had been published yet

The EPO provides application and grant data by technology field.[155] Plant breeding falls into the field of biotechnology. Between 2015 and 2024, a steady growth with an average annual growth rate of 4.5 % over the entire period could be observed in this field, which is above the average annual growth of all patents (2.5 %). The share of plant biotech patents among all patent applications rose from 3.6 % to 4.3 %.

In terms of granted patents, a different picture emerges in 2015, the share of granted patents for all technology fields was 42.8 %, with biotech patent slightly above with 46.4 %. While between 2016 and 2019 the share of granted patents rose to 76 %, the share of granted biotech patents reached its peak already in 2017 with 58.3 %. In 2024, 21.8 % were granted, the lowest share among all technology fields. Thus, the grant rate of patents in the biotech field

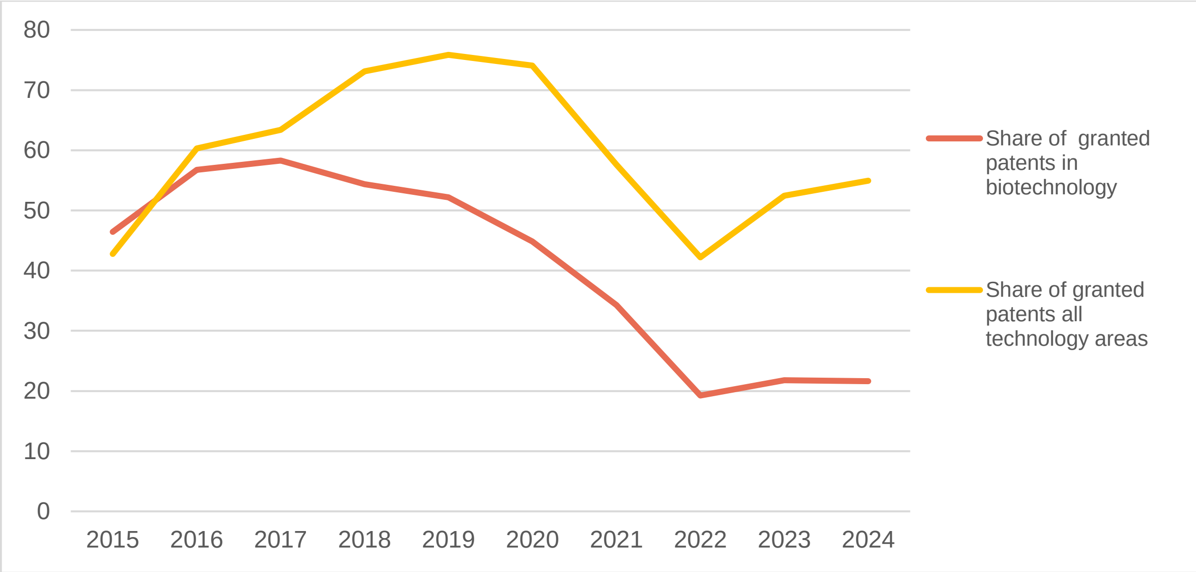
[153] EPO (2024, 2025), EPO practice for plant- and animal-related inventions: status report. Available at: https://link.epo.org/ac-document/CA/PL %2018/24 %20- %20En.pdf. The 2025 report was not yet available online by the time of finalisation the study report.

[154] EPO Q&A on plant patents, 14.05.2024 fact sheet, available at: https://www.epo.org/en/news-events/press-centre/fact-sheet/447625#q6

[155] See https://www.epo.org/de/about-us/statistics/statistics-centre#/customchart

decreased on average by -4 % annually, while the overall share of granted patents rose on average by 5.4 % annually (see Figure 8).

Figure 8 Development of granted patents biotechnology vs all technology fields, EPO, 2015-2024



Data: EPO, https://www.epo.org/en/about-us/statistics/statistics-centre#/customchart

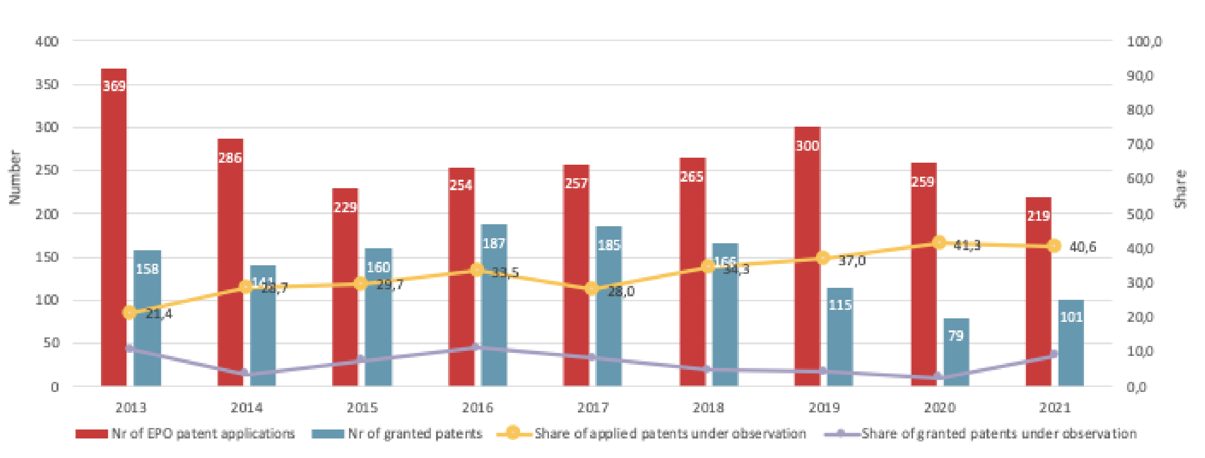
The German bio-patent monitoring[156] identified for 2020, 259 bio-patent applications at the EPO and 79 granted bio-patents. In 2021, the number of applications decreased to 219 but the number of granted patents increased to 101 (see Figure 9). The report concludes that about 75 % of the applications and 79 % of the granted patents relate to the production or use of genetically modified organisms (GMOs).

The bio-monitoring includes equally statistics on patent applications and granted patents which are deemed ‘worth to observe’ – these are cases in which essentially biological processes or products derived from essentially biological processes are claimed such as heterosis[157] and hybrid breeding, as well as marker-based precision breeding and mutagenesis-based breeding. In Figure 9, the lines show these two indicators. While in 2020 and 2021 the absolute number of patent applications and the number of ‘observable’ patent applications decreased, the development over time indicates a growing share of ‘observable’ patents. In 2013, the share was roughly 21 % - within less than ten years it almost doubled. The lower application figures for 2020 and 2021 were partly explained with “*an increasingly stringent examination at the EPO, not least due to the amended Rule 28(2) of the Implementing Regulations*”.

[156] Deutscher Bundestag (2021), Fünfter Bericht der Bundesregierung über die Auswirkungen des Patentrechts im Bereich der Biotechnologie unter anderem hinsichtlich ausreichender Technizität sowie Auswirkungen im Bereich der Pflanzen- und Tierzüchtung., Drucksache 20/3845, see: The bio-patent monitoring was established in 2012 with the aim to examine whether there is a need for legislative action in relation to patentability due to developments over longer periods.

[157] Plant breeders exploit heterosis by mating two different pure-bred lines that have certain desirable traits. The first-generation offspring generally shows, in greater measure, the desired characteristics of both parents. This vigour may decrease if the hybrids are mated together. Thus, the parental lines must be maintained and crossed for each new crop or group desired. See: https://www.britannica.com/science/heterosis

Figure 9 Bio-patent applications/granted patents at EPO (2013-2021)



Source: Deutscher Bundestag (2021), 5th Bio-monitoring (see fn 155)

In a detailed analysis of CRISPR/Cas related patents by SCBT-Centredoc (2024), the study provides a range of indicators including the leading positions of patent-holding firms. Corteva has the largest relevant patent pool and the highest patent asset portfolio. Smaller firms with much smaller patent portfolios may however have a competitive advantage – depending on the relevance of the patents owned and the services the companies can provide (i.e., Cellectis, Benson Hill Holdings) (see Figure 10).

The study further details that there are more than 17,000 patent families covering CRISPR related technology with over 14,000 having claims covering genome editing. Since 2020, China has overtaken the -until then- leading USA. Today, almost 50 % of CRISPR patents have priority filings in China. Less than 10 % of the Chinese priority filings have been extended to other countries. The main filing organisations from China are the Chinese Academy of Sciences and the Chinese Academy of Agricultural Sciences. Research in China relies almost entirely on the CRISPR/Cas systems.[158]

[158] See: Swiss Federal Institute of Intellectual Property (2024) CRISPR technology: patent and license landscape

Figure 10 CRISPR/Cas related patent asset index

Top Owner by Patent Asset Index

Modified plant (CRISPR Plants Main players 538)

	Owner	Patent Asset Index	Portfolio Size	Competitive Impact	Technology Relevance	Market Coverage
1	Corteva	536	116	4,6	2,4	1,6
2	KWS Saat	165	41	4,0	2,1	1,8
3	Benson Hill	149	57	2,6	1,2	1,2
4	Monsanto (in: Bayer)	147	37	4,0	1,8	2,2
5	Cellectis	128	7	18,2	10,1	1,6
6	Syngenta (in: Sinochem Holdings)	124	31	4,0	2,0	1,9
7	PAIRWISE PLANTS SERVICES	115	32	3,6	1,8	2,1
8	TROPIC BIOSCIENCES UK LIMITED	89	12	7,5	3,0	2,3
9	INARI AGRICULTURE INC	78	27	2,9	1,7	1,7
10	Limagrain	78	69	1,1	1,0	1,1
11	Keygene	52	10	5,2	2,5	2,1
12	Cibus Global	33	7	4,7	2,5	2,0
13	BETTERSEEDS	21	11	1,9	1,1	1,9
14	BENSON HILL HOLDINGS	20	1	19,9	7,0	2,9
15	Sakata Seed	19	53	0,4	0,4	1,0
16	SINOBIOWAY BIO AGRICULTURE GROUP ...	18	19	0,9	0,7	1,3
17	University of Tennessee	16	10	1,6	1,4	1,2
18	Enza Zaden	11	6	1,9	0,8	2,1
19	Battelle	11	8	1,4	1,4	1,0
20	G FLAS LIFE SCIENCES INC	5	6	0,9	0,8	0,5
21	HM CLAUSE S	3	4	0,8	0,8	1,0
22	KEYGENE NV	3	1	2,8	1,0	2,7
23	PAIRWISE PLANTS SERVICES INC	3	1	2,7	1,0	2,7
24	SAKATA SEED CORP	2	3	0,6	0,6	1,0
25	HM CLAUSE INC	1	2	0,7	1,0	0,7
26	SAKATA SEED COPRORATION	0	1	0,4	0,4	1,0
27	BETTERSEEDS LTD	0	1	0,1	1,2	0,1

Source: Swiss Federal Institute of Intellectual Property (2024) CRISPR technology: patent and license landscape. Report prepared by SCBT-Centredoc, version 05.02.2024

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6.4. Plant Variety Rights

6.4.1. Introduction

The Plant Variety Right (PVR) system in the European Union harmonised plant variety protection across Member States, complementing the already existing national systems with a unitary right at Union level. PVRs are granted under the EU Plant Variety Rights Regulation[159]. It is based on the 1991 revision of the UPOV Convention and provides intellectual property protection specifically tailored to plant varieties. PVRs are granted through a *sui generis* title, acknowledging the unique nature of plants as the protected subject matter. A notable feature of the system is the integration of technical and legal criteria. Unlike patents, where assessments on the protection requirements are conducted through examination of application documents and prior art, the PVR system requires not only examination of an application, but also physical cultivation and testing of the candidate variety in the field or greenhouse. In other words, the protection is granted on the basis of the phenotype of the plant variety i.e. the result from the expression of the genetic code (its genotype) and the organism interactions with its environment.

This testing is performed in collaboration with national authorities across the EU in various climatic zones. These authorities conduct field trials according to standardised technical protocols that outline how each species must be grown, observed, and assessed.

The technical evaluation criteria are distinctness, uniformity, and stability (DUS):

- **Distinctness**: the variety must differ from existing known varieties by at least one characteristic
- **Uniformity**: the characteristics must be consistent across the individual plants of the variety in the field
- **Stability**: the traits must remain unchanged through successive growing cycles.

Testing can range from one year for ornamental crops to over six years for plants such as fruit trees. Upon completion, a technical report and variety description are provided.

Compared to the patent system, the PVR system differs significantly in both procedure and scope:

- **Procedural differences:** PVRs in the EU require an official field testing for phenotypic traits, and bio-molecular techniques in some cases, whereas patents rely solely on document examination.
- **Novelty**: a variety is novel if it has not been commercialised in the EU more than one year prior to filing, or more than four years prior to filing outside the EU. The period is extended to six years for trees and vines. As long as the one-year period has not expired, priority can in be claimed. The filing in different countries can happen at different points in time within this 12-month period. In contrast, patents require an absolute novelty. Any disclosure to the public would destroy novelty.
- **Priority:** Questions of priority arise when two or more applications are filed for the same variety. Priority can in be claimed if an applicant has an earlier application for a right within a Member State or an UPOV Convention Member country within 12 months

[159] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights

before application. In case two applicants file for the same variety, the earliest priority application prevails. If this cannot be established, the same priority will be applied.

- **Legal scope and exceptions**: The otherwise exclusive right of the PVR is limited by (i) a (full) breeder's exemption, allowing protected varieties to be used in breeding new varieties and commercialise the latter without the rights holder's authorisation (except for essentially derived varieties), (ii) a research exemption, and (iii) an exemption for farm-saved-seed ("farmers privilege"), which entitles farmers to use harvested material of certain species as seed in a subsequent season
- **Term of protection:** PVRs are granted for up to 25 years, except for trees, vines, potatoes, asparagus, flower bulbs, woody small fruits and woody ornamentals, for which the protection extends to 30 years. In contrast to patents, the protection term does not start from the date of filing but from the end of the year of grant. Annual fees are required to keep the protection.

6.4.2. Scope of protection of PVP rights

The scope of these rights primarily covers whole plants and plant reproductive material which are any part of the plant from which a new individual can be reproduced, be it seed, tubers or others ('variety constituents') of the variety. However, under certain conditions, the scope also includes harvested material of the variety, such as fruits or cut flowers. Infringement concerning harvested material occurs only if it was obtained through the unauthorised use of propagating material of the protected variety, and if the right-holder has not had a reasonable opportunity to exercise their rights in relation to this material. This could arise, for instance, when unauthorised use takes place in a country where the right-holder lacks equivalent PVR protection, and the resulting harvested material is subsequently imported into the EU.[160]

Specific rules also exist for **essentially derived varieties** (EDVs). An EDV is a variety that is distinct (see above) from an initial variety but is predominantly derived from the initial variety. Except for the differences which result from the act of derivation from that initial variety, an EDV conforms essentially to the initial variety in terms of the expression of its essential characteristics. If an initial variety has PVR protection, its EDVs fall within the scope of that protection. Therefore, the permission of the holder of the CPVR on the initial variety is required to commercialise an EDV of it in the EU, otherwise commercialisation constitutes an infringement. An EDV can be the subject of PVR protection if it meets the **DUS criteria**. The PVR on the EDV can be owned by a different person than that on the initial variety. In this situation, the EDV-holder needs a licence from the holder of the initial PVR to commercialise the variety. A third party needs licences from both right-holders if and for as long the respective rights are still active and unexpired.

The EDV definition raises concerns by both conventional breeders and breeders using NGTs. Conventional breeders are concerned that the PVR for their initial variety could be easily and rapidly circumvented by using NGTs. NGT-using breeders are concerned that all their varieties would be considered EDV and sanctioned with dependency and a limited scope of protection, as there is no EDV from an EDV. This would limit the breeder's exemption, a cornerstone of the PVR system, to conventional breeding based on crossing and selection. The UPOV explanatory notes on EDVs[161] do not provide clarity on this dilemma, which can hardly be solved

[160] J A Kemp (2024), Plant variety rights in the EU and UK. Available at: https://www.lexology.com/library/detail.aspx?g=ee45ec58-482b-44cf-9899-d7b4432e8595&filterId=efcf1597-4ca2-49e5-b38e-72b3b22bcb85

[161] https://www.upov.int/documents/d/upov/explanatory-notes-en-upov_exn_edv.pdf

with the current EDV definition. However, an amendment would likely require a further revision of the UPOV Convention.

6.4.3. Limitations to the scope of protection of PVP rights

The PVR system has limitation to the scope of rights, known as the breeder's exemption and the farmer's privilege. The breeder's exemption limits the right holders' exclusive rights in respect of the use of a commercial variety by third parties for the "purpose of breeding, or discovering and developing other varieties"[162] thus offering other breeders a right to use otherwise protected varieties when developing a new variety. In contrast to the limited breeder's exemption in patent laws, the PVR's breeders' exemption extends – with the exception of EDVs - to the commercialisation of the new variety. In consequence, the PVR system is characterised as a more open framework compared to the patent system, facilitating broad access to genetic material to foster the development of new plant varieties.

6.4.4. Costs and benefits of the PVP system

Overall, interviewees highlighted the **positive nature of the plant variety rights system**. The well-established breeder's exemption is welcomed by the majority of respondents. In addition, the transparency of the system for stakeholders is seen positively. As breeders uniformly indicated in interviews, the free and unrestricted access to the genetic pool – including the ones of their competitors – is key that there is sufficiently genetic diversity for new crossing and selection and the development of robust plants. (ID_1, 5, 6, 7, 8)

Application of **PVR** can be done online for a fee of €450 or on paper €800. There are examination fees in the range of €1980 – €4130 depending on the species fee group. The annual renewal fee at the CPVO is €380[163], considerably less than patent fees. The EUIPO SME Fund is offering vouchers to support SMEs with plant variety protection applications. As with patents, breeders concerned about infringement need to invest in monitoring to ensure their plant reproductive material falling under plant variety rights protection are not reproduced. In this respect collective management organisations (CMOs), active for example in Spain and Italy, were mentioned as a useful tool to help breeders enforce their PVRs (ID_1, 26).

To the interviewed breeders, the PVP rights are often a sufficient incentive for breeding innovations. Given the advantages of **being first on the market** with a new, attractive variety, breeders can gain a market share and **exclusivity** for the length of a breeding cycle i.e., for at least four to five years, or even longer (six to eight years) if seed market authorisation is required. Even if the new variety is "only" protected through a PVR, the right prohibits a simple reproduction of the variety. The turnover from these years is typically sufficient to make a profit and the financial means needed to invest in R&D. Several interviews highlight that plant variety rights are well-understood and protected and varieties are findable with relative ease in the related databases. When patent protection comes into play, however, almost all interviewees raised concerns about the complexity and costs of freedom-to-operate analyses for small and medium-sized actors, since information is not (as readily) available about which plant or variety includes a trait that is subject to a patent. (ID_1, 3, 5, 6, 11, 12, 20).

[162] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, Article 15

[163] Prices as of 7.6.2023. Updated fees are published in the Official Journal of the EU. See: https://cpvo.europa.eu/en/applications-and-examinations/fees-and-payments

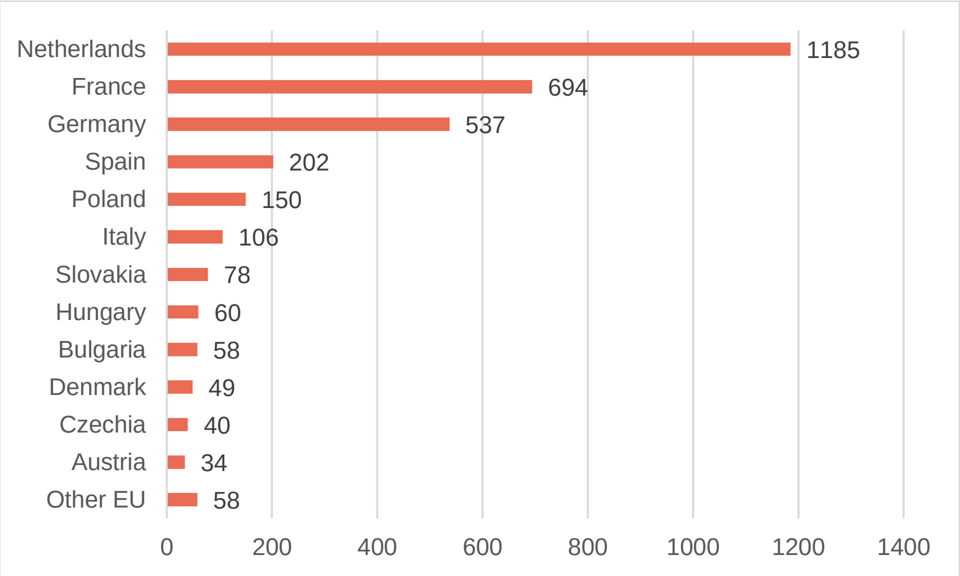
6.4.5. Use of the EU PVP system

The **EU Plant Variety Protection Regulation**[164] governs the Community Plant Variety Rights (CPVR) system. It is administered by the Community Plant Variety Office (CPVO), an EU Agency based in Angers (France). It is responsible for managing a unitary protection system of plant variety rights. Since its inception in 1995, more than 65 000 rights were granted in total, of which 31 317 were still in force as of the end of 2024.[165] The difference between total rights granted and in force is due to the fact that most rights are surrendered by breeders before the maximum term of 25-30 years. PVRs for fruit varieties are typically longer maintained (69 % still in force) than for agricultural varieties (51 %) or ornamental varieties (40 %), mostly due to the longer innovations cycle for fruit varieties. Figure 11 Number of CPVR applications (2024)

shows that within the EU, applicants from the Netherlands are (by far) leading with 45 % of all applications, with France and Germany following with 10 %, and 15 %, respectively. The number of applications per year from the Netherlands decreased from ~1400 in 2014 to 1002 in 2023, while other countries remained relatively stable.

This can be explained by trends in crop sectors (see Figure 13), where the number of applications for ornamental varieties decreased disproportionally and The Netherlands being particularly strong in the ornamental and vegetable sectors, whereas Germany and France are strong in the agricultural crops sectors. Spain and Italy are leaders in fruit-crop-related variety applications.

Figure 11 Number of CPVR applications (2024)

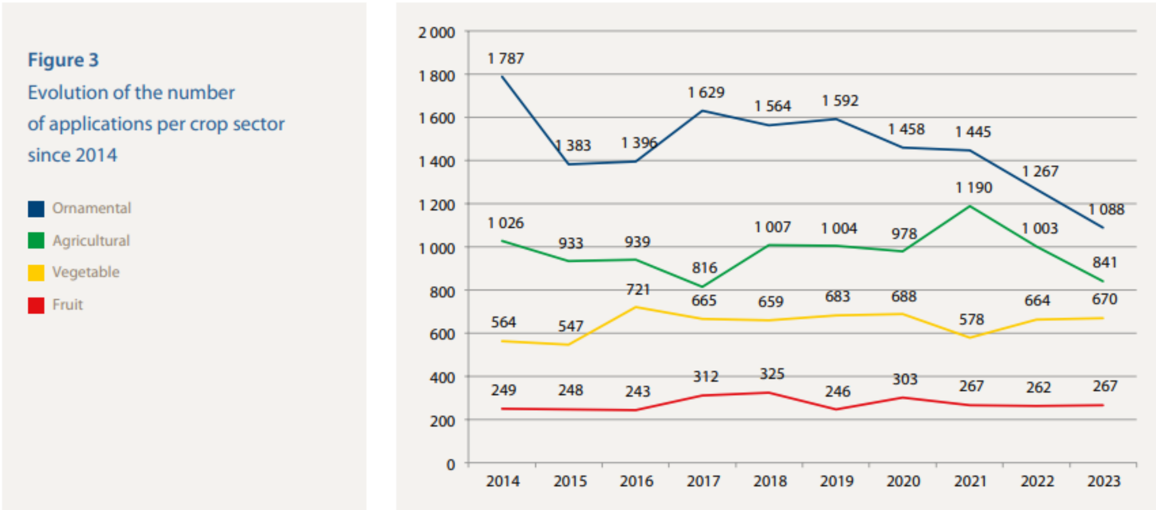


Source: CPVO. Applications dated up to and including 31/12/2024. *CPVO register*. Retrieved September 5, 2025, from https://online.plantvarieties.eu/publicsearch

[164] Regulation (EC) No. 2100/94.

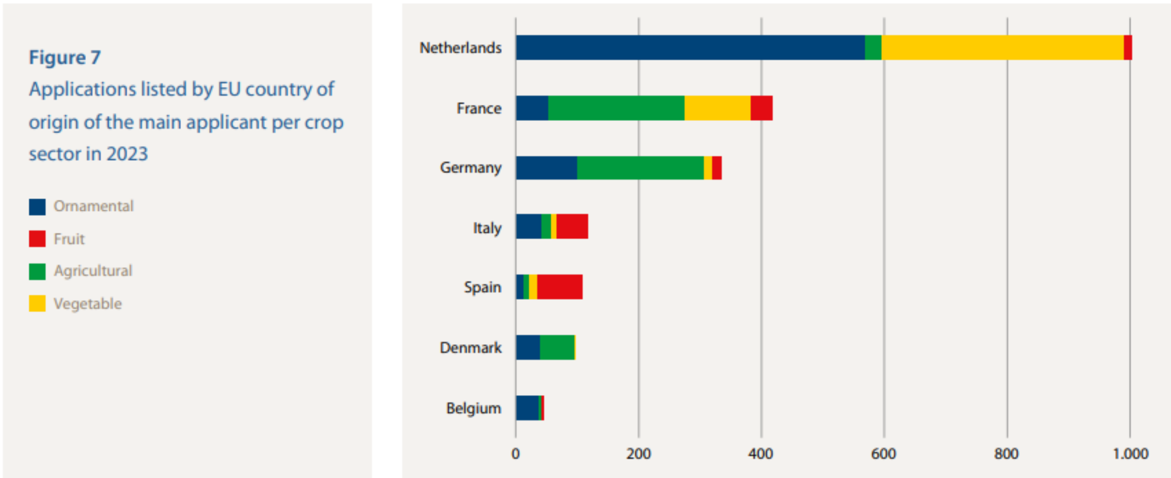
[165] CPVO Annual Report Annex 2024. https://cpvo.europa.eu/sites/default/files/documents/2025-02/ar2024_0.pdf. For comparison, the U.S. Plant Variety Protection Office of the U.S. Department of Agriculture currently has 8.450 protection certificates issued. At: https://www.ams.usda.gov/sites/default/files/media/PlantVarietyProtectionFactsheet.pdf.

Figure 12 Evolution of the number of applications per crop sector (2014-2023)



Source: CPVO

Figure 13 Applications by country and crop type



Source: CPVO Annual Report 2023

6.4.6. Concerns on PVR and NGTs

Concerns and suggested changes to the PVP system in the context of NGT-derived varieties are limited. While broadly regarded as a functioning system by most interviewed stakeholders, the potential use of NGTs in the plant breeding sector raises some questions with regards to some aspects of the PVR system, especially the criteria for DUS and EDV.

The DUS criteria are currently based on a defined list of phenotypical characteristics which form a distinguishable "fingerprint" of the variety. NGT-derived traits with agronomic relevance cannot necessarily be recognized through the DUS criteria. Especially in a scenario where patent protection is not available for NGT-derived plants, changes to the DUS criteria could be beneficial to motivate investment and innovation in precision breeding.

6.5. Other IPRs

6.5.1. Trade secrets

The Trade Secret Directive ((EU) 2016/943) is the legal basis for trade secret protection in the EU. In particular, it establishes protection against unlawful acquisition, disclosure and use of trade secrets. Some interviews referred to them as an alternative measure to patents, and described them as “largely interchangeable” (ID_4, 11, 15, 16). In practice, companies decide on a case by case whether to patent an innovation or keep it secret.

Trade secrets and patents have different effects on innovation. Patent applications disclose inventions to the public after they are published. This enables third parties – including competitors – to make follow-on innovation, an effect which is missing with trade secrets. Given climate change and urgent needs to provide adapted varieties in a short period of time, secrecy is seen by some breeders as detrimental to accelerate variety development. Relying mainly on trade secrets was seen as hampering the needed innovation. In addition, trade secrets are usually not licenced and therefore limit the available options for value capture. (ID_5, 9)

Interviews with breeders suggest that they are likely to continue to innovate and invest in the research and development of new plant traits even in the absence of patents (ID_11). For conventionally developed traits, this has typically been the approach: breeders keep their breeding history and the markers for their traits confidential, and commercialise varieties under PVR. In this scenario, the price of seed for a variety with a valuable trait is higher than that of a comparable variety without the trait, for as long as the breeder can maintain exclusivity. However, once the variety is released (i.e., commercially launched), the trait is generally disclosed and becomes available to the public for further breeding by competing breeders. Consequently, the period of exclusivity (i.e., the “effective protection term”) is reduced to the time required by a competing breeder to create his or her own variety and secure the necessary seed market approval. As a result, the role of trade secrets is essentially limited to “complex traits”, i.e., those based on multiple alleles, which are difficult to breed into other varieties without access to marker information.

6.5.2. Trademarks

A trademark is a sign used to distinguish the goods or services of one business from those of others. Trademarks are legally enforceable IPRs, giving their owners the exclusive right to use the mark and to prevent others from using identical or confusingly similar signs without permission.

Trademarks are relevant for plant products with a high consumer awareness, such as apples or kiwi varieties and are usually more widely known than the variety's denomination name. So is the apple related ‘Pink Lady™’ trademark more widely known than the ‘Cripps Pink’ denomination name. While PVRs have a maximum term of 25 or 30 years, trademarks can – in principle - be renewed indefinitely. This makes them an interesting complement to PVR, which can create license income beyond the term of the PVR provided the trademark has value and is used in commerce.[166] However, once a PVR expires, any grower can use the variety and commercialise it under the denomination name.

[166] The growing benefit of trademark protection, available at: https://www.lexology.com/library/detail.aspx?g=74d1dec4-8e19-44e9-a8a6-b5870bb1b9c9

The Israeli seed breeder Genesis Seeds Ltd. is an example of a company that developed a resistance trait against downy mildew from wild basil to sweet basil. The basil seeds are commercialised as hybrids under the Prospera™ trademark.[167] The company holds to national listings for basil varieties in Italy (under the denomination name of Basilio and Gervaso) but does not seem to have applied for PVR. The company distributes the seeds through various licensed seed companies.

[167] See https://genesisseeds.com/about-us/ and its Prospera™ F1 varieties. The development is described in Ben-Naim, Y., Falach, L., Cohen Y (2018), Transfer of downy mildew resistance from wild basil (Ocimum americanum) to sweet basil (O. basilicum), Phytopathology, 108: 114-123, see: https://doi.org/10.1094/PHYTO-06-17-0207-R

7. International benchmark

The following overviews provides key parameters of plant-related patent law, plant breeder's rights, IP litigation, and regulatory laws for the United States (U.S.), China, Japan, and the United Kingdom (UK). Summarising tables are provided at the end of this chapter.

7.1. United States

Key factors

- The U.S. allows for IP protection of plants by a combination of different regimes with very limited exception from patentability and practically no limitations to patent rights.
- For patent protected plants there is neither a research nor a breeder's or farmer's exemption.
- Approvals for genome edited plants are granted rapidly and pragmatically. Up to now, 339 approvals are reported. However, only three commercial use cases were identified.

IP Systems

The U.S. IP system for plant innovations combines three main legal protections:

- Plant Variety Protection (PVP) certificates.
- Plant patents (which are distinguished from utility patents on plants).
- Utility patents.

The central patent authority is the United States Patent and Trademark Office (USPTO). PVP certificates are granted under the Plant Variety Protection Act (PVPA) and administered by the USDA's Plant Variety Protection Office (PVPO). A plant-related invention can be protected in the U.S. through utility patents, plant patents, and PVP certificates.

Plant Breeder's Rights / Plant Variety Protection (PVP)

The United States has been a member of UPOV 1991 since ratifying it in 1999[168]. Its Plant Variety Protection Act (PVPA) [169] dates back to 1970 and was amended in 1994. The PVPA provides PVP certificates for eligible varieties. Protection lasts 20 years for most crops, and 25 years for trees, vines, and certain perennials.

The rights granted cover production, reproduction, sale, import, export, and conditioning for propagation. The PVPA also includes two important exemptions: a research exemption, which allows protected varieties to be used in developing new ones; and a farm-saved seed exemption, which allows farmers to replant saved seed on their own farms. However, the latter is restricted, since it does not allow sale or exchange.[170]

[168] https://www.upov.int/edocs/pubdocs/en/upov_pub_438_85.pdf

[169] https://www.upov.int/export/sites/upov/members/en/npvlaws/usa/uspvpa.pdf

[170] Section 113 and Section 114. https://www.upov.int/export/sites/upov/members/en/npvlaws/usa/uspvpa.pdf

Unlike in many other UPOV 1991 countries, U.S. farmers are not required to pay a 'reasonable fee' when replanting farm-saved seed, even though UPOV now considers this essential for new members.

Distinctness, Uniformity, and Stability (DUS) testing is required. This is not carried out directly by the office but is based on data supplied by the breeder. Applicants must also submit seed samples to the National Centre for Genetic Resources Preservation. In practice, PVP in the U.S. is mainly used for field crops such as wheat, soybean, and rice, as well as turf and forage grasses.[171]

Patents on Plant Related Inventions

The U.S. has its patent law under Title 35 of the United States Code.[172] Unlike the EU and the UK, the U.S. has no statutory exclusion for "plant varieties" or "essentially biological processes". Utility patents on plants are permitted since the decision on *J.E.M. Ag Supply v. Pioneer Hi-Bred International* in 2001.[173] This decision confirmed that plants can be protected with a utility patent. The utility patent can apply to traits, genes, breeding methods (molecular markers, gene editing), as well as entire plant varieties. Patents cover not only plants with genetically engineered traits but also those with conventionally bred traits. For new, distinct, asexually reproduced plants, the U.S. has plant patents[174], excluding tuber-propagated plants. The U.S. does not have a research or breeder's exemption in its patent law. Using patented material in breeding generally requires a license.[175]

In the U.S., utility patents are the primary IP tool for agritech. Since the 1990s, utility patents have exceeded PVP rights for new crop developments.[176] In 1990, 61 % of new crop varieties were protected by PVP certificates, but by 2020 that had dropped to 38 %, with the remainder protected by patents.[177] In biotech-intensive crops, the shift is even more pronounced. For example, in soybeans, PVPs accounted for 97 % of IP in 1990 but only 31 % in 2020. In corn, the share fell from 68 % to 44 % over the same period.[178] In the U.S., about 20.000 plant-related utility patents (mentioning crop names) were issued from 1976 to 2021, compared with roughly 13.800 PVP certificates issued from 1973 to 2022. In other countries that in principle allow patents on specific plant varieties, the number of granted patents remains low. By contrast, in the U.S. both the number and the allowance rate are very high. This is largely due to how the non-obviousness criterion is applied: essentially, every new plant variety is considered patentable, provided it represents a new combination of characteristics.

IP litigation related to plants

Plant IP litigation is more common in the U.S. than in most other countries largely because both patents and PVP rights are available for plant varieties. Disputes frequently concern the

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[171] https://www.upov.int/export/sites/upov/about/en/pdf/353_upov_report.pdf

[172] United States Code, Title 35 – PATENTS https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35.htm

[173] https://supreme.justia.com/cases/federal/us/534/124/

[174] United States Code, Title 35 § 161

[175] https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-79-4-Weschler.pdf

[176] https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf

[177] https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf

[178] https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf

unauthorised propagation or sale of patented or PVP-protected seed, infringements of biotechnology trait patents, or contract disputes over seed licensing agreements.

One landmark case was *Bowman v. Monsanto* (2013),[179] in which the Supreme Court upheld patent rights in self-replicating seeds. There have also been multiple lawsuits involving Roundup Ready soybean and cotton technologies, particularly against farmers who saved and replanted seeds.

Legal challenges in this area often pit large corporations against small firms or individual breeders. Litigation costs can easily reach tens of millions of dollars, making such cases prohibitively expensive for smaller players. U.S. courts may impose injunctions, damages, and even treble damages in cases of wilful infringement.

Adding to the complexity, plant material in the U.S. can be protected by multiple IP frameworks at the same time. This overlap can create confusion. For instance, a variety may be covered by PVP rights - which would normally allow breeders to use it in further breeding - but if the variety also carries a patented trait, then use is prohibited without a licence.

Regulatory systems

Seed laws in the U.S. are administered by the USDA under the Federal Seed Act[180] alongside state seed laws. These cover variety labelling, certification, and quality standards. Unlike in many countries, there is no mandatory seed market authorisation that requires DUS or VCU assessment before a variety can be commercialised.

The U.S. also has a permissive approach to GMOs. GMO ingredients are generally accepted without restrictions, and GM plants are widely cultivated. Commercial cultivation and sale are permitted once a GMO plant meets regulatory requirements under the Coordinated Framework for Regulation of Biotechnology.[181] Since May 2020, GMOs and gene-edited plants have been regulated under the USDA's revised Part 340 SECURE rules. However, on 2 December 2024, the U.S. District Court for the Northern District of California vacated the SECURE rule.[182] While the ruling is not retroactive and approvals granted between 2020 and 2024 remain valid, new applications must follow the pre-2020 process until new rules are in place. Gene-edited crops, which are not considered plant pests, or those that did not trigger the older regulatory requirements, are less impacted, as the former 'Am I Regulated' (A.I.R.) process was already quite pragmatic.[183] Approvals under this system are usually granted within one month.

Overall, the U.S. regulatory system for NGTs is less strict than the EU's GMO framework. Up to 22 August 2025, 225 approvals have been granted under the AIR process, and 84 under the newer Regulatory Status Review (RSR) process.[184]

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[179] Bowman v. Monsanto Co., 569 U.S. 278 (2013) https://supreme.justia.com/cases/federal/us/569/278/

[180] https://www.ams.usda.gov/rules-regulations/fsa

[181] USDA determines whether a plant is regulated; APHIS assesses plant pest risks; FDA oversees food and feed safety under the Federal Food, Drug, and Cosmetic Act; EPA regulates pesticidal traits. For many CRISPR-edited crops without foreign DNA, no pre-market regulatory review is required from USDA. https://usbiotechnologyregulation.mrp.usda.gov/sites/default/files/coordinated-framework-plain-language.pdf

[182] The court ruled that the USDA had not adequately addressed its own long-standing concerns about noxious weed authority. It also found that the agency had provided insufficient scientific justification for the broad exemptions it granted to conventionally breedable modifications. See https://blog.aspb.org/policy-update-federal-judge-vacates-usda-rule-regulating-biotech-crops/; https://www.feedstuffs.com/agribusiness-news/new-court-ruling-overturns-usda-rule-on-genetic-engineering-in-plants.

[183] https://www.science.org/content/article/judge-blocks-rule-eased-u-s-reviews-biotech-crops

[184] Regulatory Status Review Table. At: https://www.aphis.usda.gov/biotech-regulatory-status/regulatory-status-review-table.

So far, three genome-edited plants have reached commercial use in the U.S.: high-oleic soybean (launched in 2019)[185], less pungent mustard greens (2023)[186], and non-browning lettuce launched in 2023.[187] The gap between the large number of regulatory approvals and the number of products on the market is not fully understood.

Since January 2022, the National Bioengineered Food Disclosure Standard requires certain GMO-containing foods to be labelled as "bioengineered".[188]

7.2. China

Key factors

- China has the largest number of patents on NGT-derived plants globally.
- There is a high number of PVP infringement cases.
- NGT-plants are still regulated under the GMO regulatory system, however, in practice, they seem to be subject to a 'GMO-light' approval practice.
- Several approvals have been granted to domestic applicants while no approvals for foreign companies are known.

IP Systems

China's system for plant-related intellectual property is centred around a Plant Variety Protection (PVP) framework that does not allow patenting of plant varieties. The China National Intellectual Property Administration (CNIPA) oversees patents. As of June 2025, new Regulations on the Protection of New Plant Varieties expand the PVP protections, and these new regulations align the Chinese system more with international standards.

Patents on Plant Related Inventions

Under China's Patent Law, Article 25,[189] patents are not allowed for "animal or plant varieties."[190] However, the exclusions do not apply to the non-reproductive components of a plant or by-products from a plant (e.g. malt, silage). However, several process claims are

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185 Marketed by Calyxt and made using TALENs. EU Parliament (2023) Plants produced using new genomic techniques. At: https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/754549/EPRS_BRI %282023 %29754549_EN.pdf; Voigt C.A. (2020) Synthetic biology 2020–2030: six commercially-available products that are changing our world. Nat Commun 11, 6379. https://doi.org/10.1038/s41467-020-20122-2. At: https://www.nature.com/articles/s41467-020-20122-2.

186 Marketed as Conscious Greens™ by company Pairwise, made with LbCas12a. Karlson D et al. (2022) Targeted Mutagenesis of the Multicopy Myrosinase Gene Family in Allotetraploid Brassica juncea Reduces Pungency in Fresh Leaves across Environments. Plants 2022, 11, 2494. https://doi.org/10.3390/plants11192494. See also https://www.pairwise.com/news/health-canada-gives-pairwises-conscious-greens-a-nod-of-approval.

187 Marketed by GreenVenus At: https://greenvenusproduce.com/collections/all

188 https://www.ams.usda.gov/rules-regulations/be

189 Patent Law of the People's Republic of China. Amended for the fourth time in accordance with the Decision of the Standing Committee of the Thirteenth National People's Congress on Amending the Patent Law of the People's Republic of China adopted at its 22nd Session on 17 October 2020. Available at: https://www.cpahkltd.com/UploadFiles/20201222110401200.pdf.

190 The term plant "refers to the life form which maintains its life by synthesizing carbohydrate and protein from the inorganics, such as water, carbon dioxide, and inorganic salt, through photosynthesis, and usually is immovable. See "Guidelines for Patent Examination 2023. State Intellectual Property Office. Chapter II, 4.4; At https://www.wipo.int/wipolex/en/legislation/details/22371.

allowed on methods of producing, using, or cultivating plants, which may provide effective patent protection for plant related inventions. To determine whether a process is “essentially biological,” the Chinese patent examination guidelines instruct the examiner to look at the extent of human involvement or intervention. *“If the human technical involvement is the controlling or decisive factor for achieving the result or effect of that process, the process is not essentially biological.”*[191] Accordingly, a patent may be granted for the process of growing plants with certain characteristics, such as higher yield. Similarly, a process patent for the cultivation of plants through irradiation or certain soil treatments are valid, as would be certain techniques of crossbreeding, as long as one or more steps involve significant intervention, i.e., forced fruiting of an asexual plant.

Plant Breeders Rights

China continues to dominate the UPOV statistics in terms of the number of PVR applications received and titles issued, as well as being the top country of residence for PVR title holders.[192] The Chinese Seed Law of 2021[193] and the Regulations on the Protection of New Plant Varieties (PVP Regulations) of 2025[194] are two key legal instruments that *complement and interact* to form the framework for plant variety protection in China. [195] While the Seed Law establishes the legislative framework, setting out the general principles, rights, and obligations related to plant variety protection, the PVP Regulations operationalise these principles, providing the *practical mechanisms* for registration, enforcement, and administration of plant variety rights. Together with case law – especially the second “Several Provisions on the Specific Application of Law in the Trial of Dispute Cases of Infringement on the Right to New Plant Varieties” issued by the Supreme People’s Court on 5 July 2021 - ("2nd JI"[196]) - these instruments are moving China’s system closer to international standards, particularly those of the UPOV 1991 Convention. While China’s PVP system is based on the UPOV 1978, many elements of UPOV 1991 were implemented. In consequence, China’s seed law could be seen as “UPOV 1978-plus”.[197] The important revisions are:

(i) Establishing an EDV system;

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[191] Guidelines for Patent Examination 2023 (Fn.190) Chapter II, 4.4.

[192] https://www.upov.int/databases/en/#QG10

[193] Seed Law of the People's Republic of China - 中华人民共和国种子法 (Dec. 24, 2021), "Seed Law". Official English version available at: http://en.npc.gov.cn.cdurl.cn/2021-11/24/c_910015.htm. Sino-German Agricultural Centre (DCZ) (2022). Policy Brief on the new Chinese Seed Law and its introduction of Essentially Derived Varieties (EDV). Available at: https://www.dcz-china.org/wp-content/uploads/2022/08/Policy_Brief_EDV-02-2022.pdf; CIOPORA (2022) China Improves its Plant Variety Protection with New Seed Law. Available at: https://www.ciopora.org/post/china-improves-its-plant-variety-protection-with-new-seed-law.

[194] Regulations of the People’s Republic of China on the protection of new plant varieties (Order of the State Council of the People’s Republic of China No. 807) - 中华人民共和国植物新品种保护条例(中华人民共和国国务院令 第807号), April 29, 2025, ‘ PVP Regulations’. Original available at: https://www.gov.cn/zhengce/zhengceku/202505/content_7022128.htm. English version and comments available at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Regulations %20on %20the %20Protection %20of %20New %20Plant %20Varieties %20Finalized_Beijing_China %20- %20People %27s %20Republic %20of_CH2025-0121.pdf

[195] The State Council of the P.R. of China (2025) China revises regulations on protection of new plant varieties. Available at: https://english.www.gov.cn/policies/latestreleases/202505/01/content_WS68133ebac6d0868f4e8f23dc.html.

[196] SPC - Supreme People’s Court (July 5, 2021) Second “Several Provisions on the Specific Application of Law in the Trial of Dispute Cases of Infringement on the Right to New Plant Varieties”(最高人民法院关于审理侵害植物新品种权纠纷案件具体应用法律问题的若干规定（二））(“2nd JI”). Available at: http://gongbao.court.gov.cn/Details/2e725813528aad93b499ab4f5c2ffd.html.

[197] USDA (2025). Regulations on the Protection of New Plant Varieties Finalized, People’s Republic of China.

(ii) Expanding the scope of PBR protection from "production, propagation, and sales" to "production, propagation, processes supporting propagation, sales, offers, marketing, import, export, or storage".

(iii) Expanding the PBR scope to harvested materials, provided the PBR owner had no reasonable opportunity to exercise rights over the propagation materials.

(iv) Extended protection periods of variety rights from 20 years to 25 years, and for other plants from 15 years to 20 years. [198]

(v) Improving the infringement compensation system by now establishing an increased number of punitive damages for intentional infringement of PBRs. The upper limit of the compensation amount increases from formerly three times to five times.

(vi) Farm-saved-seed (FSS): Although the new Seed Law and PVP Regulations retain the farmers' rights to conduct FSS[199], the 2nd JI provides that farmers can reproduce and use the propagating material of protected varieties for self-consumption, so long as this is carried out on their own land and is agreed by the rural collective. If farmers deviate from the scope of use, the court will determine if it is an exceptional situation by considering all relevant factors such as the purpose, scale, and presence of profit. The court provision aims to prevent infringements on the abuse of farmers' rights.

IP litigation related to plants

China has a number of high-profile cases up to the highest courts. Among very recent ones are the following:

- **Bromeliad – Deroose**: In a 2024 ruling, the Beijing Supreme Court ruled in favour of Deroose Plants in a case against a Guangdong infringer of Bromeliad varieties. It instructed the defendant to immediately cease all unauthorised actions and pay a significant (non-disclosed) financial penalty. It is the final judgement that cannot be contested.[200]

- **Maize variety 'NP01154' – Limagrain**: On appeal, the Supreme People's Court accepted the plaintiff's evidence showing that the defendant's variety was identical to the protected 'NP01154' variety. As the infringing variety was intentionally used to produce substantial amounts of 7 hybrid varieties over at least 5 years, the court found serious infringement and awarded punitive damages in addition to compensatory damages, totalling 53.3 million RMB, approximately €6.3 million. [201]

- **Apple variety 'Scilate' – HortResearch**: In appeal, the Supreme People's Court upheld the ruling and on 26 February 2025 and set the compensation - including punitive damages – at RMB 3.3 million (about €400 000).[202]

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[198] PVP Regulation Article 35. The term of protection of a variety right is 25 years for woody and vine plants and 20 years for other plants, commencing from the date of announcement of the grant.

[199] PVP Regulation Article 12(2).

[200] Floral Daily (2024) China: Plant protection ruling by Supreme Court in favor of Deroose Plants. At: https://www.floraldaily.com/article/9664406/china-plant-protection-ruling-by-supreme-court-in-favor-of-deroose-plants/

[201] Bosse J (2025b) A-maize-ing award of damages for corn variety rights infringement in China. At: https://ipkitten.blogspot.com/2025/06/a-maize-ing-award-of-damages-for-corn.html. See also: https://natlawreview.com/article/frances-limagrain-wins-highest-chinese-damages-ever-new-plant-varieties

[202] Bosse J (2025) Apple variety infringement ruling sees record-breaking amount of damages in China. At: https://ipkitten.blogspot.com/2025/03/apple-variety-infringement-ruling-sees.html

Regulatory Systems

China regulates GMOs under its 2001 Regulations on the Safety Administration of Agricultural Genetically Modified Organisms, managed by MARA through the Office of Agricultural Genetic Engineering Biosafety Administration (OAGEBA) and guided by the National Biosafety Committee. The approval process for GMOs has three stages: pilot testing, environmental release, and pre-production testing. There is no separate framework in China yet that differentiates NGTs from GMOs or conventional breeding. They are assessed on a case-by-case basis and usually follow the Chinese GMO regulations.[203]

In an attempt to simplify the process for gene-edited plant approval, since 2022, producers may apply for production certificates post pilot trials, to bypass longer environmental release stages. In December 2024, MARA issued safety certificates for 12 GM and five gene-edited crop varieties.[204] So far, all approvals are granted to domestic Chinese companies. No approval for a foreign company is known.

Furthermore, it is unclear whether any of the approved varieties is already commercialised. Like the EU, China requires seed market authorisation, including official DUS and VCU trials and applicants have to ensure their variety is included in national lists of protected species.[205] Thus, after obtaining the biosafety certificate, edited varieties still need to go through the seed market authorisation process, which may take an additional 2-3 years.

7.3. Japan

Key factors

- Japan allows for patents on a broad range of plant-related inventions, including varieties.
- Japan's PBR law provides no exemption for farm-saved-seed.
- Japan has adopted a specific regulatory law for NGT-derived plants, first approvals have been granted, and first products commercialised.
- Like the EU, Japan requires seed market authorisation with DUS/VCU requirements.

IP system

The Japanese IP framework provides a dual system with

- patents under the Patent Act[206] for certain biotechnological inventions, and
- Plant Breeder's Rights (PBR) under the Plant Variety Protection and Seed Act.

Furthermore, Japan is a member of UPOV.

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[203] Ahmad, A. (2023). GMOs or non-GMOs? The CRISPR Conundrum, Frontiers in Plant Science. https://pmc.ncbi.nlm.nih.gov/articles/PMC10591184/

[204] China approves more GM crops to boost yields, ensure food security, see: https://www.reuters.com/markets/commodities/china-approves-more-gm-crops-boost-yields-ensure-food-security-2024-12-31/; China Approves Gene-edited Wheat and GM Maize, see: https://www.isaaa.org/kc/cropbiotechupdate/ged/article/default.asp?ID=20821

[205] https://news.agropages.com/News/NewsDetail---31216.htm

[206] Patent Act (1959) https://www.japaneselawtranslation.go.jp/en/laws/view/3118/en

Patents on Plant related inventions

Japan's Patent Act allows patenting of plants including plant varieties. The number of patents on specific plant varieties is low (see Table 4).[207] Essentially biological processes are generally excluded from patentability based on the principles outlined in the Japanese Patent Act that an invention must be a "technical idea utilising laws of nature" and must be "industrially applicable" to be patentable.

Essentially biological processes are defined as methods that involve natural biological mechanisms, such as traditional breeding techniques that do not incorporate significant human intervention or technical innovation. These processes are not patentable inventions due to their lack of technical character. The presence of human intervention alone does not suffice to qualify a process as patentable if it remains fundamentally biological in nature and usually does not meet the inventive step requirements. [208] Isolated DNA sequences can be patentable if they meet specific criteria related to novelty and inventive steps. It is not required that the DNA exhibits "markedly different characteristics" from its natural form.[209]

Once a patented product is sold by the patentee or with their consent, the buyer can use and resell it freely but is not allowed to propagate the plant from patented seeds, i.e., farmers are not allowed to replant patented seeds. Under Article 3(2)(iii) of the Japanese Patent Law, the scope of protection for patented processes can extend beyond just the direct product of the patented process, as long as the product remains equivalent to the product directly obtained by the process.

The research exemption under Japanese patent law[210] is interpreted broadly, allowing for the use of patented inventions for experimental and research purposes. This includes activities aimed at acquiring knowledge, conducting experiments, and developing new products or processes and is usually understood to include experiments on and with the patented invention, i.e., also the use as a research tool. The exemption applies equally to commercial and non-commercial entities. There is no distinction between for-profit companies or a non-profit institution.[211] Thus, patented traits and varieties can still be used for non-commercial experimental or research, which likely includes breeding activities.

Plant Breeders Rights

Japan is a UPOV-1991 member and provides plant variety protection under the Plant Variety Protection and Seed Act (PVPSA).[212] Under this act, breeders can obtain exclusive rights for propagating material of registered varieties if it is distinct, uniform, stable, and novel. The

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[207] Plant-related inventions are assessed under the conventional patentability criteria (eligible subject matter, novelty, inventive step). JPO (2015). Examination Guidelines for Patent and Utility Model in Japan https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html

[208] Hiraki, Y. (2007). Reality and Problems of Plant Protection under Patent Law and Seed and Seedlings Law in Japan. In: Agricultural Biotechnology and Intellectual Property: Seeds of Change https://www.cabidigitallibrary.org/doi/pdf/10.5555/20073163496

[209] This deviates from the stricter requirements of US patent laws. See Iida M (2024) Patent eligibility of bio inventions in Japan. Available at: https://www.managingip.com/article/2dpqf91n977h1mg6nv668/sponsored-content/patent-eligibility-of-bio-inventions-in-japan.

[210] Japan Patent Act. Article 69(1) A patent right is not effective against the working of the patented invention for experimental or research purposes. https://www.japaneselawtranslation.go.jp/en/laws/view/3118/en

[211] Johnson J.A. (2003) The Experimental Use Exception in Japan: A Model for U.S. Patent Law? 12 Pac. Rim L & Pol'y J. 499. Available at: https://digitalcommons.law.uw.edu/wilj/vol12/iss2/7. See also under: https://www.wipo.int/scp/en/exceptions/replies/japan.html.

[212] Plant Variety Protection and Seed Act (1998). https://www.japaneselawtranslation.go.jp/en/laws/view/4036/en

National Centre for Seeds and Seedlings conducts DUS tests. The protection term is 25 years for most crops and 30 years for trees (incl. fruit). PBR enforcement is done by MAFF's PVP Office. A breeder's exemption is provided under Article 21(1)(i) of the PVPSA which includes research purposes. In contrast to almost all other UPOV 1991 countries, as a consequence of the reforms in 2020-2022, there is no longer a farm-saved seed exemption under PBRs in Japan without permission of the breeder.

IP litigation related to plants

There were 508 1st instance IP cases in Japan in 2024.[213] Very few relate to plants. Two notable cases under the PVPSA are the 'shiitake case'[214] and the 'nameko case'[215].

Plant-Related Regulatory Systems

NGT-derived plants are regulated under the "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms"[216] concerning GMOs, and the Plant Protection Act[217] concerning phytosanitary (import and export) controls as well as certificates for plants and propagating material. NGT-derived plants are assessed on product-based criteria with two approval tracks. The first track (SDN-1) concerns living modified organisms (LMOs) with small edits and no foreign DNA in the plant. These are not regulated as LMOs and no approval is needed, however, the Ministry of Agriculture (MAFF) and/or Ministry of Environment (MOE) need to be notified. In practice this equals an approval or verification process. These plants don't require a GM label when sold as food. The second track (SDN-2/SDN-3) concerns LMOs where foreign DNA remains. These require biosafety risk assessment. Food needs to be labelled as GM.[218]

An example is the Sanatech High-GABA tomato, which had no foreign DNA (SDN-1) and entered the Japanese market in 2021 without GM label as the first CRISPR-edited food sold in Japan. The GABA content in the tomato is up to 12 times higher than regular tomatoes.[219]

Before a seed variety can be marketed, it must be registered in Japan's national catalogue of cultivated species. Japan requires official testing for distinctness, uniformity, and stability (DUS) and, for certain crops, value for cultivation and use (VCU) to register and market new varieties, similar to the EU's approach. When seeds are sold, they must have mandatory labelling or certifications attached, or information about them must be provided on labels, catalogues, order forms, or websites. [220]

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[213] https://www.ip.courts.go.jp/eng/documents/statistics/index.html

[214] This case is notable as it decided that the breeder could enforce their rights on the harvested shiitakes, not just the seeds/seedlings. https://innoventier.com/archives/2018/10/7223 [automated translation]

[215] This case is notable as it determined the direct comparison of the plants themselves should be the standard for judging variety similarity, rather than relying solely on registered characteristic tables. https://www.ip-bengoshi.com/archives/2415 [automated translation]

[216] https://www.japaneselawtranslation.go.jp/en/laws/view/3252

[217] https://www.japaneselawtranslation.go.jp/en/laws/view/3916/en

[218] https://pmc.ncbi.nlm.nih.gov/articles/PMC9789915/

[219] CRISPR-Cas9 technology was used to remove the autoinhibitory domain of the GAD gene, which boosts production of gamma-aminobutyric acid (GABA), associated with stress relief and blood pressure reduction.

[220] https://www.apsaseed.org/storage/2020/09/Status_of_seed_legislation_and_policies_in_the_Asia_Pacific_region_83678.pdf

7.4. United Kingdom

Key factors

- The UK has already adopted a specific regulatory regime for genome-edited plants.
- The UK is a member of the European Patent Organisation and the European Patent Convention.
- Deviations in the national patent law from the EU and/or EPC practice are possible.

IP Systems

The IP system combines national plant breeder's rights and patent protection. The central body is the UK IPO. The UK grants Plant Variety Rights under its national law aligned with UPOV conventions. A patent on plant-related inventions can be obtained at the national level via the UK IPO or by validation of a European Patent.

Patents on Plant Related Inventions

While there is an increasing number of national UK patent applications on biotech inventions, the majority of UK biotech patents (incl. patents on plant related inventions) is still granted through the EPC, thus the exclusions and interpretations of the EPC apply. This means that essential biological processes for producing plants and the resulting plants cannot be patented, but microbiological and other technical processes (e.g. CRISPR, TALENs) and the resulting plants are patentable.[221] Specific plant varieties cannot be patented, plants comprising traits or genes that cover multiple varieties are patentable.[222] The UK has its own patent rules for biotechnology inventions, which are largely identical to the EU Biotech Directive[223], which was implemented into UK patent law via the Patents Regulations 2000.

Plant Breeders Rights

Since Brexit, the UK has its own PBR system, relatively similar to the EU. The UK has been bound by the UPOV 1991 convention since 1999.[224] The Plant Varieties Act 1997[225] is the UK law implementing the UPOV 1991 standards, and it applies the same DUS criteria. PBR can be granted over protected varieties for 25 years (most species) or 30 years (trees, vines, potatoes). It covers production, reproduction, sale, marketing, export, import, and stocking. PVRs are administered through the Animal and Plant Health Agency (APHA), which leads on plant variety registration and trials. In practice, APHA's Plant Variety Rights Office conducts DUS testing and maintains the national PVR registry. For species without UK testing capacity, EU DUS reports are accepted, allowing parallel EU/UK filings and faster processing. Smaller breeding companies typically use PBRs due to lower costs and easier procedures without the inventive step requirement. The Act has a breeder's exemption that allows the use of protected varieties for developing new varieties. It also has a farmers' privilege that allows farm-saved

[221] Patents Regulation 2000, Schedule A2, 76A.02 & 76A.04 https://www.legislation.gov.uk/uksi/2000/2037/contents

[222] Patents Regulation 2000, Schedule A2, 76A.05

[223] (98/44/EC)

[224] https://www.upov.int/edocs/pubdocs/en/upov_pub_438_85.pdf

[225] Plant Varieties Act 1997 https://www.legislation.gov.uk/ukpga/1997/66/contents

seed use under specific, limited conditions, often with royalty payments to the holder of the PBR.

IP litigation related to plants

Litigation related to plant IP rights is rare the UK. A notable example of PBR enforcement is the Nadorcott mandarin variety case in which mandarins of the 'Tang Gold' variety are claimed to be essentially derived from the Nadorcott variety. A key patent case related to the import of soybean meal from Argentina, where the related herbicide tolerance trait was still subject to a granted UK patent.[226] CJEU case law made before 31 December 2020 is binding. Rulings after Brexit are not automatically binding, but as the UK and EPO still work with essentially the same EPC framework for patents, the UK can consider these rulings persuasive.

Regulatory Systems

Since Brexit, the UK has maintained most of the EU GMO rules.[227] Northern Ireland continues to follow EU rules, meaning the UK internal market now has two regulatory frameworks. [228]

GMOs are regulated under the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (SI 2002/2443).[229] Since March 2025 the UK (only as regards England) regulates NGT plants as Precision-Bred Organisms (PBOs) under the Genetic Technology (Precision Breeding) Act 2023 and the Genetic Technology (Precision Breeding) Regulations 2025: PBOs that could be obtained through conventional breeding are no longer categorised as GMOs and are regulated as conventional organisms. Food and feed products produced from precision bred organisms require a marketing authorisation to be placed on the market. Depending on the characteristics of the product, an assessment of the safety of the PBO for use in food and feed may be required. The Department for Environment, Food and Rural Affairs (Defra) must confirm if a plant is a PBO, not a GMO, before it can be commercialised. Businesses have to apply to Defra for a marketing notice and to the Food Standards Agency (FSA) for food/feed authorisation.

The UK regulates variety registration, seed certification and compliance with health and agriculture standards for seed and plant reproductive material under agricultural and plant health regulations.

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[226] In Monsanto Technology LLC v. Cargill International SA (Case No: HC06C00585; decision of October 10, 2007) HJ Pumfrey for the UK High Court of Justice denied extension of the scope of process claims to down-stream progenies. He decided that "[t]he phrase 'directly obtained by means of the process' means 'the immediate product of the process'," (No. 35) and found that "all the RR soybean plants in Argentina […] can be described as the ultimate product of the original transformation of the parent plant. But I cannot see that it can be properly described as the direct product of that transformation, a phrase I would reserve for the original transformed plant. This aspect of the claim must fail" (No. 37). Available at: https://www.casemine.com/judgement/uk/5a8ff75f60d03e7f57eabda1.

[227] APHA (2024). Import plants and plant products from non-EU countries to Great Britain. https://www.gov.uk/guidance/import-plants-and-plant-products-from-non-eu-countries-to-great-britain. APHA (2024). Import plants and plant products from the EU to Great Britain. Available at https://www.gov.uk/guidance/import-plants-and-plant-products-from-the-eu-to-great-britain

[228] AERA (2025). Import and export of plants. Available at: . https://www.daera-ni.gov.uk/articles/import-and-export-plants

[229] This regulation is the implementation of the EU Contained Use Directive and is retained post-Brexit. Available at: https://www.hse.gov.uk/pubns/books/l29.htm

The following tables provide summaries on main elements for the third countries.

Table 6 Patentable subject matter

	Specific Plant varieties	Plants	NGT-derived plants	Non-propagating plant products	Natural DNA sequence	Breeding Processes based on sexual crossing	NGT-Processes
EPC	✗	✓ *	✓	✓	✓	✗	✓
U.S.	✓	✓	✓	✓	✗	✓	✓
China	✗	✗	✗	✓	✓	✓ **	✓
Japan	✓	✓	✓	✓	✓	✓ **	✓
UK	✗	✓[230] *	✓	✓	✓	✗	✓

Note: * Excluding varieties and plants from essentially biological processes, ** Yes, if decisive human interference

Table 7 Patent and PVR/PBR law rights and limitations

	Patent Laws				PVR/PBP Laws		
	Scope of process claims	Exemptions			Exemptions		
		Research	Breeders	FSS	Research	Breeders	FSS
EU/ EPC	Direct products & progenies(1)	Yes (narrow)	Some EU countries, limited	Yes (= PBR)	Yes	Yes	Yes (limits/fees) (2)
U.S.	Direct products & progenies	No	No	No	Yes	Yes	Yes (no fees)
China	Direct product	Yes (broad)(4)	No	No	Yes	Yes	Yes (limited to self-consumption)
Japan	Direct products & progenies	Yes (broad)(4)	No	No	Yes	Yes	No
UK	Direct products & progenies	Yes(3) (narrow)	Yes	Yes (= PBR)	Yes	No	Yes (limits/fees)

Notes: (1) The extension to progenies is debated for general process patents as there is arguably no specific characteristic as the result of the invention. (2) In the EU, FSS is limited to certain privileged species. ,but does not apply to, for example, vegetables or ornamentals. Furthermore, farmers must pay a reasonable compensation unless they are small farming businesses. (3) It remains to be seen whether the current restrictive EPC practice will also apply to national UK filings, both regarding the definition of essentially biological processes and plants derived from them (4) Likely incl. breeding.

[230] t needs to be seen whether the very restrictive EPC practice continues for national UK filing both with respect to the definition of essentially biological processes and plants derived therefrom

Table 8 Plant related patent applications and granted patents, priority years 2014-2025

	Plant related inventions[231]		Patent on specific varieties[232]		NGT technology with plant relevance (incl. NGT-plants)[233]		NGT-derived Plants (at least on example with NGTs on plants)[234]	
	Appl.	Granted	Appl.	Granted	Appl.	Granted	Appl.	Granted
PCT	7367	N.A.	52	N.A.	1203	N.A.	156	N.A.
EPC	3393	448	25	*0*[235]	639	60	92	7
U.S.	38 150	22 454	9558	7625	1321	582	415	158
China	6814	1930	12	6	4012	1473	539	183
Japan	1561	366	15	6	280	102	-	-
UK	193	6	0	0	22	5	0	0
Total	78 810	29 915	10 766	8130	9873	2801	1364	377

Note: Status: Aug. 20, 2025. Search conducted in PatSnap™, one document per application

[231] Excluding U.S. “Plant Patents” for 8under 35 U.S.C. 161 for certain asexually propagated varieties. Search profile: MCPC:(A01H5* OR A01H6* ORC129N15/82) NOT PN:(USPP*).

[232] Excluding U.S. “Plant Patents” for under 35 U.S.C. 161 for certain asexually propagated varieties and GM events. Search profile: MCPC:(A01H5* OR A01H6*) AND CLMS:(ATCC OR NCMA OR NCIMB OR deposit*) NOT PN:(USPP*) NOT CLMS:(event*)) AND TA:(variety* OR cultivar* OR hybrid OR inbred* OR parent* OR line* OR Strain*

[233] ((TA:(seed OR plant OR植物 OR种子 OR maize OR wheat OR soy* OR 玉米 OR 小麦 OR大豆) OR CLASS:(A01H* OR C12N15/82))) AND (TAC:(Cas9 OR CRISPR/Cas9 OR CPF1* OR CPFI* OR CPF-1* OR "Cpf 1“ OR CAS1* OR "Cas 1“ OR CAS2* OR "Cas 2“ OR CAS3* OR "Cas 3“ OR CAS12* OR "Cas 12") OR TAC:(*Cas9 OR *Cas12a OR *Cpf1 OR CAS-12* OR C2c1 OR C2c3 OR C2c2 OR CRISPR* OR tracrRNA OR crRNA) OR TAC:((指导* OR tracr*) $w3 (RNA* OR 核糖核酸* OR 核酸 *)) OR CLASS:(C12N2310/20))

[234] DESC:(("Example 1“ OR “实施例1”) $w40 (cas9 OR CRISPR/Cas9 OR MAD7 OR Cas12* OR "guide RNA“ OR protospacer*)) OR DESC:(("Example 2“ OR “实施例2”) $w40 (cas9 OR CRISPR/Cas9 OR MAD7 OR Cas12* OR "guide RNA“ OR protospacer* OR 指导*)) OR DESC:(("Example 3“ OR “实施例3”) $w40 (cas9 OR CRISPR/Cas9 OR MAD7 OR Cas12* OR "guide RNA“ OR protospacer*)) OR DESC:(("Example 4“ OR “实施例4”) $w40 (cas9 OR CRISPR/Cas9 OR MAD7 OR Cas12* OR "guide RNA“ OR protospacer*))) AND MCPC:(A01H5* OR A01H6* OR C12N15/82*)

[235] Since the EPO does not consider certain fungi (e.g. mushroom) to constitute “plants” and “plant varieties”, there are isolated cases (5) in which the EPO granted a patent while at the same time the CPVO granted PVRs on such species. An example is EP1993350B2 "Brown mushrooms for commercial production".

Table 9 Plant variety applications, 2023

Office	Rank	Resident	Non_Resident	Total	Non_Res_Share
CPVO[236]	2	2219	647	2866	22.6
U.S.	3	542	607	1149	52.8
China	1	15 528	656	16 184	4.1
Japan	9	404	187	591	31.6
UK	6	759	60	819	7.3

Source: WIPO Statistics Database, August 2024 [237]

Table 10 Regulatory frameworks

	GMO	Specific NGT	Mandatory seed market authorisation DUS/VCU
EU/ EPC	Yes (in practice limited to import)	No	Yes
U.S.	Yes (bifurcated USDA / EPA)	Yes	No
China	Yes	No ("GMO light")	Yes
Japan	Yes	Yes	Yes
UK	Yes	Yes	Yes

[236] In general, the national offices of CPVO member states receive lower volumes of applications, because applicants may choose to apply via the CPVO when seeking protection within any CPVO member state

[237] https://www.wipo.int/edocs/pubdocs/en/wipo-pub-941-2024-tech4.xlsx

SECTION II
PATHS FOR IP PROTECTION OF NGT PLANT-RELATED INVENTIONS

8. The patent system

8.1. Approach for this section

The proposal for a new *Regulation on plants produced by certain new genomic techniques* has spurred a debate about appropriate IPRs for NGT-derived plants. While the patentability of NGT technologies is rarely debated, views on IPRs on NGT-derived plants range from voices calling for a general exclusion of NGT-derived plants from patentability and/or patent rights to supporters of the current dual system of patent and plant variety protection. Against this background, the study was tasked with providing an assessment of current and potential IP issues relating to NGT-derived plants and suggesting measures to mitigate such issues.

As the issues can be associated primarily with either the patent system or the PVR system, Chapter 8 assesses the issues and potential measures related to the patent system. Under this chapter, requirements for patentability, scope of protection rights, as well as access and transparency measures are discussed. Each subchapter presents the state of play, measures incl. their costs and benefits, as well as risks and challenges including the impact on innovation systems and market dynamics. This complements **Chapter 6.4 which** provided a similar assessment of **the role of the PVR system** and its interplay with NGTs, its current state of play, costs and benefits, scope of protection, and relevance for innovation and market dynamics.

8.2. Patentability

Patents are conferred on inventions if they meet specific requirements of novelty, inventive step, and have an industrial application. The questions of (i) what is patentable (i.e., clear standards of patentability) and (ii) what falls under a patent's scope (i.e., clear definition of the rights conferred by patents and their limitations) are crucial both for potential patentees but also for their competitors. This section discusses the patentability of NGT-related inventions, resulting patent rights and limitations, and the potential impact on innovation systems and market dynamics. It also provides a synopsis of potential changes suggested by stakeholders, experts, and the EU co-legislators.

8.2.1. Patentability of NGT-Related inventions under the EPC and the Biotech Directive[238]

NGT-related inventions can be largely distinguished between

(i) technologies and tools which are used to make an NGT-derived plant, and

(ii) the NGT-derived plant itself including its parts, components (e.g., modified DNA sequences), and products derived therefrom.

As NGT-based processes are, in general[239], not considered "essentially biological processes"; both the processes and the resulting plants are deemed patentable under the EPC if they also meet the general requirements of patentability and as long as the invention is not limited to a single variety. However, according to the Guidelines for Examination in the EPO[240], a claim on an NGT-derived plant must be limited by a disclaimer as by definition such plant could also be derived by conventional breeding or in nature. The disclaimer excludes from the scope of a plant-related claim plants which are exclusively obtained by essentially biological processes. The EPO Examination Guidelines (G-II, 5.2 and 5.4) specifically also require a disclaimer in cases where the description mentions only a technical production method and contains no information about the use of an essentially biological process.[241] If, on the other hand, the feature in question can unambiguously be obtained by technical intervention only, e.g. a transgene, no disclaimer is required.[242]

8.2.2. Rights conferred by patents on NGT-related inventions and their limitations

The EPC is largely silent about rights conferred by patents and related limitations.[243] A harmonised framework on the rights conferred by patents relating to biological material and their limitations within the EU is provided in the Biotech Directive and the UPCA (for the participating Member States). Rights and limitations are implemented in the national patent laws of EU Member States and the UPCA. The following rights and limitations set out in the Biotech Directive are of importance in the context of NGT-related inventions:

(i) Patents on biological material extend to any biological material derived through propagation or multiplication possessing the same characteristics (Art. 8(1))

[238] For general requirements and limitations related to patentability of plants under the EPC see Section 6.2.2.1.

[239] Rare exceptions are NGT processes which depend on sexual crossing e.g., EP3316676 - HAPLOID INDUCER LINE FOR ACCELERATED GENOME EDITING (UNIV MINNESOTA; see Office Action dated 16.11.2023); EP3547825 - SIMULTANEOUS GENE EDITING AND HAPLOID INDUCTION (Syngenta; see Office Action dated 10.06.2022)

[240] Examinations by the EPO are conducted by a division of three examiners, and a lawyer may join if there are legal concerns (e.g. ordre public or exclusions from patentability) (ID_23). If issues arise, the applicant is contacted and may amend the application. Ultimately, the patent is either granted or rejected. Any third party can file observations once the application is published. Following the grant, there is a nine-month opposition period for anyone to challenge the patent.

[241] See EPO: 5.4 Plant and animal varieties or essentially biological processes for the production of plants or animals, https://www.epo.org/en/legal/guidelines-epc/2023/g_ii_5_4.html

[242] ibid

[243] Article 64 EPC merely provides that (i) "A European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State, and (ii) If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process. In consequence, other than the extension of the protection a process to its direct products, the EPC refers to the national patent laws when it comes to patent rights and limitations.

(ii) Patents on a process for producing biological material with "specific characteristics as a result of the invention" extend to material directly obtained through that process and to any other biological material derived therefrom through propagation or multiplication possessing the same characteristics (Art. 8(2)).

(iii) Patents on genetic information extend to all material in which the genetic information is contained and performs its function. [244] (Art. 9).

(iv) Patents do not extend to biological material placed on the market by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed (*Art. 10).*

(v) Patents do not extend to plant propagating material sold to a farmer by the holder of the patent or with his consent for agricultural and the farmer uses the product of his harvest for propagation or multiplication (under the conditions of Article 14 of Regulation (EC) No 2100/94).[245]

(vi) A breeder is entitled to a compulsory cross-license if he/she cannot acquire or exploit a plant variety right without infringing a prior patent, and the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent (Art. 12).

The scope of several of the rights and – especially – limitations is uncertain, which hampers their practical use.[246] For example:

(i) The interpretation of a "significant technical progress of considerable economic interest" as a requirement for a compulsory cross-license is unclear when it comes to new plant varieties. As the compulsory license can only be requested when a PVR rights has been obtained (i.e., at the end of a lengthy breeding process), breeders would take a very high risk in relying on a chance of obtaining a compulsory cross-license. [247]

(ii) The interpretation of "specific characteristics as a result of the invention" in the context of patent rights related to processes in unclear. While some argue that also general processes extend to products as long they cause a specific characteristic, others argue that only characteristics which are essential for the inventive step are entitled to an extension. [248]

[244] The protection of a patented gene sequence only extends to material applies in situations where the sequence performs the function originally disclosed in the patent application. This effectively prevents broad, untethered claims over genes that do not specify a concrete use or biological function. Under C-428/08 (Monsanto v Cefetra), the CJEU clarified that Article 9 of the Biotech Directive limits patent protection strictly to cases where the genetic information is actively performing its function in the material concerned. The Directive's scope is exclusive and harmonizing, leaving no room for broader national protections, including for older patents, and remains consistent with WTO/TRIPS obligations.

[245] Article 11 of the Biotech Directive allows farmers who have lawfully acquired patented plant propagating material to use the resulting harvest for reproduction on their own holdings without infringing the patent, provided that the conditions mirror those set out in the EU Plant Variety Rights Regulation. This ensures that traditional agricultural practices can continue despite the existence of patent protection. In consequence, the right of a farmer to use farm-saved-seed does not change whether a variety is protected by a PVR, patents, or a combination of both.

[246] Kim, D., Kock, M. et al. (2024). New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector. 'GRUR International', 73 (4), 323–335.

[247] Ibid.

[248] In German, this is covered under "erfindungsgemäße Eigenschaften". For a review of positions see Kim et al 2024(Fn. 246).

(iii) The term "incorporated" in Article 9 is unclear. Does this term only cover incorporation by technical processes (i.e., transformation) or also incorporation by breeding processes (i.e., trait introgression breeding)? [249]

A breeder's exemption is not provided for in the Biotech Directive. However, it is argued that such exemption is inherently foreseen (likely as part of the research exemption) otherwise it would be impossible to establish a plant variety right to trigger the compulsory cross-license under Article 12.[250] Starting with Germany, several national patent systems in the EU and the UPCA offer a limited breeder's exemption. The Member States which provide for this exemption in their national patent laws are Austria, Belgium, Spain, Finland, France, Germany, Italy, Latvia, the Netherlands, Portugal, and Sweden. The patent law's limited breeder's exemption enables "the use of biological material for the purpose of breeding, discovering and developing a new plant variety"[251]. Unlike the research exemption[252], the breeder's exemption is not limited to experiments on the subject matter of the invention but allows experiments with the subject matter. This allows breeders to use patent-protected biological material not only as a research tool but also to develop new varieties[253]. However, the exemption is "limited" as the consent of the patent owner will be required for commercial activities with the new variety if it still comprises the patented characteristic and the patent is unexpired.

Several EU member states have implemented further specific limitations for plant-related patents in their national patent laws in addition to the Biotech Directive. According to ALLEA, "*There is currently no universal standard of the limited breeder's exemption in all EU member states, which understandably affects harmonisation efforts and creates uncertainties for breeders*." Table 11 provides on overview of national plant-related patent exemptions which are not provided for in the Biotech Directive. Further harmonisation in terms of material scope and geographical coverage (e.g., EU-wide adaptation of exemption not provded by the Biotech Directive such as the breeders exemption) has been brought up as desirable in interviews.

Table 11 Selected countries with additional plant-related patent limitations in national patent laws – prior to the UPCA

Country	Exemptions
Austria	• Limited breeders' exemption[254] • Full breeder's exemption for plant varieties developed independently from the patented material through conventional breeding. [255][256] • Exemption for materials obtained *"accidentally or in a technically unavoidable manner" (e.g., natural* cross-pollination. [257]

[249] Ibid.

[250] Kock M. (2023), 'Intellectual Property Protection for Plant Related Innovation Fit for Future?' Springer. Available at: https://link.springer.com/book/10.1007/978-3-031-06297-1

[251] https://www.gesetze-im-internet.de/patg/BJNR201170936.html

[252] A research exemption can be found in various national patent laws. The UPCA includes in Art. 27 a range of exemptions, including (b) *acts done for experimental purposes relating to the subject matter of the patented invention* – which is interpreted as an exemption for research.

[253] Ibid.

[254] Austrian Patent Act (Fn.291), Article 22(1a). *§ 22. (1a) The effect of the patent does not extend to the use of biological material for the purpose of breeding, discovering and developing a new plant variety.*

[255] Austrian Patent Act (Fn.291), Article 22(1b). *§ 22. (1b)*

[256] However, in Austria the requirement to work independent from the material of the patentee does not apply if the material of said breeder is itself obtained exclusively by an essentially biological process. See Explanatory Notes: "A breeder also fulfils the requirement of independence if he uses plant varieties of third parties (including those of the patent holder) which in turn have been obtained exclusively by an essentially biological process." At: https://www.parlament.gv.at/gegenstand/XXVII/I/1955.

[257] Austrian Patent Act 1990 (Fn.291) Article 22c (4).

Country	Exemptions
France	• Limited breeders' exemption (Article L613-5-3) • Full breeder's exemption for plant varieties developed independently from the patented material through an essentially biological process (L613-2-3, Article 10 para. 3) .[258]
Germany	• Limited plant breeder's exemption (Article 11(2a)) • Exemption for materials obtained "accidentally or technically unavoidable" e.g., natural cross-pollination (§9c(3)). [259]
Netherlands	• Limited breeders' exemption (Art. 57, 3.c)[260]
UPCA	• Limited plant breeder's exemption (Art 27(c))[261]

8.2.3. Costs and benefits

While the patent system is not without complexities, it remains a fundamental mechanism for supporting innovation, particularly in sectors with long development timelines and high costs. An increasing impact of patents is an inherent consequence of the "technification" of any industrial sector.

Historical experience from the software sector illustrates the risk of exclusion due to a lack of awareness: many small enterprises failed to protect their innovations when patents on computer-implemented inventions started to be used, simply because they were unaware that patenting was possible. The **technical transformation** the breeding sector is facing, and the growing role of patents in this transformation, presents both opportunities and challenges. While some small and medium-sized breeders may struggle with the complexity of patents and their unpredictability in terms of enforcement costs and required legal knowledge to deal with this right, others may benefit from the exclusivity and commercialisation that patents offer. (ID_23)

8.2.3.1. Benefit: Market exclusivity & license income

In case a plant trait is covered by a granted patent or pending patent application the patentee has two options: to grant a license and exploit the patented invention, or to deny a license and keep the exclusivity.

Interviews with breeders suggest that traditionally, breeders develop their own plants and market them, but they also license (or cross-license) their traits to competitors. This has a) **economic benefits** of license income (~5 % of net sales of the protected variety from every licensee) and b) potentially wider **societal benefits** to enable faster market penetration of the trait. Furthermore, denying a license affect **reputation**: '*Nobody in the breeding sector wants to be known as not sharing an innovation*' and keeping the trait exclusively. Yet, some indicated that there are exceptions: In some cases, it is not in the interest of a breeder to grant licenses. Depending on the importance of a trait, such exclusivity can lead to exclusion of other market actors and market concentration. (ID_5, 20, 22).

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[258] France IP Code L613-2-3, Article 10 para. 3:. At: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000033033605/.

[259] German Patent Law §9c(3).

[260] https://wetten.overheid.nl/BWBR0018040/2020-01-01/#Hoofdstuk7_Paragraaf3

[261] This exemption is available for the Unitary Patent and for non-unitary European patents which fall under the jurisdiction of the UPC in the 18 Member States which have ratified the UPC Agreement. With this, the limited plant breeder's exemption is more widely available in Member States but only for a Unitary Patent.

8.2.3.2. Benefit: Company valuation and partnerships

NGT-related technologies and plants are also created by **academic institutions** and **start-ups**. To them, patents have functions which go beyond market exclusivity, as often there is no or no significant market share. Having a patent on certain aspects of a technology provides a **stronger position in negotiating** partnerships, license agreements, or financial funding. Patents allow new companies to spin-off through attracting venture capital (VC) as they are a key component in company valuation. Thus, a patent portfolio is a goal of public research organisation.

However, the licensing policy of public institutes is not without criticism, especially when exclusive licences are granted: From an economic perspective, permitting patents on government sponsored research provides a double reward: first through the public funding and second through the patent.[262] Interviews suggested that the fact that CVC granted an exclusive license to its CRISPR/Cas9 technology in major crops to one commercial entity (Corteva) is problematic, as the licensee in this case decides to whom, and under which conditions, access to the Cas9 technology may be sub-licensed.[263] Therefore, interviews preferred a policy of non-exclusive licenses. In collaborative research projects, however, academic institutions may prefer to grant exclusive licenses to their commercial partners or to their own spin-offs. Such exclusive licences may be limited to a specific use or geographical area, thereby allowing for the establishment of a broader range of exclusive licences. (ID_3, 15, 17, 25)

8.2.3.3. Cost: Patent filing, examination and maintenance

The costs to establish a patent on plant-related invention, usually go far beyond the costs to merely establish a marketable plant variety. Ensuring an adequate written description and distinguishing the own trait from the prior art requires capability in molecular marker development and testing, sequencing, target gene verification etc. This typically requires dedicated research labs, technical equipment, and trained personnel. With the help of technical methods – for which breeders either need to obtain licenses or develop own methods – patentable new plant traits can be developed. All this increases costs for the R&D process.

Once a patentable invention has been developed, the process of preparing a patent application starts. This requires involvement of experts in patent law. While small firms typically do not employ legal counsels and patent experts, medium-sized and larger firms do so. Within a large company, the typically high costs of IP experts have a relatively much lower impact than for small companies.

Among the **patent** costs to consider are the costs for preparing the patent application – charged by patent law firms – , the **fees to be paid during the patent grant procedure** and the **annual maintenance costs charged** by the patent office. These costs can be multiplied if a patent is filed in different jurisdictions, which in additions comes with translation costs.[264] The Dutch patent office estimates the one-time filing costs between €200 and €920 and legal costs for the application of about €900. Different reports and services range from €5 to €544.

[262] See Scotchmer, S. (1991), Standing on the shoulder of giants: cumulative research and the patent law, *Journal of Economic Perspectives*, 5/1991, pp29-41

[263] In the further discussions it was also highlighted that the still missing clarification about the foundational patents from U.S. courts equally affect Corteva. If the foundational patent is found invalid in the U.S., the provided sub-licenses would be unlawful.

[264] See https://www.epo.org/en/service-support/faq/applying-patent/fees-and-costs/how-much-does-european-patent-cost and https://www.epo.org/en/applying/european/unitary/unitary-patent/cost

Annual maintenance fees add up to €11 040 for 20 years of protection.[265] The filing fees for a European patent application cost on average €6 800 according to the EPO.[266] The EPO offers a 30 % fee reduction for micro-enterprises, individual applicants, non-profit organisations, universities, and public research institutions.[267] This measure aims to lower financial barriers and promote broader participation in the patent system. The EUIPO SME Fund is also offering vouchers to support EU SMEs with patent and other IPR applications.[268] In addition to the filing and examination fees, the renewal fees for patents need to be considered, too.[269] In total the costs for a single European patent application can easily accumulate to more than €100 000, which does not include the costs of defending a patent in a potential opposition, appeal, or court proceedings if any. The costs to file a patent were mentioned in several interviews as a key consideration whether to use patents, or PVRs – often in combinations with trademarks, or trade secrets – as an alternative.[270]

Fees for application of **PVR** can be done online for a fee of €450 or on paper €800. There are examination fees in the range of €1 980 – €4 130 depending on the species fee group. The annual renewal fee is €380.[271]

8.2.3.4. Cost: Managing Freedom to Operate (FTO)

Patent applications are published 18 months after the first application date and may be reviewed free of charge in publicly accessible databases such as the Espacenet database of the EPO.[272]

However, to identify and evaluate the patents relevant for an own research and breeding activity or a third-party plant variety requires extensive technical and legal knowledge. The results and their associated risks need to be interpreted, placed in the appropriate economic context, and risk mitigation strategies need to be established. This can be done by in-house legal and patent experts, or external patent attorneys.

A key challenge is the identification of patents which pertain to a specific plant variety. This is only possible, if the breeder provides the necessary information. The relevant patents relating to plant traits or gene sequences can, in theory, be identified by molecular testing, which may be cumbersome: A variety needs to be checked against all patents which could potentially cover biological material or genetic information incorporated in it, which could in some instancesbe dozens of patents. In addition, based on the variety alone, it is practically impossible to identify patents which relate to technologies and processes used to produce it. These patents usually do not leave a detectable fingerprint in the resulting variety, while still possibly covering material incorporated in it.

[265] https://english.rvo.nl/en/topics/patents-intellectual-property-rights/types-ip-rights/patents/system-and-fees-nl/fees Fees as of 23.3.2021

[266] https://www.epo.org/en/service-support/faq/applying-patent/fees-and-costs/how-much-does-european-patent-cost

[267] Decision of the Administrative Council of 14 December 2023 (CA/D 4/23)

[268] Cf fn 289

[269] See https://www.epo.org/en/applying/european/unitary/unitary-patent/cost for an overview of patent renewal fees at the EPO

[270] The recent survey of EUIPO (2025) shows clearly more favourite choice of SMEs towards the 'cheaper' trademark. While overall 50% of large companies but only 9.7% of SMEs own IPR, almost 13% of large companies own patents – compared 10 1.1% of SMEs. Similar ratios are true also for design rights. Yet, when it comes to trademarks, still 46% of large companies have a trademark, but also 9.2% of SMEs.

[271] Prices as of 7.6.2023. Updated fees are published in the Official Journal of the EU. See: https://cpvo.europa.eu/en/applications-and-examinations/fees-and-payments

[272] See : https://www.epo.org/en/searching-for-patents/technical/espacenet

The challenges associated with the **increasing number of process or technology patents** was specifically addressed indicated in interviews and the literature. Since the first foundational CRISPR/Cas patent applications in 2012, there has been an increase in NGT related patent applications and *"a large number of applications [were] filed within a short timeframe. Under the EPC post-published earlier applications are only relevant for novelty (Art. 54(3)/56 EPC)*." As a result, multiple patents with closely related subject matter were granted which adds to the complexity of the IP landscape.[273] According to interviewees, simply reading patent applications does not provide clarity in this complex situation which has been described by interviewees as "confusing", "disturbing", "not providing clarity", or as "hampering breeding programmes" (ID_2, 3, 6, 11, 16, 20). However, the challenges of overlapping patents is not specific to the plant industry but occurred also in other technology sectors. In certain cases[274], **overlapping patents or patent thickets** (complex webs of dependencies between patents[275]) can limit innovation due to the fact that the cost or ability of actors to pursue follow-up innovation is reduced[276]. Strategic patenting practices such as defensive portfolios or exclusive arrangements, may affect market dynamics and access to technology. Tools such as cross-licensing and patent pools may help address these issues – which are common to most sectors.

The need to conduct FTO analysis increase operational costs for breeders without leading to better varieties. For example, if a breeder needs to check if patented material is among the breeding material, they will need to test with biomolecular markers against the presence of patented characteristics. For a known marker, every check costs ~€3. For every potential product it can be easily 100 to 300 known markers that need to be tested. Yet, the use of technology has positive impacts on the time needed for the research process so that the breeder may benefit from the extra operational costs. For conventional breeders with limited patent experience, an increase of patent-protected plant varieties comes with additional costs as they have to outsource the required FTO analysis. Even to large companies, the costs to manage FTO – including potential licence negotiations – are substantial.

These costs remain substantial, even with transparency databases such as PINTO and licensing platforms such as the ACLP and the ILP Vegetable. Whether a specific variety is associated with a patent or patent application in the PINTO database depends on the interpretation and opinion of the patent holder and is not in itself an indication that the patent covers the material of a variety in question. For example, it may merely relate to molecular markers. Thus, according to an interview, further investigation and legal analysis are required to determine whether a patent listed in the PINTO database is relevant. (ID_11)

FTO costs vary with the complexity of the search and analysis. In addition to the costs of molecular testing, substantial costs for patent search, and analysis may apply. Since patent attorneys tend to charge different rates, the search costs in the EU-MS vary, but are usually

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[273] CRISPR-Cas Gene Scissors are set to cut their way through EU Regulation on genetically modified plants, in: Hoffmann, Eitle, Quarterly, June 2024. See: https://www.hoffmanneitle.com/news/quarterly/he-quarterly-2024-06.pdf#page=5

[274] Klein, M., Şener, F (2024), Schumpeterian growth theory and the patent puzzle, in: Park, W. (ed.), Handbook of Innovation and Intellectual Property Rights, chapter 7, pages 102-119, Edward Elgar Publishing. Available from https://ideas.repec.org/h/elg/eechap/20438_7.html

[275] von Gravenitz, G., Wagner, S., Harhoff, D. (2013), Incidence and Growth of Patent Thickets: The Impact of Technological Opportunities and Complexity, Journal of Industrial Economics, 61/3, pp521-563., see: https://onlinelibrary.wiley.com/doi/10.1111/joie.12032

[276] Zingg, R. (2021), Foundational Patents in Artificial Intelligence, book chapter in. Lee, J-A (et al) (eds), Artificial Intelligence and Intellectual Property, see: https://doi.org/10.1093/oso/9780198870944.003.0005; also: fn 262

start with €200 per hour. Thus, legal fees can easily reach €5,000 to €16 000[277], but can also be substantially higher.

As breeders often integrate multiple third-party varieties in their breeding programmes[278] - sometimes 100-120 varieties over time[279] - depending on the crop the costs related to **prior art searches** can be substantial up to a point where they make breeding economically unattractive. If the percentage of varieties covered by patent rights in a certain species becomes significant and/or the relevant patents cannot be identified, breeders may stop using any third-party variety in their breeding programme. For small breeders, which depend on the access to third-party germplasm this would impact their ability to compete, while larger breeders can rely on their usually substantial in-house germplasm collections. An example was given of a small breeder with less than 50 employees (including less than 10 breeders). For such a firm, it takes on average half a day per week of one administrative employee to do the searches for the FTO including checking the various databases and identification in gene banks. In larger firms with more breeding programmes, the effort can be larger. These small firms do not have the means – nor would it be efficient – to employ dedicated legal experts to perform this work. (ID_8, 18, 22).

8.2.4. Cost: Patent enforcement and challenging patent validity

So far, patent-related court cases within plant breeding are limited. The Netherlands indicate that there are no more than 25 cases per year – while there are about 141 000 patents in force in the country. In terms of costs, the Dutch patent office suggests that a patent holder should maintain a reserve between €20 000 and €70 000 to assert its right.[280] However, the costs could be substantially higher. Especially if experts and testing is required the costs could easily reach several hundred-thousand euros.

To some interviewees, the absence of litigation is not a good sign, and **the threat of litigation** has been indicated as the **greatest deterrent** for small and medium-sized breeders. Out-of-court settlements, which are typically ending in a licence agreement, are more common, according to one interviewee. (ID_9, 13, 16, 28)

While breeders can challenge the validity of a granted patent in oppositions before the EPO, also here the related costs can be substantial. Unless there is a clear novelty-destroying prior art and convincing related evidence, the proceedings can be complex, may include multiple rounds or arguments, and be followed by appeal proceedings. Related costs can easily reach €100 000.

To mitigate enforcement costs, EUIPO maintains the IP Scan Enforcement Voucher. This instrument supports SMEs facing issues related to IPR infringement. Whether they have been accused of infringement themselves or another party is violating their rights, the IP Scan Enforcement service provides SMEs with tailored consultancy and a clear report outlining actionable steps, delivered by an expert in their own language. The voucher reimburses 90 % of the cost, up to the limit applicable in the relevant country.[281]

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[277] Schweizerische Eidgenossenschaft (2024), Vorentwurf der Revision des Bundesgesetzes über die Erfindungspatente, p.7

[278] See for example Kwiatkowski, P (2023) Buckwheat breeding and seed production in Poland, Fagopyrum 40/2, pp29-40, see: https://ojs.sazu.si/fagopyrum/article/download/8043/7522; the potato breeding programme at Teagasc: https://teagasc.ie/crops/crops/potatoes/research----breeding-programme/, the breeding programmes of Julius Kühn Institut https://www.julius-kuehn.de/zuechtungsforschung

[279] Cf fn 277, p. 7. The example is made for small cereal crops

[280] https://english.rvo.nl/topics/octrooien-ofwel-patenten/octrooi-aanvragen/patent

[281] https://www.euipo.europa.eu/en/sme-corner/ideas-powered-for-business/ip-scan-enforcement

8.3. Views on potential changes to the patent system in respect of NGT plant-related inventions

A granted patent confers the owner an exclusive right to prohibit unauthorised use of the patented invention. However, there are legal uncertainties with respect to the scope of these rights, especially for patents on technical processes for the production of plants (see explanations above under 8.2.2[282]). Likewise, while there are specific limitations in relation to plant-related patents which aim to balance exclusivity with third parties and societal interest (e.g., compulsory cross-licensing), interviewees indicated that at this stage these limitations lack clarity to have any practical benefits. The possibility of revising the criteria for the patentability and/or the scope of patent rights of NGT plant products and processes is discussed as a possible course of action for the EU.

Notably, any reform must align with the overarching international legal framework, including the TRIPS Agreement. While some of the suggested changes are possible within the TRIPS framework according to experts, a TRIPS revision through the WTO is unlikely.[283]

Further, there are substantial differences between amending exceptions to patentability and limitations to patents rights, both with respect to the amendment process and the legal implications. While limitations to IPR rights in the EU can be implemented by a Regulation with direct effect on all EU patents rights[284], the 'normal' instrument is a Directive and a subsequent amendment of national patent law (and in some cases the EPC, indirectly). In addition, depending on the impact of the amendment, transitional measures could be necessary in case the amendment substantially reduces the economic value of the existing patents. In the case of the limited breeder's exemption in patent laws, no such transitional measure was deemed necessary.

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[282] Kim, D., Kock, M. et al. (2024). New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector. 'GRUR International', 73 (4), 323–335.

[283] Metzger, D. A. (2024). Rechtliche Möglichkeiten zur Änderung des Patentschutzes von Pflanzen in Deutschland, Europa und im internationalen Recht (Gutachten im Auftrag der Bundestagsfraktion Bündnis 90 /Die Grünen), p. 35

[284] For example, the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights provides under Article 92 (Cumulative protection prohibited) "1. Any variety which is the subject matter of a Community plant variety right shall not be the subject of a national plant variety right or any patent for that variety. Any rights granted contrary to the first sentence shall be ineffective.

Table 12 Categories of legal changes, their requirements and consequences

Options of legal changes	Requirements and impacts
Exception from patentability	• Require change of Biotech Dir. 98/44 • Require change of EPC by Diplomatic Conference (unanimous consent of all 39 EPC Member States).[285] • Will only affect patents filed after entry into force of the amendment (i.e., no retroactivity).[286]
Limitations to patent rights	• May require change of Biotech Dir. 98/44.[287] • May require change of national patent laws and UPCA. • Affect all unexpired patents and patent applications - transitional measures might be required.

The following sections discuss the uncertainties and risks related to rights conferred by plant-related patents and their existing limitations, options for clarification, and potential additional limitations. There is little data so far that would allow quantification of these risks. Data from other jurisdictions, such as the U.S., is not entirely comparable due to different patent and plant variety systems for plants, the structure of the sector, as well as the business models of major corporate actors. Nonetheless, several options were raised in the interviews. Suggestions of potential reforms to Directive 98/44/EC[288] serve to expand or further clarify the limitations to patent protection in the area of biotechnological inventions.

8.3.1. Exceptions to patentability

Views on patentability are nuanced. The patentability of NGT processes and methods was not challenged by interviewees or focus group participants, but the patentability (and/or patent protection) of NGT-derived traits or plants was subject to some criticism. The views ranged from as a matter of principle opposition to patentability of plants to suggestions to improve patent examination guidelines and change patentability criteria. An exclusion of “NGT plants, plant material, parts thereof, genetic information and process features” by changing Article 4 of Directive 98/44 has been brought forward by the European Parliament in the context of the ongoing co-decision process on the NGTs proposal, seeking the exclusion of NGTs in Category 1 and 2 and conventional plants from patentability. ALLEA has suggested a stricter

[285] See Art. 33 EPC, including 33.1.b. Experts have expressed concerns about introducing broad exceptions to patentability, as these could conflict with the intentions of Articles 52 and 53 EPC or require a change of these Articles by a diplomatic conference. They have also questioned proposals to redefine NGT processes as “non-technical. Experts emphasized that after the recent G 3/19 ("Pepper") decision it is unlikely that a fundamental expansion of the limitations to Art. 53(b) EPC is feasible by a decision of the EBA or a decision of the Administrative Council with simple majority. Metzger, 2024, p. 36-37

[286] The lack of reactivity results from the "legal certainty" principle (see rational in G03/19 "Pepper"). Since already filed patents and patent applications are not affected, this approach results in a fragmentation of the system, with patents from different periods remaining in force simultaneously until the expiration of their term of protection. Kock, M. A. (2025) NGT proposals by the EU Commission, European Parliament and Council – state of the trilogue with respect to intellectual property rights, presentation at 12TH GRUR meets Brussels Workshop, 25 June 2025.

[287] A direct implementation of a limitation through a regulation is possible if it does not create a conflict with the existing Biotech Directive. A broad exception from patentability covering plants, seeds, genetic resources, and plant breeding technologies may not be reconcilable with the Directive, either for naturally occurring plants or for NGT plants. Whether broader exception from patent rights (e.g., a full breeders exemption) are compatible is debated. Metzger, 2024, p. 44

[288] As presented in Metzger (2024), ‘Rechtliche Möglichkeiten zur Änderung des Patentschutzes von Pflanzen in Deutschland, Europa und im internationalen Recht’. Gutachten im Auftrag von Bündnis 90/Die Grünen Bundestagsfraktion

interpretation of patentability requirements in the EPC, in particular those defining the requirements for inventive step and the required supporting evidence for inventiveness brought forward during patent application procedures.[289] One academic expert refers to the possible use of the exception to patentability based on '*public order'* reasons. It is argued that this pathway based on Article 53 EPC may be implemented without changes to the EPC but could face challenges whether the rationale for the exception is indeed based on ethical grounds.[290]

Some interviewees raised that patentability of traits, even under the EPO's disclaimer approach, can still lead to unintended infringement. So far, the EPO considers random mutagenesis using technical means as a technical method and grants patents based on this.

It is still debated if random mutagenesis is a "technical process": While such processes use technical means (e.g., UV- or gamma-irradiation or chemicals) they are by definition "random" i.e., not reproducible, which is a key requirement for technical processes. Based on this consideration, the Austrian patent laws defines random mutagenesis as an essentially biological process.[291]

Conventional breeders may come to the same result with spontaneous or some random mutagenesis using for example natural UV light – which is a classical breeding technique, and if – for example – a mutation of a certain target gene happens spontaneously during a breeding process. Depending on the scope of claim of the granted patent (with or without disclaimer depending on the filing date), the granted patent can prevent other inventors to commercialise their own invention since the result of the classical random mutagenesis may accidentally infringe the granted patent. (ID_9, 11).

The probability of such cases depends on the breath of the granted claims and is substantially higher for claims which cover - for example - any knock-out mutation of a certain target gene.

As pointed out in the legal expert panel, under the reversed burden of proof, this could lead to unnecessary litigation and, therefore, avoidable costs overall. Some interviewees highlighted options they perceive as feasible to address this issue, such as amending patent examination guidelines or changes to the EPC. The former, updating examination guidelines, was perceived as less costly and more feasible than a reform of the EPC to this end. Other interviewees argued that an exclusion from patentability could lead to a move of R&D activity from Europe to other jurisdictions. (ID_4, 11, 17).

8.3.2. Limitations to Patent Rights

8.3.2.1. Amendment of the Biotech Directive: Scope of product claims

One suggestion discussed in the legal focus group is to exclude biological progeny, such as seeds obtained from a patented plant, from the scope of product patents set out in Article 8(1)

[289] ALLEA | All European Academies. (2024). ALLEA Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development. ALLEA. https://doi.org/10.26356/IP-NGT

[290] Metzger, 2024, p. 46

[291] Austrian Patent Act (amended March 1, 2023). BGBl. Nr. 259/1970 (WV) idF BGBl. Nr. 137/1971 (DFB). §2(2) Theorem 3: A process for the production of plants or animals is essentially biological if it is based entirely on natural phenomena such as crossbreeding, selection, non-targeted mutagenesis, or random genetic modifications occurring in nature. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10002181. See also the explanatory notes: "In accordance with the decision of the Enlarged Board of Appeal of the European Patent Organisation in G2/07 "Broccoli", a process remains essentially biological even if it contains a technical process step designed to enable or support the execution of the steps of sexual crossing or subsequent selection." Available at: https://www.bundeskanzleramt.gv.at/dam/jcr:159cc09c-62fb-40a9-9457-80110641bbb1/49_14_erlaeu.pdf.

of the Biotech Directive, thereby preventing the extension of patent protection to reproduced material.

8.3.2.2. Amendment of the Biotech Directive: Scope of method claims

ALLEA proposed maintaining genome-editing technologies patentable, “whereas patents of products and the extension of patent protection to the immediate product of the process might no longer be feasible”.[292] Other experts suggested a more stringent interpretation of the scope of patent rights for “general processes”[293] under Article 8(2) of Dir. 98/44. This means, to limit the extension to such processes where the specific characteristic is disclosed in the patent claim and is instrumental for the inventive step of the related patent.[294] According to an academic expert, clarifications to the scope of protection of method claims (i.e., its extension beyond direct products to progenies) under Article 8(2) of Directive 98/44 could also be provided by a Commission Communication, without an amendment of the Directive.[295] However, an interpretation by the Commission would not have the same effects as a legislative change, as it would not bind patent authorities and courts.

8.3.2.3. Expansion of the limited breeder’s exemption

The patent laws of several EU Member States and the UPCA include a **limited breeder’s exemption.** According to the Legal Focus Group, one option would be to **harmonise this exemption** across all EU Member States. This would extend the exemption beyond those countries that had already introduced their own version of it in national law as well as those that are part of the UPCA.

In countries where a limited breeder’s exemption exists in their national patent laws (see section 8.2.2) breeders may use patented material in their research phase without the need to obtain a license. However, if breeders decide to retain a patented trait, they must negotiate a licence before commercialisation. If the patent holder refuses, innovation can stall. Developing around the patented trait requires more time and resources, which can put smaller breeders at a disadvantage.

Based on interviews with breeders and associations in the Netherlands and Germany, the breeder’s exemption in the national patent law is of great benefit since it provides the breeders with time to decide on a commercial license. While the limited breeder’s exemption allows that breeders work with patented material in their R&D phase, they can still decide in that phase if they possibly want to retain a specific trait and can start negotiating with the patent holder of the trait, or they can innovate around and try to find another solution with their available tools. The second option will typically require additional time. The time needed for an own development needs to be balanced against earlier sales with the licenced trait and a better market position than other competitors.

However, the limited breeder’s exemption is not without challenges: Breeders need to start licensing negotiations in time to not be trapped at a stage when a license becomes a must and

[292] ALLEA | All European Academies. (2024). ALLEA Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development. ALLEA. https://doi.org/10.26356/IP-NGT

[293] "General processes" means technologies which could result in various genetic changes and where the inventive step rather relies on the process features than on the characteristics created by it.

[294] Metzger, A., Zech, H., Kock, M. (2025). Whitepaper. Mitigating impact of patents on plants obtained from New Genomic Technique (NGT). Available at: https://www.rewi.hu-berlin.de/de/lf/ls/mzg/humboldt-white-paper-on-ngt-patents-27-1-2025.pdf

[295] Metzger, 2024, p. 62

the licensee is in a better position and can obtain a higher profit than during an earlier phase. According to an interview with a public authority, breeders know this and are cautious about the breeding material used.

The fact that granting a license is largely at the discretion of the patentee, limits the benefit of the limited breeder's exemption. In terms of market dynamics, the exemption helps prevent a lock-up of genetic resources by ensuring that breeders can test patented material, keeping markets somewhat open to new entrants. However, since the exemption stops at the commercialisation phase, patent holders retain strong bargaining power. (ID_5, 10, 11, 19).

8.3.2.4. Introduction of a full breeder's exemption for plants developed independently with essentially biological processes

Based on exemptions in the Austrian and French patent law (see section 8.2.2), a full breeder's exemption could be expressly established for plants obtained independently from the patent material using exclusively essentially biological processes. As this exemption affects all granted patents irrespective of their filing date it complements the effect of the EPO's "disclaimer solution" which only applies to patents filed after July 1, 2017.

While such an exemption could increase legal certainy and mitigate the fears that conventional breeders may infringe a patent, it does not resolve the problem of FTO analysis and access when it comes to using third party varieties. It is argued that such a change could be achieved through an interpretation of Article 8 Directive 98/44 and would be aligned with national patent law, for instance in France. [296] However, such limitation could also be seen as a de-facto erosion of the scope of protection for NGT patents and could be interpreted as contrary to the EPC.[297]

8.3.2.5. Introduction of a full breeder's exemption in patent law

A further proposal raised in literature is to introduce in patent law a **full breeders exemption** for "(i) breeding, discovering and developing of a new plant variety for food and agriculture and (ii) the multiplication, offering and placing on the market of that new plant variety, and (iii) using that new plant variety for any purpose in food and agriculture". [298] A pathway to implement this change is through changes to the scope of rights in Article 11 of Directive 98/44.

The compliance of a full breeder's exemption with TRIPS has been questioned.[299] Specific concerns exist that the broader scope of the breeder's exemption might clash with the three-step test for exceptions and limitation to patent protection in Article 30 of the TRIPS agreement.[300] In addition, a full breeders exemption may be seen as equivalent to a complete loss of protection and contrary to the norms applied to international treaties such as the EPC.[301] However, there are also arguments that such limitation is supported by Art.27(3)b TRIPS which allows to exclude plants entirely from patentability. In that case, such change would be

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[296] Metzger, 2024, p. 59-60

[297] Ibid., p. 61

[298] See Metzger, A., Zech, H., Kock, M. (2025). Whitepaper. Mitigating impact of patents on plants obtained from New Genomic Technique (NGT). Available on line at https://www.rewi.hu-berlin.de/de/lf/ls/mzg/humboldt-white-paper-on-ngt-patents-27-1-2025.pdf/@@download/file/Humboldt %20White %20Paper %20on %20NGT %20Patents %2027-1-2025.pdf

[299] Bostyn, S. (2025). Presentation at 12TH GRUR meets Brussels Workshop, 25 June 2025.

[300] Metzger, 2024, p. 52

[301] Metzger, 2024, p. 55

permissible at least for patent filings after the date of entry into force. Whether such limitation can apply to patents already granted is uncertain.[302].

8.3.2.6. Farm-saved seed exemption

Interviews with farmer associations as well as civil society organisations suggested that Article 11 of the Biotech Directive concerning **farm-saved seeds** (FSS) is not fully known and understood by farmers. Many of them "fear" that they potentially infringe patents with their farm saved seeds (ID_3, 8, 22). This would, however, only be the case if they do not pay the fees to use farm saved seeds under the CPVR system.[303]

One area of uncertainty is however, how the collection of information and royalties in relation to FSS should be conducted in cases where not only one PVR but also several patents owned by different parties are relevant.

8.3.2.7. Compulsory cross-licensing

The Biotech Directive provides for a compulsory cross-licensing mechanism in favour of plant breeders (Article 12). If a breeder cannot obtain or exploit a plant variety right without infringing a prior patent, the breeder may request a non-exclusive licence to use the patented invention, provided that this is necessary for the exploitation of the new variety and subject to the payment of fair compensation, and provided that "*the plant variety […] constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent* […]". Conversely, the patent holder may also request a cross-licence to use the new variety.

According to interviews and the available literature, this provision has never been applied and has limited practical value. Reasons are (i) the license can only be requested late in the process for a license i.e., when there is already a PVR, and (ii) the legal uncertainty how to interpret the requirement of a "*technical progress of considerable economic interest"* for plant varieties. Interviewees reported instances where breeders had abandoned breeding lines if they were under the impression that they may require a (cross-)license. The risks and costs related to the procedure and the potential high licence fee provide a strong deterrent (ID_22). The requirement to demonstrate that "the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety"[304] has been described as too uncertain to apply for compulsory licenses. Interviews with breeders indicated that at this stage licensing is solely based on the principle of voluntariness. Compulsory cross-licensing – even if intended to help access – may deter breeders also due the consequence of sharing rights on the developed new variety with a competitor.

A **clarification of compulsory cross-licensing provision** is suggested to reduce the present legal uncertainties and enhance its practical use by the adoption of a model similar to that used in the Swiss Patent Act.[305] Under this approach, a plant variety which is eligible for authorisation under seed law would qualify as significant technical progress of considerable economic

[302] It may require compensatory rights (e.g., PVPs) for patentees which otherwise may lose substantial protection for the plant varieties.

[303] In the EU Member States different systems of remuneration of farm saved seed have been set up, with some systems being more efficient than others. To the German Plant Breeder Association, this is a problem since it deprives breeders of their lawful income which is also needed to invest in R&D. In Poland, this is a most widespread problem.

[304] Article 12(3)(b) of Directive 98/44 EC

[305] Kim, D., Kock, M. et al. (2024). New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector. 'GRUR International', 73 (4), 323–335.

importance[306]. Such a change could be addressed through a change or an interpretation (e.g., by a Commission Communication or Notice) of Article 12 of Directive 98/44[307]. Experts have discussed whether changes analogue to the Swiss patent law are compatible with TRIPS and the EPC, arguing that an alignment of the criteria in Article 12 of Directive 98/44 with relevant provisions of the CPVR or the EU seed market authorisation (e.g., VCU) could fulfil this purpose[308]. Such a change might be compatible with TRIPS and could make , more accessible for breeders due to alignment with concepts from plant variety rights law. Such interpretation would have the benefit that for a variety which obtained seed market authorisation only the fair remuneration has to be decided by the judge. Such approach would not only strengthen the practical use of the limited breeder's exemption, but also encourage parties to join licensing platforms, where the decision on reasonable prices is made by an expert committee instead of a judge, which likely will have limited experience in seed licensing practice.

Since a key challenge preventing compulsory licensing from being used in practice is the uncertainty about the outcome, ALLEA suggests that an alternative could be a "licence as of rights", which functions as "a commitment from the patent holder to grant any interested party a licence under reasonable terms".[309]

As another alternative to compulsory cross-licensing, some experts in the Legal Focus Group proposed treating **NGT-related patents as "essential facility"**. This would create an obligation to license such patents on fair, reasonable, and non-discriminatory (FRAND) terms, similar to standard-essential patents (SEPs), and ensuring access while safeguarding patent holders' returns. This approach mirrors licensing frameworks in other sectors and was viewed as more likely to comply with TRIPS. However, whether NGT-derived varieties could meet the requirements of essential facilities in all species (incl. ornamentals) and with all traits is – at least – uncertain.

The lack of examples and precedent for compulsory cross-licensing suggests that even if the provision could be clarified, it will take time to be used and obtain clear examples that breeders, taking the license, can obtain access with legal certainty and at reasonable costs.

8.3.2.8. Patent information and patent transparency

Patent transparency must be distinguished from patent information. Patent information is provided by patent offices and can be accessed through dedicated public databases. It is often highly technical and requires both technical as well as legal expertise to be fully understood.

In the context of plant breeding, patent transparency refers to information on which patents cover and/or are relevant for a specific variety. Such information cannot usually be obtained from patent information alone, nor is it currently included in any PVR or seed market authorisation dossier. Instead, it typically resides with the breeder of the variety, or must be derived through cumbersome analysis involving the physical comparison of a variety with the features described in multiple patents.

Transparency measures aim to reduce these barriers by providing information on whether specific plants, traits or related technologies are subject to patent protection, the scope of

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[306] Article 36a para. 1 Swiss Patents Act

[307] Reference: Metzger, A., Zech, H., Kock, M. (2025). Whitepaper. Mitigating impact of patents on plants obtained from New Genomic Technique (NGT). Available at https://www.rewi.hu-berlin.de/de/lf/ls/mzg/humboldt-white-paper-on-ngt-patents-27-1-2025.pdf/@@download/file/Humboldt %20White %20Paper %20on %20NGT %20Patents %2027-1-2025.pdf

[308] Metzger, 2024, p. 64

[309] ALLEA - All European Academies. (2024). ALLEA Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development. ALLEA. https://doi.org/10.26356/IP-NGT

patent claims, and the links between plant variety databases and patent databases. However, at present no mandatory transparency measures exist in any EU country.

8.3.2.8.1. NGT verification procedure

Article 6 of the Council negotiating mandate for NGT Regulation[310] proposes that the requesters during the verification procedure for Category 1 NGT plants, must declare patents related to the plant submitted for verification. Such an addition could increase the transparency of information concerning NGTs and related patents. However, this approach has received some expert criticism for its declaratory character due to a lack of consequences for potential mismarking or non-naming of patents, as well as for the omission of process patents[311]. Some experts of the Policy Focus Group emphasised that declarations should be written in plain language, not just in legal-technical language, ensuring that breeders can use them effectively in practice.

However, there are concerns that a patent transparency with mere declaratory character may undermine existing legal measures against unjustified declaration of patent protection (i.e., patent mismarking) or withholding information on patent protection on request (i.e., forfeiture of rights). The legal expert panel concluded that any future transparency mechanism needs to avoid undermining these mechanisms and should instead build on these approaches and make them more efficient. [312]

8.3.2.8.2. Patent information clearinghouse

Clearinghouses as a means to increase transparency have been seen in the life sciences.[313] For plant breeding, a clearinghouse solution is currently considered in Switzerland.[314]

The reason provided by the Swiss Justice and Police Department (EJPO) is that in the field of plant breeding, analysing patent literature proves to be challenging as patent documents typically do not include references to PVPs. However, as plant breeding becomes increasingly technical, patent information is becoming ever more important for breeders. Although patent holders in this area have launched various voluntary initiatives to improve transparency, according to the EJPO, these efforts remain incomplete.

The clearinghouse aims to enhance transparency around patent rights in plant breeding. At the centre of the system is a notification platform, where plant breeders can voluntarily submit the plant varieties they intend to use in breeding programs. Once a breeder submits this notification, the IPI is responsible for alerting any relevant patent holders whose rights might intersect with the declared material. Patent holders then have a 90-day window to respond. If they assert that their patent covers the notified variety, the breeder can use this information to seek a license or redirect their breeding efforts. However, if no response is received within the deadline, the breeder gains a legal "safe harbour" – allowing them to proceed with the use and

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[310] https://data.consilium.europa.eu/doc/document/ST-6426-2025-INIT/en/pdf

[311] Kock, M. A. (2025) NGT proposals by the EU Commission, European Parliament and Council – state of the trilogue with respect to intellectual property rights, presentation at 12TH GRUR meets Brussels Workshop, 25 June 2025.

[312] Similar in the literature, see: Matthews, D.; Ostapenko, H. (2025), The Patent Governance of Agricultural Genome Editing: An Expert Report (June 05, 2025). Queen Mary Law Research Paper No. 465/2025, Available at SSRN: https://ssrn.com/abstract=5436674 or http://dx.doi.org/10.2139/ssrn.5436674

[313] van Zimmeren, E., et al (2011), Patent pools and clearinghouses in the life sciences, *Trends in Biotechnology*, Vol 29/11, pp. 569-576. Available at: https://www.sciencedirect.com/science/article/pii/S0167779911000965

[314] EJPO (2024), Vorentwurf der Revision des Bundesgesetzes über die Erfinderpatente. Erläuternder Bericht zur Ero4fnung des Vernehmlassungsverfahrens. Available at: https://www.news.admin.ch/de/nsb?id=101122

commercialisation of the new variety without needing to obtain a license, even if it incidentally incorporates a patented trait. This shifts the burden of vigilance on patent holders, who must proactively monitor the clearinghouse to preserve their rights.

For breeders, the clearinghouse offers clear advantages by enhancing transparency and reducing legal uncertainty. It allows earlier licensing decisions, mitigates infringement risks, and, in cases of non-response, enables breeding and commercialisation without additional licensing obligations.

At the same time, industry stakeholders and legal scholars have raised concerns[315]. One major concern is the administrative burden on patent holders, especially foreign companies or SMEs, who may struggle to keep pace with the notifications. Critics argue that this effectively reverses the traditional enforcement model, exposing patent owners to disproportionate risks.

Legal scholars of the Legal Focus Group further stress that the clearinghouse serves as a procedural safeguard rather than a substitute for a sector-wide transparency register, offering protection to the notifying breeder but not delivering broader visibility across the intellectual property landscape. Thus, the proposed clearinghouse is also criticised as burdensome for patentees, not creating public transparency (as only the requesting breeder is informed of the relevant patents), and creating a false assumption of FTO, as the safe harbour only applies for commercial acts in Switzerland but not in any other country which could interfere with the export of seed or harvest products.

8.3.2.8.3. Patent transparency: Potential changes

The establishment of a **mandatory transparency register** for plant-related patents and their links to plant varieties has been suggested as a measure to increase clarity regarding existing patents and their scope of application[316]. Such a requirement could be realised through a change of Article 11 of Directive 98/44 and implemented through either dedicated patent databases or through PVR data bases and the Common Catalogue[317]. It could also be **linked to the authorisation process of plant reproductive material**[318]. The European Parliament has proposed to introduce such information on patents in the databases on plant reproductive material to be marketed in the EU. In practice, this information would be based on breeder’s declarations in the application process for variety registration.

The European Common Catalogue[319] currently contains more than 200 000 varieties. About 800 applicants’ names are indicated for registered varieties. Adding patent data has been suggested during interviews and the Legal Focus Group. However, it should be noted that authorisation is not required for all species and plant varieties and thus data in the Common Catalogue are not exhaustive.

Thus, while mandatory transparency may sound simple, it is likely to be far more challenging in practice.

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[315] https://swiss-food.ch/en/articles/patente-auf-technisch-erzeugte-pflanzeneigenschaften-machen-absolut-sinn?
https://www.patentlitigation.ch/patents-on-plants-a-misleading-cry-for-transparency-and-a-barely-hidden-agenda/

[316] See also Kim/Kock/et al., New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector, GRUR Int. 2024, 323, 335

[317] Metzger, A., Zech, H., Kock, M. (2025). Whitepaper. Mitigating impact of patents on plants obtained from New Genomic Technique (NGT). Available on line at https://www.rewi.hu-berlin.de/de/lf/ls/mzg/humboldt-white-paper-on-ngt-patents-27-1-2025.pdf/@@download/file/Humboldt %20White %20Paper %20on %20NGT %20Patents %2027-1-2025.pdf

[318] Metzger, 2024, p. 66

[319] See https://ec.europa.eu/food/plant-variety-portal/

(i) It will be important to avoid an undesired deterrence by a declaration of patents which do not cover plant material as such, but merely selection processes or detection tools. For the majority of breeders without legal training distinguishing such patents is not possible, and they may not use any variety for which a patent (or patent application) has been declared. The Legal Expert Group emphasised that achieving such clarity will be a challenge as can be seen in the debate on the U.S. Orange Book procedure.

(ii) It will be necessary for patentees to adjust their declaration if the scope of a patent application changes over time.

(iii) It will require complementing mechanisms for varieties which are not subject to variety registration and do not have a common catalogue (e.g., ornamentals).

(iv) It will require user education to assess the different risks resulting from application vs. granted patents, composition claims vs. method claims etc.

It will be critical to ensure enforceability: The refusal by a patent holder to enable patent transparency (i.e., clarity which patents cover his variety) could be met with a limitation of their enforceable rights.[320]

As an alternative to a mandatory transparency, ALLEA suggested “encouraging registration by patent applicants/holders and licensees”, without further specifying potential incentives to do so[321].

8.3.2.9. Patent litigation

As of now, there are no patent infringement related litigation cases involving plant breeders and NGTs in the EU. This has been expected as currently no commercial activities are possible with NGT-derived plants in the EU and related R&D activities are likely deemed non-infringing under the limited breeder’s exemption in patent laws of key breeding countries such as Germany, France, and the Netherlands. However, there are numerous NGT-related patent oppositions and appeals which also involve companies active in plant breeding. These could be seen as a "prelude" to later infringement-related litigations. Some interviewees also suggest that legal uncertainty, particularly regarding overlapping patents and the complex licensing landscape, may contribute to a cautious approach among EU breeders. (ID_4, 7, 9, 27)

To smaller breeders, the potential costs of litigation due to **accidental infringement** are mentioned as a barrier, which may threaten their mere existence. Such accidental infringement may occur when a variety protected by patents is inadvertently used in a breeding programme (e.g., by natural cross-pollination from neighbouring field or traces in breeding material). The legal uncertainty and threat of litigation may also have a negative effect on the innovation of conventional breeders (ID_8, 16).

A key concern in the context of potential NGT-related litigation is the **burden of proof** in patent infringement cases. Under Article 54 and Article 59 of the UPCA, the burden of proof lies with the patent holder, who must demonstrate that the defendant has used a patented technical process to create the contested plant. In practice, this means that a patent holder must prove that the alleged infringing material is covered by the patent. The UPCA provides under Article 55 for a possibility of a **reversal of the burden of proof** in cases where the subject-matter of a patent is a process for obtaining a new or the same product produced by a person other than the rights holder.[322] A reversal of the burden of proof may also occur in cases, where the

[320] See also Kock, ‘Intellectual Property Protection for Plant Related Innovation Fit for Future?’ (2023), 286

[321] Cf fn 289

[322] See also Metzger, 2024, p. 55-56

defendant claims that his variety is excluded from the scope of protection by a disclaimer (i.e., the result of an exclusive essentially biological process) or – in France and Austria - that they developed a variety independently from the patent material exclusively with essentially biological processes. Here the defendant needs to provide sufficient evidence for his allegation. Regarding enforcement, Article 59 of the UPCA allows a patent holder to request that the court orders the defendant to disclose relevant breeding records if the claimant has already provided sufficient evidence supporting his or her infringement claim. However, the court must balance this requirement with the need to protect confidential business information, as stipulated in Article 58 UPCA.

Legal experts expect more litigation, mainly due to co-existing patents with similar subject matter (e.g., Cas9 patent thicket) and the legal uncertainty related to the scope of method claims under Article 8(2) of the Biotech Directive.[323] Some experts expect that over time, patented traits may be stacked in plants and their offspring; how this could or would be dealt with, remains unclear (ID_7). It is thus likely that various trait and process patents may affect a single variety. The related complexity will likely render it impracticable for breeders to obtain all necessary licences to ensure freedom-to-operate. Options to mitigate this are (i) a more stringent interpretation of the scope of process claims, (ii) voluntary licencing platforms, as well as (iii) mandatory transparency (see section 8.4.1).

Some interviewees emphasise that a perceived imbalance between large, patent-active corporations and SME breeders with limited patent knowledge leads to widespread concerns of the bargaining power and costs of potential litigation, that "could cost millions of euro" and threaten the survival of smaller companies. Yet, there is no evidence of plant-related patent litigation cases in Europe yet. The legal vulnerability of SME defendants in patent infringement cases was also pointed out in interviews. If a defendant wants to avoid revealing sensitive information, the breeder may be inclined to settle - even if they have not infringed. There have been cases mentioned where breeders stop breeding lines because of fear of a potential patent infringement.

8.3.2.10. Soft measures / Support to SMEs

Interviewees suggested that there is room for further support of SMEs, which so far have limited knowledge about the IP landscape. Their main understanding lies with PVRs. Several interviewees indicated fears about litigation, a limited knowledge about access to, costs, and benefits of the existing licensing platforms as well as the overall limited knowledge about the patent system and its potential, improving which would require dedicated information campaigns and testimonials. In a rather conservative sector, it is important to be transparent about both the risks and the opportunities.

In this respect, national patent offices could more closely align with EPO and further advertise existing offerings such as EPO's SME support that includes training, awareness raising campaigns, and tools like the Deep Tech Finder[324], which connects innovative SMEs with potential investors. The Swiss Patent Office (IGE) provides patent searches for the breeders. It mentions fees for searches in the explanations for a clearinghouse but does not indicate the specific amount.[325] ALLEA envisages that "A similar assisted search could be introduced in other EU countries, and this service could be offered for free to small breeders and farmers.

[323] For example Feeney et al (2018).

[324] https://dtf.epo.org/datav/public/dashboard-frontend/host_epoorg.html#/explore?dataSet=1

[325] Schweizerische Eidgenossenschaft (2024), Vorentwurf der Revision des Bundesgesetzes über die Erfindungspatente,

This measure would not require any change of the patent agreements and legislation and could most likely be implemented rather quickly"[326].

The EPO encourages **intention-to-license registrations** in the unitary patent register, which helps foster openness and collaboration, especially useful for small breeders and research institutions.

8.3.2.11. Effectiveness of the patent-related measures in an international context

A scenario in which patent protection for NGT-derived plants is not available, would still be associated with costs (and challenges) concerning the international obligations of the EU and its Member States, such as ensuring compliance with the EPC and TRIPS. Drastic limitations to patentability and/or patent rights may require a transition period and would not address patents outside the EU which could affect the export of seeds or harvested materials to third countries.

On the other hand, imports of seeds into the EU should not be affected when patent protection is only available in the exporting jurisdiction. The example of Argentina illustrates that (GMO) seeds under patent protection elsewhere can gain a large domestic market share. Following the argumentation of the CJEU Grand Chamber in Case C-428/08,[327] the risk of patent infringement in import markets should be limited as long the imported material is considered "dead".

[326] Cf fn 289

[327] Case C-428/08, Monsanto Technology LLC v Cefetra BV and Others, ECLI: EU:C:2010:402, https://curia.europa.eu/juris/document/document.jsf?docid=80491&doclang=eN. Monsanto had a patent relating to a DNA sequence which once introduced into the DNA of a soybean plant, makes it resistant to the herbicide glyphosat. This GM soybean was grown in Argentina, where there was no patent protection for Monsanto's invention. Some of this soybean was exported to the Netherlands. The case addressed the question whether the mere presence of the DNA sequence protected by a European patent is sufficient to constitute infringement of Monsanto's patent when the soy meal is marketed in the European Union. The CJEU ruling clarified that a European patent can only be relied on in relation to an invention which actually performs the function for which it is patented. See https://curia.europa.eu/jcms/upload/docs/application/pdf/2010-07/cp100073en.pdf

8.4. Private Systems

Currently, private systems attempt to address the challenges of (i) patent transparency and (ii) access to patent traits.

8.4.1. Licensing platforms

Licensing platforms are voluntary platforms governed by private law which seek to ease access to patented plant material and to facilitate the licensing process by reducing transaction costs and uncertainty. This section explores the state of play, costs and benefits, impact on innovation on market and market dynamics, as well as risks and challenges of licensing platforms through the examples of the International Licensing Platform Vegetable (ILP Vegetable) and the Agricultural Crop Licensing Platform (ACLP). It also summarises suggestions for changes to the operation of licensing platforms in the context of the proposed NGT Regulation.

8.4.1.1. International Licensing Platform (ILP) - Vegetables

The ILP Vegetable was set up as a sector response to the growing number of patents in plant breeding in the vegetable sector in the early 2000s. There was the fear that if a trait was to be patented and included in a new variety, the patent protection or the plant characteristics would imply that breeding with that variety would not be possible anymore, and this would severely damage the innovation within the sector. In a sector that was predominantly characterised as '**friendly' and based on the principle of 'sharing'** during interviews, the rise of patents saw a lot of opposition; their need, relevance for innovation, or societal benefit is questioned still today by many breeders, most farmers, and some associations. At the same time, large agrochemical companies that had invested in plant breeding or bought breeding firms in the 1990s voiced the importance of patents and were actively engaged in patenting activities.

The licensing platform started with four members – family owned and large agrochemical firms – with their known opposing views on patents. However, one of the **uniting factors of the sector is the need to access material.** While large companies may have their own gene banks, they need to tap into the genetic resources of competitors. Therefore, **access to genetic resources** is a common requirement and in each breeder's interest, whether large or small, being for or against patents. The solution that was in the end presented with the ILP Vegetables balances the different views and visions of the companies involved but also shared a "common vision" and set up a solution that is acceptable for all parties. After four years of preparation, the platform was launched in 2014.

While access to germplasm may be the main reason for some breeders to join the platform, others may be interested in the traits, members have developed. Only if there is a value to the patented trait, a breeder will seek a licence from another breeder. It was seen as a further advantage of the license platforms that breeders who do not wish to invest in the costly (and somewhat) risky product development of a trait themselves, can licence a developed trait and incorporate it in their germplasm. In this model, breeders rely on the breeding success of previous breeders and create valuable products.

The ILP is global and in addition to a mechanism to obtain licenses to patented traits at a fair (i.e., independently reviewable price) provides a cost-free mutual non-assert to conduct breeding (incl. with varieties protected by U.S. variety patents). License fees are only due for commercialisation of a variety in a country where such variety is still covered by a patent. Parties can utilise all breeding material which is legally available.

The working principle is simple: transparency and commitment to internal cross-licensing. All members with potentially blocking patents, that is patents that may relate to a trait, include these patents in a register. There are 390 patents listed[328]. In case a party believes that the license fee associated with a license offer is unreasonably high, such party can request review by an expert committee in a arbitration process. The arbitration model is 'baseball arbitration' which has been mentioned as highly effective for the parties to agree on fair deals for a licence. A licensor may want to obtain a royalty fee of say 10 % while the licensee may want to pay 3 %. If they cannot agree and would need to use the arbitration system, the arbitrator cannot simply decide on the middle but needs to choose the price which is viewed "more reasonable" – either what the licensor asked or what the licensee was willing to pay. Following the arbitrator's decision, there is no further negotiation, the fee is set and the party whose proposal was not selected loses. This arbitration system is intended as a deterrent to posturing and as incentive to remain in realistic, fair boundaries. The system is described to result in FRAND conditions[329].

There is no information about the number of licence agreements that were made. Publicly known is the exchange of all of their patents between Syngenta and Rijk Zwaan in 2016 due to the dialogue the two companies had in the setting up of the platform[330]. This is also not known to the platform's secretariat. Interviewed members indicated that "many" licence agreements were concluded and so far, no negotiation about the royalty fees ended in arbitration.

The platform is voluntary. Currently, there are 17 members from Europe and some non-EU countries. This voluntary principle has been indicated as **preferable to a mandatory platform** since voluntary members are more motivated and constructive. Yet, an interviewee also indicated that they would support if platforms were made mandatory. (ID_1, 3, 4, 5, 6, 7, 8, 9, 11, 16, 17, 20).

8.4.1.2. Agricultural Crop Licensing Platform (ACLP)

The ACLP was established in anticipation of an increase in NGT traits and patents in April 2023. The platform has currently ten members. These companies represent more than 95 % of the patents on agricultural crops. All large crops corporations (Corteva, Bayer, Syngenta, BASF) are members. With the ILP Vegetable as a successful model organisation, the ACLP negotiated among its members the internal rules of procedures. Members pay a limited membership fee for the maintenance of the platform. The membership also includes transparency: members have the obligation to include relevant patents in the PINTO database.

The members sign non-assert agreements and have agreed on guaranteed licensing among themselves. The platform includes an internal limited breeder's exemption, which enables the members to use commercially available patented material in their breeding lines for research. That means, members get access to patented material and can use it in their research phase. In this respect the rules of the platform are similar to the UPCA and countries that offer a limited breeders right in their patent legislation. Thus, for companies located outside the UPCA

[328] The list can be downloaded from https://www.ilp-vegetable.org/patents/

[329] Kock M, ten Have F (2016) The 'International Licensing Platform—Vegetables: A prototype of a patent clearing house in the life science industry. J Intell Prop Law Pract 11(7):496–515. https://doi.org/10.1093/jiplp/jpw073. Available under: https://www.ilp-vegetable.org/uploads/Bestanden/News/Article %20ILP %20Journal %20of %20Intellectual %20Property %20Law %20& %20Practice %202016.pdf..

[330] Syngenta and Rijk Zwaan to exchange all of their patents, Horti daily, 9.9.2016. see: https://www.hortidaily.com/article/6028700/syngenta-and-rijk-zwaan-to-exchange-all-their-patents/

countries and countries that do not offer the limited plant breeder's right, ACLP membership is a means to profit from this right within the limits of the partnership.

For members which are interested in the material, this internal limited breeder's exemption provides time. They can decide to only work with the germplasm, or they can later decide if they are (also) interested in the patented trait - for which they will negotiate among themselves the royalty fee -, or they cross out the trait. Beside the large members, there are equally smaller members. While they may not have the capacity to develop traits on their own, or because they have a different business model, being a member guarantees them access and a licence to the traits.

Compared with 1:1 negotiations outside the partnership – which typically require legal services, can take a more than a year, and can also end without a licence agreement – ACLP members negotiate under a different framework. If they fail to reach an agreement within six months, arbitration begins, ensuring that even under less-than-ideal conditions a licence is concluded within a maximum of one year. In order to come to a fair solution, ACLP arbitration also uses the 'baseball' method mentioned above. In theory – the mechanism has not yet been used – three arbitrators are nominated and one selected. During the arbitration the two parties will have to make their business cases, explaining the rationale behind their proposed royalty fees, such as the market, and the value of the trait.

If all goes well, such a licence deal can be concluded within as little as two months. The licence covers all EPC countries, Russia and Ukraine (40 countries). The ACLP does not grant rights outside this territory (including export of harvested material).

8.4.1.3. Patent pools

A patent pool is an agreement between two or more patent holders to license their patents as a bundle to third parties, often on standardised terms. In the context of plant breeding, pools would aggregate patents for traits, technologies, or breeding tools - enabling easier access and licensing for breeders. Patent pools can be effective means to overcome the problem of patent thickets, where many overlapping rights hamper innovation. They have been suggested in the literature for foundational patents and their cumulative research impact,[331] Pools help to de-fragment the IP landscape and simplify access, an aspect that it key when considering a potential higher complexity of the IP landscape. For ALLEA, even mandatory patent pools are an option in the area of NGTs in crop development.[332] In the literature, this position is not shared more widely. Instead, the literature points out that exclusion from patent pools would have an anticompetitive effect.[333]

Some interviewees agreed that publicly funded research outcomes and outputs should at least be licensed under FRAND conditions. Despite some attempts to establish patent pools for NGTs like Cas9, to date, no patent pool was developed in the area of biotech- or plant-related innovations.

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[331] Scotchmer, S. (1991) Standing on the shoulders of giants: cumulative research and patent law. *Journal of Economic Perspectives*, 5/91, pp. 29-41.; Feeney, O. (et al) (2018), Patenting foundational technologies: lessons from CRISPR and other core biotechnologies.

[332] ALLEA (2024), ALLEA statement on measure tp ease the impact of the IP system on new genomic techniques for crop development.

[333] Clark, J. (et all) USPTO (2000), *Patent pools: a solution to the problem of access in biotechnology patents*? Available at: https://www.consultstanton.com/wp-content/uploads/2015/02/PATENT-POOL-WHITE-PAPER.pdf

8.4.1.4. Assessment: Costs and benefits of licensing platforms

Licensing platforms such as ILP Vegetable and ACLP enable licenses to patent-protected traits for commercial purposes and to access germplasm for breeding under a standard license agreement. The licenses included in platform membership for development are non-exclusive and non-discriminatory. A negotiated license fee is only required when a newly developed variety is commercialised, covered by the patent, and the patent is unexpired. While there are similarities between the ILP-Vegetables and the ACLP, there are also substantial differences (see Table 13).

Table 13 Comparison of ACLP and ILP-Vegetables

	ACLP (Field Crops)	ILP-Vegetables
Territory	Members states of the EPC, Russia, and Ukraine. No rights in other countries (including import of harvested material)	Global
Scope	Use of patented traits from varieties approved for commercialisation in the area of conventional breeding by means of crossing and selection (i.e., only subsequent breeding)	Use of patented traits as long as the material is legally accessible or is produced by the licensee owner without infringing the patent owner's process patents (i.e., subsequent and parallel/independent breeding).
Permitted Source Material	Material of plant varieties commercialised in the EU.	All legally obtained materials (incl. patent deposits).
Restrictions	i. Traits classified as GMOs under Reg. 2001/18 or equivalent. ii. Traits only used in closed-loop cultivation systems. iii. Combination of regulated traits (likely incl. NGT traits)	Traits classified as GMOs under Reg. 2001/18 or equivalent in countries where such trait is regulated as GMO.[334]
Membership Fee	Currently free for small entities (initially)	Three classes of membership fees for small, medium, and large entities
Arbitration Mechanism	Each party elects an arbitrator from an established list. The two referees then unanimously elect a third referee. Baseball arbitration is used.	Two groups of 3 arbitrators each, confirmed by at least 2/3 of the members. Baseball arbitration is used.

The pros and cons of licencing platforms as a solution were highlighted in various interviews. Members consider the platforms as a very good solution and were all positive about the direct and indirect effects. Respondents indicated that they are being effective and being used in practice among members. Among the direct effects are guaranteed access to germplasm, guaranteed access to traits, shorter negotiation phase on license conditions and royalties, and a wide territorial coverage. Furthermore, it is considered beneficial to have a platform that is as large and inclusive as possible, as it can facilitate access and reduce fragmentation.

[334] GMO's require elaborated stewardship measures which can be mastered by large seed companies but not by small and medium breeders. Licensing GMO traits in consequence requires a qualification of the breeder, which conflicts with the principles of the ILP to grant licenses to very requesting party i.e., non-discriminatory.

Interviewees also welcome the ‘baseball procedure’ to resolve licensing fee disputes, ensuring fair levels of compensation for the commercialisation stage (ID_1, 4, 5, 9, 20).

No cases of members requesting an arbitration procedure have emerged, highlighting the functioning of existing licensing and arbitration rules within the platforms. The attractiveness of the platforms is likely to increase with the development of ‘must-have’ traits by members and with a greater understanding among plant breeders about the advantages of membership. The indirect effects are worth noticing as well: bringing together competitors with varying business models and economic power to develop jointly conditions which benefit a large and diverse set of companies is likely to bridge different existing business models and reconcile the sector that has value generation based on the collective efforts in its DNA.

Some interviewees, less familiar with the details, have a more critical view. Interviewees indicated that a potential licensee still needs to analyse if a given patent would be infringed and then would seek a discussion with the patent holder. The interpretative scope of a patent that leaves uncertainty also applies to the patents within the platform. Further, some respondents saw the voluntary nature, coverage and the lack of publicly available data about their effectiveness as challenges, which make a robust assessment of their overall impact on the market difficult.

Plant breeders interviewed during the project pointed out that the non-mandatory nature makes licencing platforms ‘incomplete solutions’ for the challenges they experience with accessing patented material. Interviewees highlighted that the effectiveness of licensing platforms is difficult to prove, due to the lack of available data on licensing agreements struck through the platforms.

While some interviewees indicated that they engaged in licensing through such platforms, information is neither collected nor released by the platform, unless arbitration is sought by members. There are concerns that mandatory disclosure of licensing activity could pose potential competition law problems[335]. Others pointed out that small players appear to lack incentives to join voluntarily and are uncertain about the costs required to become a member of the existing platforms. In addition, the declaratory character of the platform was seen as a shortcoming, with respondents pointing out that potential licensees cannot be certain whether the patents are valid or whether specific plants are actually covered by the patents. Yet, also critical interviewees acknowledge that the existence of licensing platforms like the ILP or ACLP is preferable to the absence of any platform. Interviewees highlighted that the platform reduces or even eliminates risk for not obtaining a licence since both platform agreements are based on guaranteed licences. (ID_4, 5, 6, 7, 9, 10, 11, 20, 22)

Overall, some interviewees consider platforms are not a final means to increase legal certainty. Only courts can definitively determine if a patent is valid or whether it applies to a certain plant. Platform members or administrators lack the legal authority to provide this certainty. While there is thus a risk of unnecessary payments by breeders for a licence they do not need, either because the patent is not valid or the plant they are using is not covered, this is nevertheless a general risk and not confined to the platforms.

Looking ahead, licensing platform will meet challenges in the future once patent landscapes become more complex. The arbitration mechanism is limited to bilateral scenarios and is not yet adapted to scenarios with multiple patentees as they may occur when multiple patented traits are stacked. Boosting the role of licensing platforms could support access to patented material. ALLEA has suggested to mandate participation in licensing platforms and further

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[335] See OECD (2019), Licensing of IP rights and competition law. Available at: https://www.oecd.org/content/dam/oecd/en/publications/reports/2019/04/licensing-of-ip-rights-and-competition-law_20595b8f/6a74221e-en.pdf

facilitated by the “use of standard and transparent licensing agreements”.[336] These proposed changes are intended to facilitate participation in licensing platforms. However, experts have also noted that licencing platforms do not fully eliminate barriers for stakeholders.[337] In addition, such an approach does not address the participation of licensees in the platform. Concerns from interviews also highlight that mandatory participation, possibly paired with mandatory disclosure of licensing agreements, could run counter to competition law. While the effectiveness of licensing platforms is difficult to prove due to the absence of supporting data about agreements reached through the existing platforms, several interviewed breeders were fully committed and positive about the effects.

8.4.2. Private sector transparency measures

Breeders who want to include a variety in their breeding programme cannot immediately determine if the variety is patent protected or not. A patent specification is not specific to one variety and does not indicate the varieties it covers. Thus, the breeder needs to conduct detailed research about the traits of the variety he or she wants to use. Even if all relevant patents are identified, a breeder does still not know if the variety he or she wants to use is affected. In addition, a company can licence its patent so that it may also affect third-party varieties i.e., varieties not owned by the patentee[338].

In an attempt to provide transparency, the EU seed industry has set the ‘Pinto’ database. The database is based on patent information provided by the members of Euroseeds in relation to plant varieties which obtained seed market authorisation in the EU. The information provision is in general voluntary, yet members of the Agricultural Crop Licensing Platform ACLP (see section 8.4.1.2) have themselves committed to include all concerned patents.

Figure 14 summarises the content of the Pinto database as of April 2025. Data has been transformed into a graphic representation where the traffic light colour coding signals with green as ‘low complexity’ (i.e., less than 10 patent claims), orange as "medium complexity" (i.e., 11-50 claims), and red as "high complexity" (i.e., above 51 claims). Obviously, even one or two claims can provide a very strong protection. Neither the number of claims, nor the number of varieties indicated in the PINTO database in relation to a patent is any indicator regarding the market share of patented varieties. The ‘quantification’ measured by claims reflects also information from interviews, namely that commercially relevant crops such as maize and sugar beets are often protected by multiple patent claims. Lettuce was described as a highly disease susceptible and self-pollinating plant that limits improvements through traditional breeding techniques. Also here, patents often have complex claim structures.

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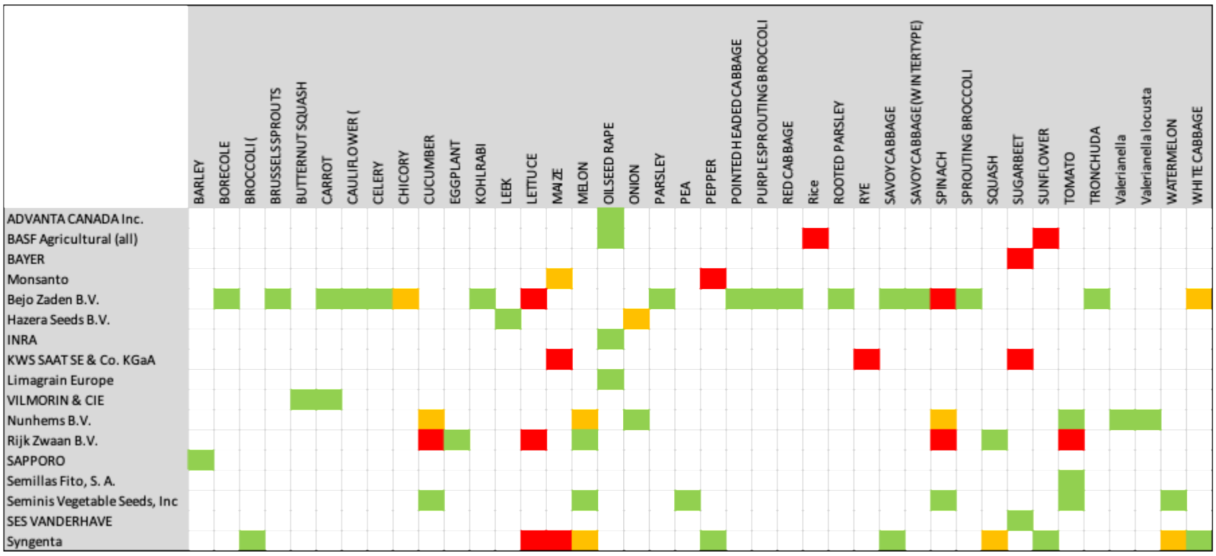
[336] ALLEA | All European Academies. (2024). ALLEA Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development. ALLEA. https://doi.org/10.26356/IP-NGT

[337] Bostyn, S. (2025). Presentation at 12TH GRUR meets Brussels Workshop, 25 June 2025.

[338] Schweizerische Eidgenossenschaft (2024), Vorentwurf der Revision des Bundesgesetzes über die Erfindungspatente, p.6

Figure 14 Patented traits by plant (PINTO)



Data: PINTO, accessed April 2025. Treatment and calculation: Technopolis Group

PART IV SYNTHESIS OF INSIGHTS AND OPPORTUNITIES

9. Synthesis of insights

The previous parts provided detailed collected evidence. In this section, the findings and insights are synthesised by study question.

Yet, in the absence of marketed NGT-based plants in the EU, we need to reiterate that various impacts cannot be empirically *quantified* but are based on *expectations*.

9.1. Potential economic impacts on plant breeders and farmers

NGT patents

For breeders, especially SMEs, a potentai increase of NGT plant-related patents could raise costs for freedom-to-operate analyses. Patent thickets, should they develop, can discourage innovation, force the abandonment of breeding efforts to avoid infringement, or lead to an opting out of breeders to consider varieties with patented traits or even traits "related" to patents in their breeding programmes altogether. At the same time, NGT patents can also create economic opportunities by providing a framework for protecting innovations which SMEs may use to scale up, attract investments, or enter into partnerships.

Larger firms are better placed to manage legal costs and risks, while smaller ones may struggle to compete. Yet, patents can be a useful tool also for smaller players to strengthen their market position and bargaining power.

Farmers face legal uncertainty around farm-saved seeds especially to whom they own a FSS royalty if a variety is protected by one PVR and one or more patents owned by different parties[339]. Whether an NGT plant is patented or not has no immediate impact on **organic or GMO-free farmers**, as the use of NGTs is not allowed in organic and GMO-free farming.

NGT-based plant varieties

NGTs are expected to shorten breeding cycles by up to a third, lowering R&D costs and accelerating new solutions. Breeders that introduce new varieties have a first-mover advantage. They often dominate markets for four to six years.

Farmers may benefit from improved yields or reduced input needs. Also, shortened breeding cycles due to NGTs brings stress-related improved varieties earlier to the market and thus at their disposal. Higher seed costs due to improved or desired traits are likely, but they are typically a small factor in total farming costs and can be offset. Adoption will vary by crop type

[339] The current FSS scenarios assume a single right holder when it comes to the collection of FSS related information and royalties.

and region, with horticulture less likely to integrate NGTs due to high costs and short product cycles.

Licences

Through licenses, breeders obtain access to traits, technologies, and germplasm. Since the process of identifying the rightholder(s), the assessment of patent claims, and the negotiation of licenses is resource intensive and time-consuming, the existing voluntary platforms help to reduce transaction costs. They do not entirely solve the need to assess the identified patents with respect to their validity and scope of protection i.e., whether a license is required or not.

The more beneficial and must-have traits get patented, the more licenses will be needed to access material and/or obtain the right to make use of the trait. While licenses can be complex and may require legal advice, in particular for small breeders, they are also a source of revenue.

When it comes to patent stacking – which is highly likely to occur over time - the accumulated license costs may be prohibitive and decrease the likelihood of a wider adoption and planting of favourable, sustainable varieties.

Large firms with dedicated legal experts are typically better able to use licences strategically, while smaller players risk exclusion.

Litigation costs

Patent-related litigation in the EU is rare and is expected to remain rare. A priority for breeders is to avoid litigation. The threat of costly disputes is the key factor for breeders to avoid using any patented material in their breeding programme, or even to stop programmes. Potential litigation costs deters smaller breeders from innovating. The potentially high costs for infringement procedures – easily €20 000 - €70 000 and more – are sums that threaten the viability of SMEs. The risk of accidental infringement, which can happen despite FTO procedures, is particularly acute for small breeders, creating significant uncertainty.

While there is a fear of farmers being made liable for accidental infringement through pollen drift, there is no evidence of such cases. When it comes to farm-saved seeds and the use of patented material without a licence, the parties are more likely to seek out-of-court redress.

9.2. Potential impacts on availability and access to plant reproductive material for breeders

Availability of conventional plant reproductive material (PRM)

Breeders highlighted that access to a wide range of conventional plant reproductive material is essential for maintaining genetic diversity and developing high-performing new varieties. The current PVR system supports this by ensuring transparency and free access for breeding purposes.

However, if protected varieties include patent protected traits, the variety does not benefit anymore from the breeders exemption, which could reduce the effective availability of conventional, freely accessible PRM for further breeding.

If patented varieties are included in conventional breeding programmes, the resulting varieties contain patented content which dilutes the new variety as patented material and thus prevents further free access. This effect is the same if a conventional variety is patent protected or an NGT-based variety. If an NGT-based variety is included in the breeding, it ‘dilutes’ the material for organic, GMO-free breeders as it includes traces of genetic-modifications.

The more widespread in the longer run, this could lead to the mentioned (intergenerational) patent thicket that adds costs to identify and check if material is IP-free, and that adds costs to those who require scarcer, conventional PRM.

Access to conventional PRM

The plant breeding sector has long relied on the principle of free and unrestricted access to competitors' genetic resources for crossing and selection. This principle remains central to conventional breeding. PVRs allow breeders to use protected varieties in their breeding programmes without needing a licence, thereby safeguarding access to conventional PRM. The more RPM is privatised through IP, the less conventional diversity is guaranteed.

Availability of organic/GM-free PRM

Although not directly impacted through NGT patents, some interviewees, particularly from the organic sector, expressed concerns that in the longer run, markets could become dominated by NGT-based varieties. This trend may narrow the availability of organic and GM-free PRM, limiting choice for breeders specialising in these sectors.

Access to organic/GM-free PRM

For organic and GM-free breeders, access is already more vulnerable. As NGTs expand, these breeders may face difficulties in finding sufficient PRM that is free from NGT traits. Search costs and the potentially higher price for scarcer organic PRM may lead to a lower premium if these additional costs cannot be passed on to the consumer. The potential admixure of NGT and organic seed streams as well as accidental cross-pollination increases the risk of unintentional presence of NGT material. This complicates access to truly organic or GM-free PRM even further.

9.3. Potential impacts of a higher concentration of the seed market

Overall competitiveness of the market

A higher concentration in markets could lead to fewer dominant players, reducing competition and increasing seed prices.

Many of the dominant plant breeders are European firms with a strong presence in and outside Europe. They acquire vertical or horizontally fitting international firms as well as European ones. Mergers and acquisitions that can be observed over time relate to the specific experience of competitors needed for a new product market penetration or expansion or enabling process patents held by competitors or specialised downstream actors.

In order to find out if patented traits could lead to concentration in product markets, one will need to monitor the market developments at the level of the different cultivated varieties in different geographies or by country. The AFBV/Science group Genomics and Genetics suggest creating an expert group to monitor the consequences of patents.[340]

[340] AFBV/ Wissenschaftskreis Genomik und Gentechnik (2024), Update on ongoing discussions on the regulatory proposal of the European Commission on New Genomic Techniques ("NGTs"): recommendations to reach the Trilogue, see: https://www.biotechnologies-vegetales.com/wp-content/uploads/2024/12/New-Genomic-Techniques-Update-AFBV-WGG.pdf

Costs

A greater concentration of the seed market could **increase costs for breeders and farmers**. Evidence from the U.S shows that a higher concentration allowed large firms to set higher seed prices, particularly for patented GM varieties. In Europe, while seed costs are still a relatively small share of farm expenditure, breeders confirmed that higher prices often reflect R&D investments and the market power of leading firms.

Diversity of varieties

Market concentration can potentially reduce the diversity of varieties available. Larger companies tend to invest in crops with larger markets or higher consumer value, leaving niche or locally adapted varieties less well served. Interviewees noted that although specialisation may persist, concentration around 'blockbuster' traits risks narrowing the genetic base, as a few firms could dominate entire crop segments. This risk is however higher in crops with more uniform, large markets (e.g. maize, soybean), than in fruits and vegetables.

9.4. How does the IP system affect the market structure of seed markets in EU and third countries?

European Union – balanced but vulnerable

The EU seed sector is characterised by a dual system of plant variety rights and patents. PVRs safeguard free access to breeding material through the breeder's exemption, supporting diversity and competition. However, when patents are involved, breeders - especially SMEs - face high costs and complexity in checking whether a trait is protected, creating barriers to entry. Even a moderate rise in NGT patents could shift the balance and increase the bargaining power of large companies.

However, will patents on NGT plants lead to market concentration? The majority of consulted experts were sceptical. Acquiring patent portfolios may be among the reasons why companies acquire other firms, but this does not necessarily mean that individual companies dominate "the plant breeding market". There may be a high concentration in a given staple crop, in a given geographic region, and for a given period, but the constant need to develop new solutions, provides room for large and small breeders to innovate. Overall, one would need to speak about 'plant product markets'. However, germplasm availability is a driver of market concentration. Large companies with large collection may cope without, but smaller companies which rely on access cannot.

The expectation was that there would likely be an increase in patents within Europe, but not necessarily a surge. In the absence of an NGT Regulation, there will be no surge with European patents at all, but **international patenting will continue**. Patents can be seen in territories where a favourable regulation is in place – such as the U.S., China, and increasingly in many other countries such as Japan, or India, and where breeders have product markets. Since many breeders are internationally active, they will offer their NGT traits abroad and protect their investments also with patents in these countries.

Interviewees considered also the very careful examination practice and low grant rate in this area at EPO. They were not expecting that this would change. Various interviewees confirmed that breeders are working on NGTs and are waiting for the legal clarification.

United States – high concentration

The U.S. IP system combines plant patents, utility patents (incl. on specific varieties), and Plant Variety Protection certificates, with no breeders' or farmers' exemptions. This creates strong exclusive rights for patent holders and has historically driven mergers and acquisitions, leading to high market concentration in particular in cash crops.

China – a domestic focus

China regulates NGTs under Chinese GMO rules, with approvals granted case by case. IP protection exists but approvals so far have only been issued to domestic firms. This suggests the system reinforces national players rather than opening markets to foreign breeders.

9.5. What is the ownership structure of patents and PVRs?

Patents

NGT-related enabling process patents (technical methods) are – currently - primarily owned by academic institutions. The most relevant foundational CRISPR/Cas9 patents are owned by two rivalling academic groups which have set up various licensing models (direct, indirect, exclusive, non-exclusive, etc.). Complexity and uncertainty in ownership in these patents limit their use in commercial plant breeding.

There is a limited number of granted plant-related patents by EPO. Alongside multinational companies, patents related to plants are also held by large and medium-sized breeders, universities, research institutes, and start-ups. The latter are often founded by scientists themselves. These actors frequently license patents to bigger firms or form joint ventures (e.g. Pairwise licensing to Bayer and Corteva). Large corporations have the largest patent holdings, particularly in traits and biotechnological innovations. Corteva, for example, holds the largest CRISPR/Cas9-related patent portfolio.

Plant Variety Rights

Since its creation in 1995, the Community Plant Variety Office has granted over 65,000 rights, of which around 31,000 were still active in 2023. Ownership of PVRs is broad and more diverse than patents. Around 800 different applicants are listed in the European Common Catalogue of plant varieties. The Netherlands is by far the largest source of applications (45 % of EU total), followed by Germany and France. Unlike patents, PVRs are widely used by SMEs, but also larger companies use PVRs. They are typically not used by universities or research organisations.

9.6. How does the IP system affect the innovation patterns in the EU and third countries?

European Union

The EU's dual system of PVRs and patents creates mixed incentives for innovation. PVRs encourage broad access to genetic resources through the breeder's exemption, which sustains incremental innovation and diversity. Patents provide stronger exclusivity. However, interviewees stressed that a rise in NGT patents will likely be moderate, given strict examination standards at the EPO, existing knowledge on native traits, and an ever-increasing disclosure of scientific and technological knowledge in publications that makes it more difficult to claim ‘novelty’. Despite the benefits IP can bring to SMEs, including a stronger market power and enabling better access to equity, many SMEs may perceive the complexity and cost of patents as a barrier. Larger firms navigate the IP system with more ease and are better positioned to benefit. This creates risks of unequal innovation capacity and growth opportunities.

United States

The U.S. system grants strong exclusive rights through patents and lacks a breeder’s exemption. This has driven innovation in biotechnology but also fostered high market concentration. The Bayh-Dole Act (1980) further stimulated innovation by allowing universities and research institutions to commercialise IP from public funding, leading to a wave of start-ups and patents in biotechnology and boosting technological development. The know-how of researchers and the patent portfolios of start-ups attracted equity investments from large pharmaceutial and agrochemical companies, to the point where major agrochemical firms acquired smaller breeders and innovative plant breeding start-ups, thereby contributing to the consolidation of the plant-breeding sector.

China

China has strengthened its IP framework, particularly in plant variety protection, and has become a global leader in NGT-related patent filings, the vast majority applied for by state-owned public research organisations and universities supported my massive subsidies. Approvals for NGT plants have so far been granted only to domestic firms. This creates a distinct pattern of innovation driven by state-supported domestic actors.

Japan

Japan applies a dual system with patents and plant breeder’s rights. Its patent law is relatively liberal, allowing patents on a wide range of plant-related inventions, including varieties. Unlike the EU, Japan provides no exemption for farm-saved seed and its PVP system, which strengthens patent holders’ control. Research exemptions are interpreted broadly, allowing patented inventions to be used for further research likely including breeding, which supports innovation while maintaining strong commercial restrictions.

9.7. What is the situation of patent applications/patents granted in the EU?

Since 1995, the European Patent Convention has allowed patents on plants obtained through technical means (e.g. genetic modification, mutagenesis), but not on plant varieties “as such” or plants derived exclusively from essentially biological processes.

Between 1982 and July 2024, there were about 9,300 European patent applications in the area of genetically modified plants. Of these, 36.5 % were granted, while around 51 % were withdrawn or refused, and about 11.8 % are still pending.

For conventional plants, patenting is much less common: around 1,000 applications were applied between 1995 and 2023. About half were refused or withdrawn, 100 were granted, while some 400 remain pending.

Patent applications in plant biotechnology have grown steadily, with an average annual growth rate of 4.5 % (2015–2024), above the overall patent growth rate of 2.5 %. However, the share of granted biotech patents dropped sharply, from a peak of 58.3 % in 2017 to only 21.8 % in 2024 – the lowest among all technology fields.

Monitoring by German authorities confirms this decline: in 2019, there were 300 patent applications at the EPO and 115 granted patents; in 2021, applications fell to 219 while grants decreased to 101. About 75–79 % of these relate to GMOs.

For CRISPR/Cas technologies, the EU landscape is dominated by a few large patent holders, with Corteva holding the largest portfolio. Smaller firms (e.g. Cellectis, Benson Hill) may still find niches for NGT developments, depending on the specific patents they control.

9.8. What is the rate of legal disputes on NGT plants

So far, litigation in the plant breeding sector is largely non-existent. Conflicts are typically resolved before they would end up in court. This can end with a potential infringer taking a license but also a potential infringer simply stopping an ongoing, potentially infringing breeding programme.

Legal experts expect that disputes may increase over time in the EU due to overlapping patents, “patent thickets,” and difficulties in proving whether a plant was obtained by an NGT or conventional breeding.

9.9. What are the likely impacts of (voluntary) transparency and licensing initiatives on access and costs of information?

Mainly three impact areas were highlighted through the consultation with the following:

- **Improved transparency**: Voluntary transparency tools such as the **PINTO database** help breeders identify whether varieties are covered by patents. This gives them a clearer basis for deciding which material they can use and reduces the risk of accidental infringement.
- **Improved access**: Voluntary licensing platform such as the ACLP and ILP Vegetables help breeders to get access to licenses.
- **Lower transaction costs**: By centralising information, these initiatives shorten licence negotiations. Because participation is voluntary, these initiatives are nevertheless incomplete so that legal uncertainty persists and the need for breeders to carry out individual freedom-to-operate analysis remains. Breeders may still need to hire legal experts to interpret whether a patent applies, but for SMEs in particular, this helps to partially reduce legal and administrative expenses.

Stakeholders noted that making transparency obligations mandatory (e.g. through registration in PVR or patent databases) would create fuller records, enabling breeders to make better-informed choices and potentially reducing unnecessary licensing costs.

9.10. What is the level of complementarity between IP and PVR and effects for different stakeholders?

Breeders

The PVR system is widely valued for its open character, in particular the breeder's exemption, which guarantees free and unrestricted access to genetic material for further breeding. This fosters diversity and incremental innovation. For commercialisation, the PVR provides exclusive rights to the rightholder. In case of PVR protected elite varieties and developed, patent protected traits classified as EDV, the PVR extends to the EDV and provides to the breeder an enforceable right.

Patents incentivise the development of high-value, complex traits. Right holders can decide on access conditions and generate income from licensing. Particularly for SMEs, existing patents can create higher costs and complexity for freedom-to-operate analyses. Some breeders indicated that patents are not always necessary as incentives, since PVRs combined with first-mover advantage can already ensure returns on investment.

Larger breeders may benefit most from the combination of patents and PVRs. PVRs allow them to protect specific varieties, while patents provide exclusivity over traits and technologies. This dual use can consolidate market power, as exclusive patents on "must-have traits" enable strategic licensing or blocking access to competitors.

For smaller, traditional breeders there is less complementarity. While they make extensive use of PVRs, the additional layer of patents introduces additional costs (licensing fees, legal advice, and negotiations). The risk of being excluded from patented traits makes them more dependent on licensing platforms or voluntary transparency initiatives.

Farmers

Farmers indirectly benefit from PVRs and patented traits, as the system ensures provision of new and improved varieties containing traits of interest. However, patents may limit seed choices if certain "must-have" traits were monopolised. Uncertainty also persists around farm-saved seeds, where patents can overlap with PVR obligations and create uncertainty on who is entitled to request FSS related information and royalties.

Public research and universities

Beside their opportunity to generate funding through licenses, patents have an additional signalling function for research organisations to attract third party funding and – if needed – equity for spin-outs. Thus owning patents strengthens their position in partnerships, helps to attract private funding, and supports spin-offs. In contrast, PVRs play a smaller – if any – role for them, as they usually focus on upstream technologies rather than commercial varieties.

9.11. Which awareness issues about the IP framework and relevant practice prevail by SMEs?

Overall, there seems to be a **limited awareness of patent options**, amplifying actual or perceived concerns. Many small and medium-sized breeders lack knowledge about how and when patents can be used. This is mainly due to their size and the fact that they do not have own legal units (which they do not need for PVRs). Without a sufficient level of awareness and capacity, SMEs risk being *de facto* excluded from using new technologies.

Key concerns are linked to the complexity of the system: patents are often perceived as difficult to understand and unpredictable in terms of enforcement. SMEs often do not have in-house legal expertise and must rely on costly external advice, which discourages them from engaging with the patent system.

Less of an awareness issue but a key barrier are **high costs of freedom-to-operate analyses.** While this applies to all breeders, SMEs reported that checking for overlapping or unclear patents and patent claims requires them to hire external patent experts. An increase in patented plants will make FTO checks even more complex and costly. These costs can be prohibitive for small companies. Furthermore, they fear unintended infringement and overlap with patents when deverlopping traits with conventional mutagenesis methods.

The perceived risks and limited legal knowledge functions as a deterrent ‘to deal with patented material’ and is a barrier to innovation.

Several interviews suggest that **support measures exist but may not be well known**: This concerns information about patents and support measures from EPO which offers tools such as a 30 % fee reduction for micro-enterprises and training or awareness campaigns. Equally, there is limited knowledge about the licencing platforms in terms of access, costs, and benefits.

There is clear scope to improve information sharing, for instance by providing more accessible offerings through national breeder’s associations.

9.12. How effective are identified regulatory mechanisms on facilitating transparency and availability?

Voluntary licensing platforms

The ILP Vegetables and the ACLP platforms can improve **transparency** by maintaining publicly accessible databases such as PINTO or the ILP Patent Register. Yet, its voluntary nature and no legal consequences of having potentially non-relevant or (if contested) non-valid patents in, limits its value in terms of transparency means. The ’simple’ inclusion in PINTO for example, function for some breeders as a deterrent to using the material included. Also the ILP Patent Register requires further inquiries by potential users.

In terms of **availability**, the voluntary platforms guarantee their members access to germplasm and traits. Members reported positive direct and indirect effects such as shorter negotiation time, an limited ‘internal’ breeder’s right, and a broad geographical IP coverage. However, due to the voluntary nature, not all companies participate. Interviews showed that information about the costs and benefits of the platforms is sometimes inconsistent or inaccurate. Smaller breeders could benefit significantly from participating, but often lack incentives to join. As the platforms are privately organised and bound by competition law, data on effectiveness is not shared – even internally – which limits wider awareness among breeders.

Compulsory cross-licensing

The EU Directive 98/44/EC provides for compulsory cross-licensing in favour of breeders if a new variety cannot be exploited without infringing an earlier patent. While in principle this facilitates access, stakeholders argue that the criteria are restrictive: compulsory cross-licensing is only possible if a breeder can show that their variety “represents significant technical progress of considerable economic interest” compared with the earlier patented invention. Since there is little clarity on how patent offices or courts would interpret “considerable economic interest,” breeders are discouraged to test this mechanism. This, in practice, renders the mechanism ineffective since it sets a high bar that is difficult to meet, or at least a legal uncertainty. No evidence was found that it was ever applied.

Clearinghouse

Although not yet implemented in practice, the Swiss Patent Office's 'Clearinghouse' model is designed to offer breeders an early check on whether a variety is affected by a patent. Breeders would report which plants they are working with, and patent holders would then be required to notify them of any relevant patents within 90 days. However, the need for patent holders to continuously monitor the market is seen as a disproportionate burden to innovators. In addition, unresolved issues remain, such as how costs would be shared and the fact that results would not be disclosed to the public, which does not create transparency beyond the requesting breeder

Registration of patents in PVR/variety databases

A short-term and viable solution can be a mandatory inclusion of patent information in plant variety databases such as the EU Common Catalogue. This would improve visibility for breeders, provided a mechanism can be found which limits the disclosure to patents which cover the related PRM.

9.13. What are the impacts on effectiveness of transparency initiatives on SMEs?

Licensing platforms and patent databases give SMEs **clearer entry points** to identify and access patented traits. This reduces the need for SMEs to carry out lengthy individual searches or complex legal analyses. Thus, effective transparency initiatives shortens negotiation times and lower the dependency on expensive external legal expertise. Platforms that function effectively provide SMEs with guaranteed access to germplasm and traits, along with an "internal breeder's exemption" during research phases. This gives smaller breeders opportunities they could not secure alone. Easier **access to reliable information** and **patented traits** helps SMEs to assess risks better and to invest more confidently in breeding activities. It furthermore supports diversity and competitiveness in the sector.

Databases can be effective by clearly indicating which patents apply to which varieties. This knowledge **reduces the risk of accidental infringement**.

With more transparent information, SMEs are better able to participate in markets that are otherwise dominated by large firms. **Transparency reduces asymmetries in knowledge and bargaining power** and helps to maintain a level playing field.

9.14. What are considerations favouring alternative measures in terms of effects on innovation and economic effects on breeders and farmers?

Existing alternative measures support or lead to different effects:

Effects on innovation

- **Licensing platforms** help reduce blocking effects of patents by improving access to traits and speeding up negotiations, allowing breeders to continue innovating without long delays.
- **Mandatory transparency through databases or registers** would give breeders clearer information on which patents cover which varieties, reducing accidental infringement, increasing legal certainty, and supporting informed R&D investment decisions.
- **Compulsory cross-licensing** could safeguard innovation if essential "must-have traits" were to fall under control by a few firms, and prevent bottlenecks in breeding progress.
- **Breeder's exemptions** are a relevant tool to lower the barriers of breeders to innovate. The limited breeders exemption – as provided for through the UPC – enables the use of patented material during R&D and breeding without a licence, thus lowering barriers for SMEs to experiment and innovate.
- While **trade secrets** protect the breeder's work without formal IP costs, they reduce information sharing and can slow follow-on innovation. This can negatively affect innovation, particularly where rapid adaptation would be needed.

Economic effects on breeders and farmers

Breeders

For breeders, alternative measures can ease economic pressures by lowering transaction and legal costs, which may be significant for SMEs. Licensing platforms and transparency tools reduce the need for costly legal advice and limit the risk of accidental infringement, making innovation more affordable and less risky. However, the costs to assess the declared patents for their validity and need to take a license remains. Compulsory licensing and broader breeder's exemptions help prevent smaller breeders from being excluded from access to key traits, supporting a more level playing field with larger firms. By contrast, reliance on trade secrets avoids upfront patenting costs but offers no protection against imitation and reduces opportunities for licensing revenues.

Farmers

Farmers are affected indirectly: when breeders face lower costs and fewer barriers, they can deliver more varieties to the market at competitive prices. Compulsory licensing, which could become an effective mechanism if clarified, could then also help to ensure that no single company monopolises "must-have traits," thereby safeguarding variety choice and preventing excessive price increases. In this way, the economic impacts on breeders cascade down to farmers, influencing both the affordability and diversity of seed available.

10. What if?

The proposed NGTs Regulation has rekindled a vivid debate about the use of patents in plant breeding.

Our analysis of the recent legal suggestions, interviews with the full spectrum of involved stakeholders and discussions with experts provided multifaceted considerations and arguments.

New genomic techniques are expected to deliver a wide range of benefits to society. For many breeders, these advantages make NGTs an attractive tool; while others, including organic breeders, prefer not to use them.

The foundational technical processes transforming the breeding sector are typically protected by patents and will remain so until 2033. Yet, a range of alternatives emerge, all of them enable the development of valuable, patented traits - an element that will remain central, and which can be observed worldwide.

In a scenario where NGTs can be marketed in Europe, Figure 15 stylises the main impact areas for breeders and research actors. Setting aside the legal considerations that make it unlikely that NGT plant patents will be banned in the near future, the figure looks at various impact areas for the main actors.

In the following we sketch two scenarios: Assuming that NGTs become marketable, what would happen if patents were no longer available for NGT plants in the EU vs. what would happen if they continue to be allowed?

What if patents related to NGT plants would not be available anymore in the EU?

Potential positive effects such as stable costs and free access to PRM may only be short-term. While patents may not apply within the EU, patented traits developed elsewhere could be marketed in the EU. Yet, to secure some form of protection, the varieties might get covered under PVR. The available material could be freely used for further breeding and commercialisation in the EU, but beyond those, patent protection may still apply. Moreover, patents already granted would likely remain in force. There would thus remain a period of up to 20 years from the decision onwards, in which granted patents would remain valid until they expire.

For breeders using patents, the absence of plant-related patents in Europe could prompt them to relocate parts of their R&D to countries where patent protection remains available. In such cases, they are likely to prioritise trait development for international markets where investment costs can be recovered through licensing. As a result, innovative traits may reach Europe only with a considerable delay, affecting farmers who could otherwise benefit from earlier access. The absence of a patent system also tends to foster reliance on trade secrets, which can slow innovation and limit competitiveness.

The effects on research institutes - often the providers of new methods, traits, and related services and nuclei for spin-offs – could be significant. Without patents, public research institutes as well as spin-offs focusing on trait development as busines model lose their ability to create license income from EU players. They would equally be losing intangible assets – which increasingly define an organisation’s capacity to innovate and remain competitive. While they could rely on contractual agreements with breeders, they would lose the signalling function of patents, which plays a key role in attracting capital, supporting start-ups, and creating growth and value. With their role less visible, public R&D funding could also become more constrained, and leading scientists might move to more competitive research environments abroad.

Such developments could weaken Europe's scientific base in knowledge-intensive key technologies and pose a serious threat to Europe's long-term competitiveness in plant breeding.

What if patents related to NGT plants continue to be allowed?

Those breeders embracing the technical options to develop plants with NGTs and patent the innovation, are likely to profit further from the system. With patents, they would strengthen their market position and bargaining power. Since they invest in new, needed traits, and licence those to recover their development costs, farmers would obtain improved varieties likely faster than with traditional breeding methods.

A growing number of patents is likely to increase the costs for FTO analysis considerably. This applies in essence to all commercial breeders. Equally increasing is the complexity that comes with patents which is often linked to a higher demand in legal expertise, which many small breeders do not possess in-house. In the longer run, patent thickets may arise, adding another layer of complexity and legal costs.

Without a reasonable intertemporal benefit sharing between accrued patent claims, the cost for breeders for stacking traits could get out of proportion. In the longer run, patent-free PRM may become scarce.

For breeders that wish to stay outside the patented traits and varieties, access to material can be more difficult and more costly. In this respect they share the concerns and longer-term potential impacts of organic and GMO-free breeders.

Effects on research actors involved in patentable technologies would be very positive: their signalling function would remain intact, enabling the scientists to attract further research funding and VC for start-ups. It would potentially help maintaining an attractive research destination with the long-term positive effects on innovation, skills, and competitiveness.

To mitigate the expected higher costs for FTO analysis and searches, a range of measures outside legislation can be promoted.

Neither technological achievements nor NGT-derived plants will cease to exist. They provide innovation opportunities for the plant breeding sector, but also pose challenges. Effective transparency initiatives that reduce transaction costs, facilitate access to PRM and promote licenses under FRAND terms, can greatly support the gradual transformation process of the breeding sector.

Opportunities

A range of potential options and opportunities for action have emerged in the discussions. Some were more accepted than others, some may require lengthy processes, others less so. The following summarises those opportunities that can be implemented relatively easily and in a reasonable time by public actors as well as by private initiatives.

- Broad consensus can be seen in terms of **mandatory transparency on patent coverage**. It could be achieved through a mandatory disclosure in CPVO databases/EU Common Catalogue by labeling PRM with pending/issued patents. Right holders would be required to update the information when necessary.
- To facilitate the use of Art. 12 Dir 98/44, the conditions for compulsory cross-licensing could be clarified - including the application of FRAND terms **and the requirements that a protected trait be of clear economic or environmental interest**. Such clarification could be achieved through the **interpretation of existing legislation.**
- **Clarifying the full extent of the limited breeder's exemption** in all EU Member States.

- Clarification of the scope of protection of general process patents. No extension to successor plants to avoid patent thickets, excessive licensing costs, and unmanageable breeding processes.
- Continue prudent patent examination, avoiding potential overlapping claims,
- **Inform about EPO's disclaimer rule, limiting the fears of small breeders to infringe patents covering native traits that exist in their germplasm.**
- Dedicated training and information sessions for breeders on patents, their pros and cons.
- Private licensing platforms should be made more widely known. Successful examples of licensing by small breeders ('testimonials') could be used to raise interest and trust. Transparency on fees, rights and obligations would also need to be more widely made known. Possibly breeders associations could be activated as multiplier.

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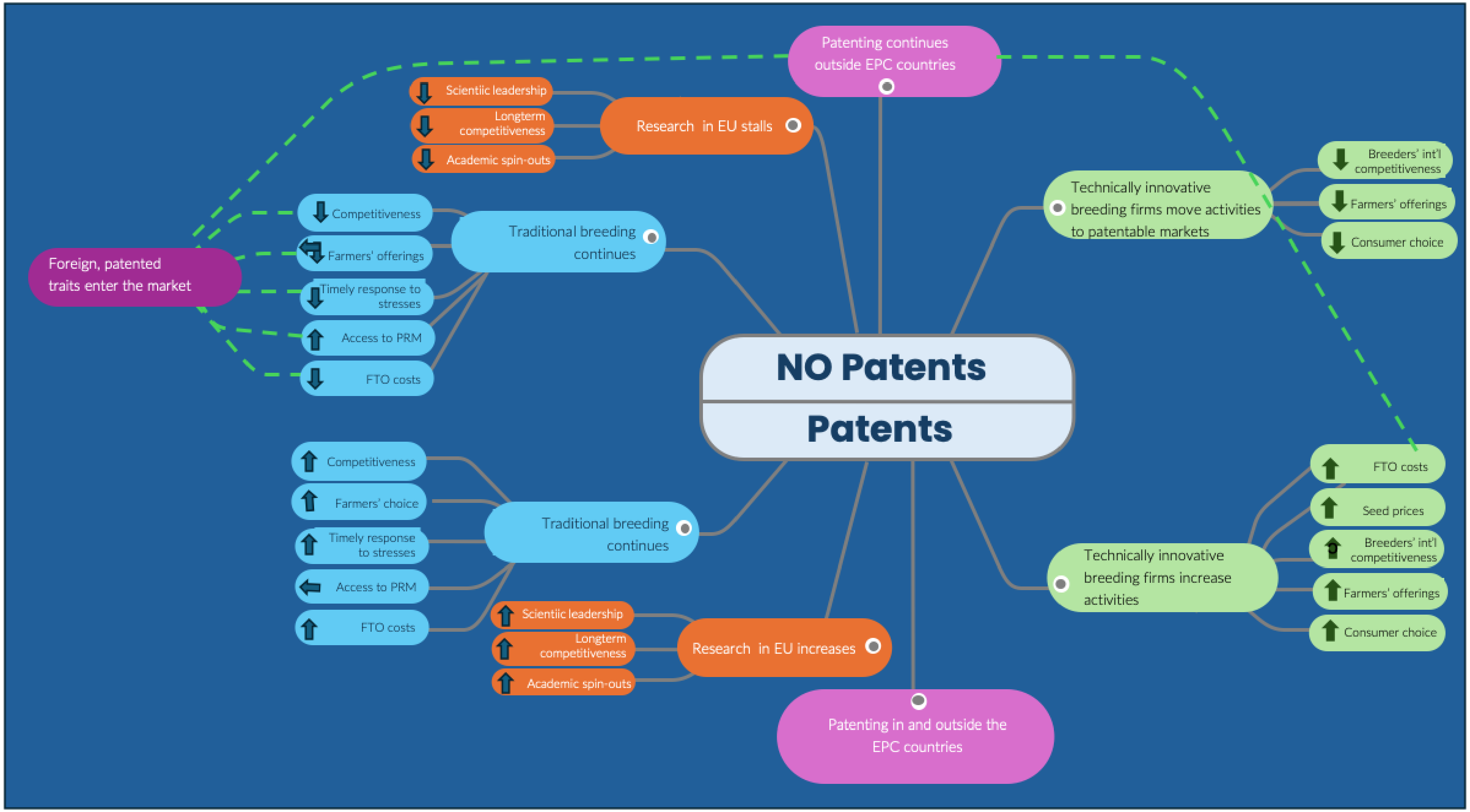
Figure 15 Main impact areas on relevant actors



Source: Technopolis Group

Table 14 Summary of options

Option	Pros	Cons	Stakeholders Affected (positively (+), negatively (–)
Exceptions from patentability (e.g. excluding NGT plants, traits, or processes from patentability via changes to Dir. 98/44 or EPC)	• Could remove uncertainty for breeders & farmers. • Reduces risk of unintended infringement. • Strengthens access to genetic resources.	• Requires changes to Biotech Dir. 98/44 and EPC (difficult consensus, diplomatic conference). • Only applies to patents filed after entry into force (no retroactivity). • Risk of R&D relocation outside EU.	+ Breeders (greater FTO, lower litigation risk). - Breeders (less incentives for technically complex innovations) - Farmers (slower availability of needed resistant plants). – Patent holders (loss of protection). – Innovation investors (weaker incentives).
Amendment of Art. 8(1): Scope of product claims (exclude biological progeny from product patents)	• Prevents extension of patent protection to seeds/propagated material. • Clarifies limits of patents. • Supports breeders' FTO.	• Reduces patent value for rights holders. • May trigger legal disputes on scope. • Risk of inconsistency with TRIPS.	+ Breeders (cheaper access, lower risks). + Farmers (more clarity on fees with farm-saved seeds). – Patent holders (weaker exclusivity).
Amendment of Art. 8(2): Scope of method claims (limit extension of patents to progeny of process)	• Keeps patents for technical genome-editing methods, but limits automatic extension to all progeny. • Reduces unintended "blocking" of traits.	• Complex to define "general processes" vs. specific claims. • May narrow patent scope significantly. • Could discourage investment in process innovations.	+ Breeders (less broad blocking, more R&D room). – Patent holders (loss of reach into progeny).
Expansion of limited breeders' exemption (harmonised EUwide rule allowing use of patented material in R&D phase; license required if trait retained)	• Provides breeders time to explore patented traits before needing a licence. • Keeps markets somewhat open to new entrants. • Already used in NL, DE, etc., so proven workable. • Also expanded to UPCA members	• Stops at commercialisation: breeders still depend on patent holder for licence. • Risk of strategic lock-in if negotiations delayed. • Patent holders retain strong bargaining power.	+ Breeders (legal certainty in R&D). – Breeders (still must negotiate for market use). + Patent holders (retain control over commercialisation).

Option	Pros	Cons	Stakeholders Affected (positively (+), negatively (–)
Full breeders' exemption for plants developed independently via essentially biological processes (Austrian/French model)	• Protects conventional breeders from infringement risk when they independently develop a trait via natural methods. • Aligns with some national laws already in place.	• Does not solve FTO when third-party varieties used. • Risk of undermining NGT patent protection scope. • Potential conflict with EPC interpretation.	+ Conventional breeders (legal protection). – Patent holders (erosion of scope).
Full breeders' exemption (broad version) (covers breeding, commercialisation, and use of new varieties in food/agriculture)	• Maximises freedom-to-operate for breeders. • Ensures access to varieties and traits without licensing.- • Strengthens farmers' access and seed choice.	• Could amount to near-complete loss of patent protection for plants. • Questionable compatibility with TRIPS (Art. 30, three-step test). • Legal uncertainty re: EPC and international treaties.	+ Breeders (full access, no licensing barriers). + Farmers (wider access to varieties). – Patent holders (severe loss of rights). – Investors (disincentive for biotech R&D).
Voluntary licensing platforms (e.g. ILP Veg., ACLP)	• Guarantee access to germplasm & traits • Shorter negotiations, lower transaction costs- • Arbitration procedures ('baseball') ensure fair fees • Foster collaboration across firms	• Voluntary → incomplete coverage • No legal certainty (patent validity not guaranteed) • Small breeders lack incentives to join • Limited/no public data on effectiveness	+ Breeders (access to PMR and traits, legal certainty (non-assertiveness), potentially lower transaction and licensing costs) – Breders (entry costs, incomplete info, need for FTO remains) + Patent holders (facilitated licensing procedures - Patent holders (potential lower license fee if baseball arbitration not in favour)
Clearinghouse (Swiss model)	• Provides "safe harbour" if patent holders don't respond • Shifts burden of vigilance to patent owners • Reduces risk of inadvertent infringement	• Burden on patent holders (esp. SMEs & foreign firms) • Only informs the requesting breeder, not the public • Safe harbour may not extend beyond Switzerland- Risk of false security on FTO	+ Breeders (legal clarity, reduced risk) – Patent holders (administrative burden, monitoring costs) – SMEs patent owners (risk of missing notifications)

Option	Pros	Cons	Stakeholders Affected (positively (+), negatively (–)
Mandatory registration of patents in PVR/variety databases (e.g. EU Common Catalogue)	• Provides full visibility on patents linked to varieties- Easier breeder decision-making- • Potentially reduces unnecessary licensing costs	• Coverage incomplete (not all species/varieties require registration) • Requires legislative changes • Dependent on accurate self-declaration by right holders	+ SMEs (clarity, lower costs) + Farmers (more seed diversity) – Patent holders (mandatory disclosure reduces control)
Clarifying compulsory cross-licensing (Art. 12 Dir 98/44/EC)	• Ensures access if a new variety cannot be exploited without infringing a patent	• Patent-holder loses its exclusive right	+ Breeders (potential access safeguard) – Patent-holder (potential lower licence income in particualr if FRAND terms apply)

Annex 1 - Additional data

Table 15 Sowing seed exports, volume (in metric tons) and value (in U.S.$), EU-MS, 2022

	Quantity (in metric tons)						Value (in million U.S.$)					
	Field crops	Vegetables	Flowers	Potatoes	Trees	Total	Field crops	Vegetables	Flowers	Potatoes	Trees	Total
France	1283313	7251	542	216332	11	1507449	1877	555	18	114	0.6	2564.6
Netherlands	175069	12844	2794	862983	110	1053800	313	2202	104	540	3.1	3162.1
Poland	841302	1704	447	4804	1	848258	424	18	6	2	0.1	450.1
Slovakia	380493				67	380560	258				1.1	259.1
Germany	196323	1352	1044	89091	38	287848	940	78	55	49	0.7	1122.7
Czechia	269973	295	36			270304	148	13	1			162
Belgium	160528	1899	15	58902	52	221396	204	3	2	21	0.5	230.5
Denmark	155069	8761	546	55202	16	219594	430	50	22	36	1.8	539.8
Romania	173691	153			19	173863	443	3			0.4	446.4
Hungary	146808	234	54		62	147158	471	9	1		0.7	481.7
Italy	104416	15360	136	2785	48	122745	351	153	3	1	0.8	508.8
Austria	114739	275		4826		119840	398	10		2		410
Spain	83794	4119	116	9225	19	97273	193	112	1	6	0.3	312.3
Latvia	69224	10				69234	43	3				46
Sweden	38605	366	193		1	39165	36	5	2		0.5	43.5
Lithuania	26733	649	37			27419	48	8	3			59
Portugal	17925	1998		5070		24993	16	6		4		26
Estonia	23522					23522	24					24
Croatia	20835	33				20868	28	1				29
Greece	13989	93				14082	13	3				16
Luxembourg	12694	405				13099	14	1				15
Bulgaria	8124	2571				10695	19	10				29
Ireland	9578					9578	6					6
Slovenia	4671	164			18	4853	11	4			0.3	15.3
Finland	802			1591		2393	2			1		3

Source: https://worldseed.org/resources/seed-statistics/

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Decision of the Enlarged Board of Appeal dated 20 December 1999, G 1/98: A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53 (b), EPC even though it may embrace plant varieties. See: https://link.epo.org/web/g980001.pdf

Decision of the Board of Appeal dated 9 December 2010, G 002/07 (Broccoli/PLANT BIOSCIENCE)

Decision of the Enlarged Board of Appeal dated 14 May 2020, G 003/19: Plants and animals exclusively obtained by essentially biological processes are not patentable under Article 53 (b) EPC. See: https://www.epo.org/boards-of-appeal/decisions/pdf/g190003ex1.pdf

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Data sources

The followinf lists only the general data sources. Individidual data hasa also been collecte from company reports (from company websites) as well as available reports.

CPVO Variety Database https://cpvo.europa.eu/en/applications-and-examinations/cpvo-varieties-database

Crunchbase - non public database - www.crunchbase.com

EU Plant Variety Portal - https://ec.europa.eu/food/plant-variety-portal/

Eurostat, Agricultural production – crops. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Agricultural_production_-_crops

ORBIS IP – non public database - Moody’s Analytics, see https://login.bvdinfo.com/R1/OrbisIntellectualProperty

PATSTAT Online - paid version of PATSTAT - data.epo.org

PINTO - https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/

Statista – public site. https://www.statista.com

Blogs

https://blog.aspb.org/policy-update-federal-judge-vacates-usda-rule-regulating-biotech-crops/;

https://ipkitten.blogspot.com/

Websites

The websites were accessed between March and July 2025. Some sub-pages indicated in the footnotes may already not be any more available. The following thus lists only the home pages of the organisations, companies, breeder associations, news outlets, etc.

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https://emea.dummenorange.com

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https://www.lexology.com
https://www.limagrain.com
https://www.nibio.no
https://www.nyulawreview.org
https://www.pairwise.com/
https://www.plantetp.eu
https://www.plantum.nl
https://www.science.org
https://www.seedabel.be
https://www.seednet.eu.com/
https://www.sementi.it
https://www.siemenkauppiaat.fi
https://www.sortsejere.dk
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