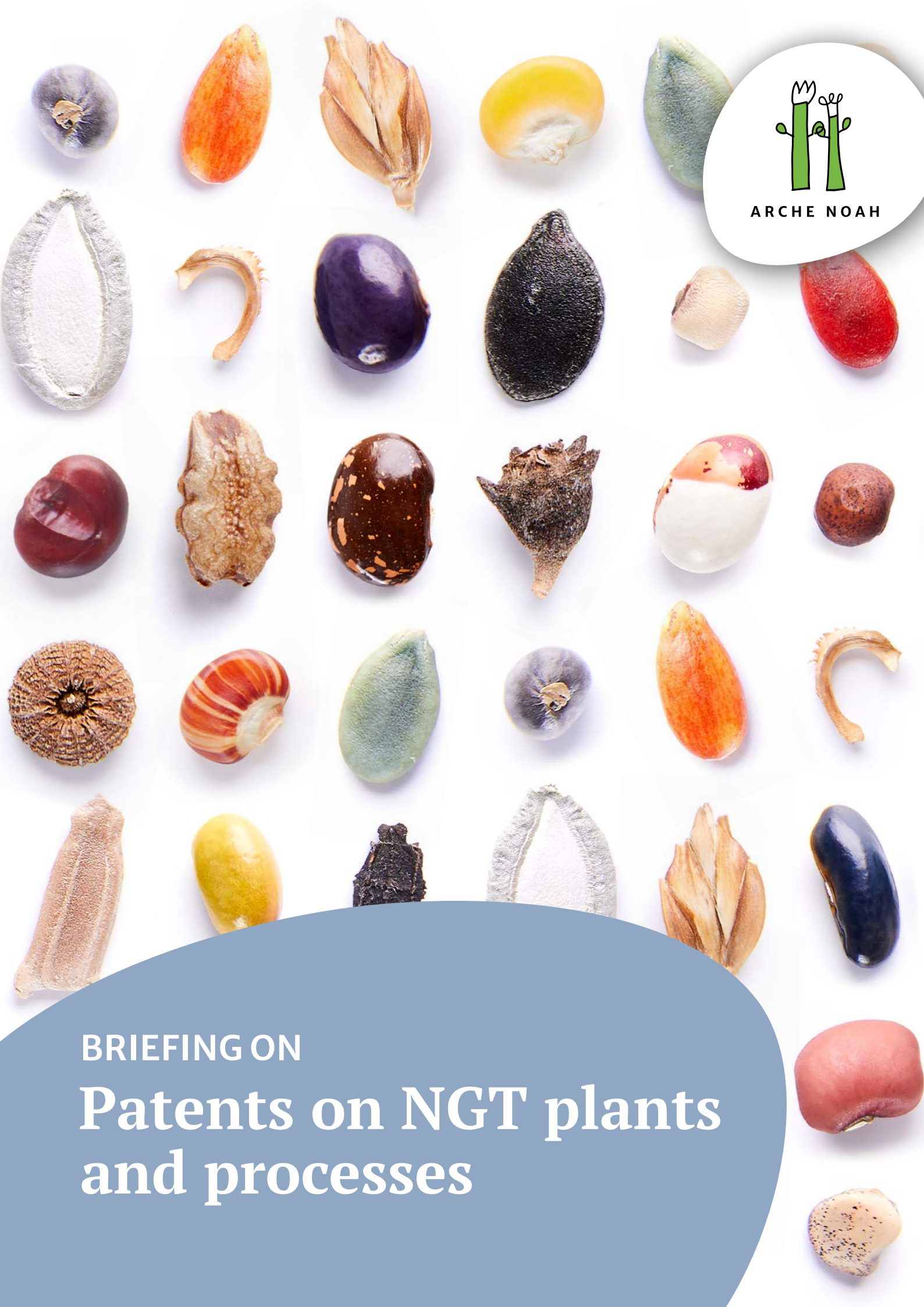


ARCHE NOAH

BRIEFING ON

Patents on NGT plants and processes

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As a non-profit association with a broad member base, ARCHE NOAH ("Noah's Ark") is dedicated to the conservation, development and dissemination of endangered cultivated plants.

For questions and comments, please contact us at seedpolicy@arche-noah.at

1 Executive summary



The purpose of the patent system is to promote innovation by granting inventors exclusive rights of the use and marketing of their "invention". The controversy of patents on seeds has grown in the context of the current debate over a possible deregulation of a new generation of genetically engineered plants in the European Union (EU). Patents on plants and seeds concern living organisms, which cannot be considered inventions, especially when derived from conventional methods of plant breeding. Further, patents on seeds actually hinder innovation, by blocking access to the biological material that is the necessary starting point for the development of every new variety. This briefing paper provides background knowledge on the legal system concerning patents on seeds, particularly for those participating in the debate on the new genomic techniques (NGT). It also examines the legal impacts of patents on breeders – and thus our food security of the future.

The briefing shows a complex legal landscape. On the one hand, the global legal framework actually gives states significant flexibility in relation to the application of patent regime to plants and seeds. Specifically, the 1994 **WTO Agreement on Trade related intellectual property rights (TRIPS)** (Article 27.3) allows states to completely exclude plants from patentability. However, in Europe this flexibility has not been fully used, notably due to the prior existence of the 1973 **European patent convention (EPC),** and the subsequent **EU Directive 1998/44 on the legal protection of biotechnological inventions (EU Biotech Directive).** Changing these two very different but interconnected legal texts to fully exclude seeds and plants derived from NGTs from patents is possible but would be a complex and long process. A more urgent issue, that can be corrected by less far-reaching changes, is a full and effective implementation of the (existing) exclusion from patentability of all seeds and plants derived from essentially biological processes. This includes plants developed using random mutations or following the screening/selection of plants for specific traits or genetic variations, on which the European Patent Office currently grants patents. Because of this lack of implementation, currently patents on NGTs/GMOs also impact conventional breeding. Therefore, limitations of the scope of patents granted on NGTs/GMOs and applying fair proportionate rules on the burden of proof would also provide plant breeders, farmers, and food processors who do not work with NGTs or regulated "old" GMOs the freedom to operate and to innovate without concerns of patent infringement.

In short, the hope of some actors to prohibit patents on NGT seeds/plants by some "quick fix" as a precondition to their deregulation is simply illusionary. Further, non-legislative systems such as patent pools and clearing-house mechanisms can only play a transitory role in relation to providing easier access to methods and/or biological material that are already subject to patents.

To once and for all put an end to legal loopholes that can be exploited by resource-rich seed giants and patent lawyers to gain monopoly rights over the plants and seeds that are the starting point for our food security, ARCHE NOAH recommends a full overhaul of the European patent legislation to exclude patents on all seeds/plants, as well as the genetic information contained therein. As a first and urgent step, the legal loopholes around plants derived from essentially biological processes, and the overarching scope of patents on GMOs/NGTs have to be stopped.

2 Introduction



The controversy of patents on seeds has become louder as part of the debate on a possible deregulation of a new generation of genetically engineered plants in the European Union (EU). As of August 2025, trilogue negotiations on the Commission proposal 2023/0226 on new genomic techniques (NGT)[1] are ongoing, with patents being a contentious issue. The European Parliament aims to exclude all NGT plants from patentability, while Member States and the Commission oppose substantial changes to patent law.

In this context it is paramount to understand **which patents exist in plant breeding and their impacts** in a field of innovation that builds on living organisms and processes, and where innovators more than ever stand on the shoulders of prior innovators. This briefing explains what patents are and what they do (part 1), and then dig into the practical reality of patents that relate to NGTs as well as the main actors involved (part 2). This paper then highlights the shortcoming of the proposals already on the table, and makes new recommendations (part 3).

1 https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2023/0226(COD)&l=en

3 What are patents and what do they do?

How do they impact farmers and breeders?



Fostering innovation through monopolies?

Patents are **artificial monopolies granted by public authorities for a limited period of time with the aim of fostering research and development** by giving patent holders greater opportunity to recoup their investment. Patent holders have exclusive rights to control and license the use of the inventions for 20 years, which means they can de facto stop their competitors from using the invention.

Rules related to patents are found in numerous legal instruments at different jurisdictional levels, creating a **complex web of rules**, which is detailed in Annex 1 of this document. In the world of plants, patents come hand in hand **with exceptions that have attempted to adapt patents to the realities of agricultural production and plant breeding**. Specifically, the development of new plant varieties to meet the needs of farmers and food production relies heavily on prior innovation – the work of earlier farmers and breeders – and requires unfettered access to genetic diversity, which constitutes the "building blocks" of every new variety.

Plant patents also co-exist with a sui generis intellectual property (IP) right that does not cover "inventions", but new plant varieties registered by public authorities on the grounds they are distinct, uniform and stable (DUS). This plant variety protection, commonly known as plant variety rights or plant breeders' rights, allows farmers and breeders to further use the variety under certain conditions. This regime is based on the 1991 UPOV Convention implemented in EU Regulation 210094, which establishes a protection regime at European level in parallel to those that exist in different Member States.



What can be patented?

Patentability requirements refer to the *general criteria that need to be met by an applicant* to obtain a patent. Applicants need to prove their product or process is new, inventive, and can be applied industrially. Patents can be granted by national or regional (e.g. European Patent Office) patent offices.

Patentability requirements concerning living organisms, plants and seeds are particularly complex, as different *exclusions from patentability* exist. In Europe, essentially biological processes for the production of plants as well as the plants obtained exclusively from these processes cannot be patented. It is also not possible to patent a specific plant variety.



Which powers does a patent give?

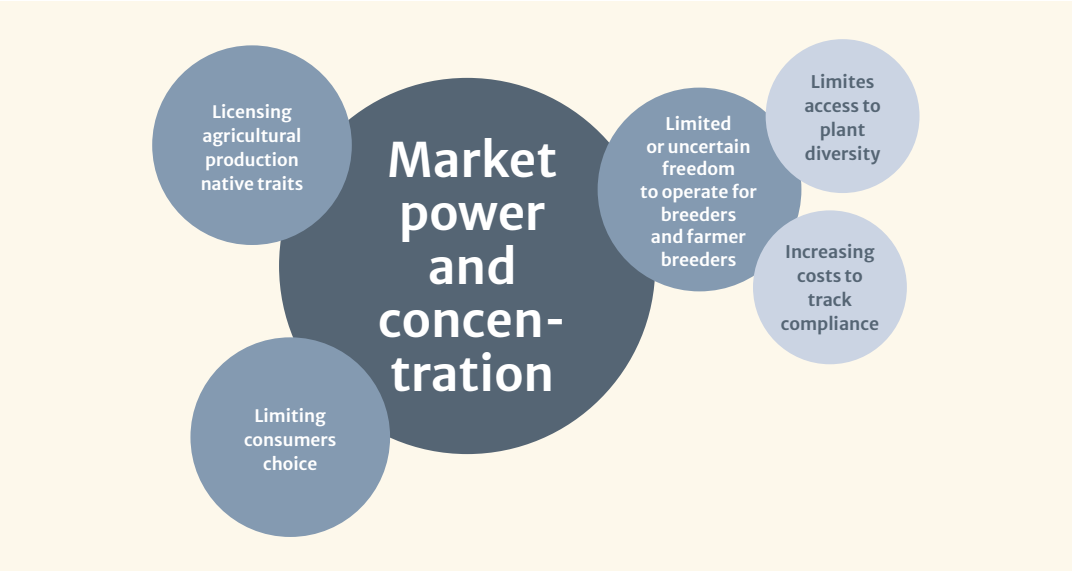
Scope of patent protection concerns the *monopoly rights and prerogatives granted to patent holders by the law* against competitors and users of the patented invention, once the patent has been granted. So-called 'absolute patent protection' is the norm, meaning a very high level of protection is granted to the patent holder.

In Europe, the scope of protection for plant-related patents has been slightly adapted, with *minor exemptions allowing farmers and breeders to use the invention in specific circumstances,* although these uses may be subject to the payment of license fees. For example, breeders may conduct research on the protected plant, like gene sequencing, without obtaining authorisation from the patentholder. However, breeders need to seek authorisation of the patent holder and pay licence fees to use the protected plant to develop new varieties in some cases, and to market the new variety that contains the patented gene sequence or trait in all cases.

Key differences between the patent system and the pre-existing system of plant variety rights are the scope and strength of protection:

- Patents cannot be limited to one plant variety, but instead impact a significant number of varieties (i.e. all the varieties containing the patented genetic sequence and/or trait).
- Patents on plants restrict the access of breeders to the genetic diversity contained in other plants (biological material) that they need to develop new varieties.

What are the impacts of patents on plant breeding and agricultural production?



Patents on plants impact the whole food chain

Patents are designed to provide an artificial monopoly to innovators for a limited period of time. Thus, patents considerably increase the **market power** of their holders, in line with their innate goal to provide a competitive advantage to inventive market actors. Such exclusive market power can have even more profound effect in market segments that are already concentrated, such as the seed industry where four multinational companies with foundations in chemicals and biotechnology (Bayer, BASF, Corteva and Syngenta) dominate the market (ETC Group/GRAIN, 2025)[2]. These dominant industry players also control most patents on plants, as (only) they have financial resources necessary to both to apply for patents and to subsequently enforce them. These large players typically use their patents as "bargaining chips" with the other industry giants to ensure they can secure the necessary access to genetic diversity to continue their breeding work. In this way, the patent holders can drive out smaller actors with less financial and human resources to apply for patents, or simply ensure freedom to operate (access to genetic diversity) in their segments.[3]

As a result of patents, small and medium sized **breeders can be blocked out** from markets because they cannot access the traits they need to develop a commercially viable product, e.g. resistance to a specific disease. They may also simply refrain from entering some crop species or discontinue their work due to legal uncertainty or lack of capacity to establish whether the plant material they wish to use in their breeding work is covered by patent protection or not. Considerable

2 www.etcgroup.org/sites/www.etcgroup.org/files/files/top__10__agribusiness__giants.pdf#page=5"

3 See KLOPPENBURG, www.apbrebes.org/sites/default/files/2022-12/Apbrebes__Kloppenburg__OpinionPaper__12-22__fin.pdf, and also HOWARD, *Concentration and Power in the Food System. Who Controls What We Eat?* Revised Edition. London: Bloomsbury Academic, 2021.

investments in **human and financial resources,** whether internal or external, are needed to follow the developments linked to NGT patents, assessing which patents may impact their breeding programs.

By acting as a driver for stronger market concentration, patents can indirectly mean **farmers have less access** to new varieties, especially those operating in lower-input or marginal conditions that the major actors of the seed industry will not cater for due to limited market size, and where smaller sized breeders will not venture due to risk of patent infringement. Further, due to the 'absolute product protection' given to patents, farmers need to show expressly that they have not used the patented invention to prove they have not infringed on a patent. This burden of proof weighs heavy on farmers, especially smaller ones, who do not rely on formal breeding protocols, and may not be able to prove that they did not use the patented material. Also, current rules that extend the powers of the patent to **'native traits'** – those already found in nature, fields, gardens, gene banks or conservation networks – essentially license agricultural production and could severely hamper the circulation of genetic resources for their conservation. The colossal blocking power of patents may limit the choice of consumers at the end of the food chain especially when patent claims reach further into transformed products.

4 Which types of patents are granted on NGT plants?

To whom do they give a competitive advantage?



Under the European Patent Convention (EPC), which provides the legal basis for the work of the European Patent Office (EPO), **all NGT methods are viewed as technical processes and are therefore patentable. Plants developed with NGTs are thus also patentable as they have been developed through a non-essentially biological process.** Due to the rights granted to patent owners by the EPC and the EU Biotech Directive, these monopolies can extend also to the plants developed without using the patented process (either by conventional breeding or any other process), or those which simply bear the same characteristics as the claimed patent, even if it previously occurred in nature, fields, gardens or breeding pools.

In practice, not only patents on NGTs are limiting the rights of farmers and breeders, but also patents on plants breeding using conventional methods. A lack of clarity on what falls under the definition of "essentially biological" (and so is excluded from patentability) in the EPC and EU Biotech directive means that patents are also granted on conventional plants. The 2023[4] and 2025[5] reports of No Patents on Seeds (NPOS) shows how some breeding methods, such as selecting gene variants from existing plant populations or screening for random mutations, are decisive for the grant of patents on plants, with wide claims that can impact the wider food chain.

Types of NGT patents

Different types of patents can and have been granted to innovations linked to agricultural biotechnology by all levels of patent offices:

Process patents protect new and inventive processes that can be used industrially and are not "essentially biological". They require anyone who wishes to use or commercialise the patented process to obtain a license from the patent holder and generally pay royalties for this use. NGT processes are considered to be fully technical processes under patent law, and can therefore be patented when shown that they are new, inventive and capable of industrial application. The patent ex-

4 www.no-patents-on-seeds.org/en/report2023
5 www.no-patents-on-seeds.org/en/report-patents

emption that exists in the EPC thus does not apply if a trait is inserted in a plant or modified in situ via a technical intervention, e.g. "gene scissors"/CRISPR-Cas.

For example, patents can and have been granted on the general precepts of the NGT gene editing technologies, just as their practical implementation to agriculture or a specific crop species, such as a process using Crispr-Cas9 to develop tomato varieties with higher amino acid levels.

Product patents give monopoly rights over the use of new and inventive products that are not the result of an essentially biological process, nor limited to a single plant variety. They require anyone who wishes to use or commercialise the patented product to obtain a license and generally pay royalties for such use. The patent will cover plants or their characteristics, giving very broad prerogatives to patent holders on their use, who can request royalties or even prevent the commercialisation of the same product even when the users have not followed the steps described in the patent application and its claims, having arrived at the same results (such as a variety resistant to a specific disease) through different means.

For example, they can and have been granted on altered DNA sequences that have been clearly identified as infusing certain characteristics to plants (as long as it is not limited to a single plant variety), such as the Japanese tomatoes that contain high amounts of γ-aminobutyric acid (GABA).

Especially in the field of biotechnology, the use of a technical process to develop a product with specific plant properties (such as the use of Crispr-Cas9 to increase starch content in potatoes) is generally put forward by applicants through so called **product-by-process claims**. This means that the monopoly of process patents (biotechnology tools) extends this way to products (plants and their characteristics), requiring anyone who wants to use the plant or its characteristics down the value chain to ask for consent and pay royalties, even if they have not used the patented process directly. Product patents are considered to restrict competition more than process patents, since they do not require explicit use of the patented invention by competitors and do impact products with the same characteristics that could have been obtained through a different process, equally as inventively as the competitor which holds the patent.

Unravelling the tangled NGT patent landscape

There are **numerous claims to rights in various NGT technologies and their applications** in life sciences, animal health and agricultural fields, in multiple patent jurisdictions.

The **foundational patents** concern the initial NGT technology, protecting methods, engineered components that can target genes and achieve specific effects. Formulated rather broadly so as to apply to as many applications of the NGT technology as possible, they will require a license from all users of NGTS, no matter the size or discipline.

Several institutes are battling for ownership of the main Crispr-Cas9 technology: University of Berkeley/University of Vienna/Charpentier on the one hand, and the Broad Institute/MIT on the other. The former seems to have more ground in the European continent, while the picture is different in the United States of America.

Since the entry of the NGT technologies into agricultural biotechnology, the situation has become even more complex, as **another layer of patents linked to a specific application of NGT**, and therefore of actors, has emerged.

Corteva has become an unescapable actor with regards to agricultural applications of Crispr-Cas through its multiple licenses from both Charpentier and Broad, along with its own patent requests on specific applications of NGT technologies, especially Crispr-Cas9, in defined crop species or in the search for specific characteristics relevant to breeding, agricultural production or industrial processes.

Assessing the status quo of the intellectual property rights for each NGT technology is not an easy task, due to changing nature of the patent landscape, and also because one needs to dive deeply into the content of each patent application and granted patent to assess what the invention truly is, and what is covered by the claims.

However, some rough numbers can be compiled through patent database searches, and have been performed in literature and reports (i.e. Testbiotech, 2021)[6]. For example, a search in the WIPO Patentscope in "any field" of patent applications, only in English language, regrouping patent families (so trying to avoid duplicates) gathers 35,000 patents (granted and applied for) in relation to "Crispr" with domination from Pioneer/Corteva (2,000 patents) and Monsanto (1,840). The same search for "Crispr plant" gathers a number of 19,000 patents, with domination from Pioneer/Corteva (2,000 patents) and Monsanto (1,840), followed by Broad Institute and MIT. Searches for "Crispr" and "plant" in the EPO Espacenet for European patents lists 5,600 patents, while 12,000 applications are listed through the Patent Cooperation Treaty. The not-for-profit Lens database 34,000 "Crispr" patents internationally, with 3,400 patent families applied for or granted in Europe, whereas a search for "Crispr plant" lists 19,000 patents internationally, with 1,480 patent families applied for or granted in Europe.

Broad patent claims encroaching on all plant breeding activities

Studies have shown that patent claims that are applied for or have been granted in relation to NGTs are quite wide. Indeed, the claims extend to plants inheriting the gene variants, regardless of whether they are derived from techniques of genetic engineering or not (Testbiotech, 2023), with subsequent impacts on plants obtained through different breeding techniques, whether NGT or not (see No Patents on Seeds!, 2023).[7]

6 www.testbiotech.org/wp-content/uploads/2021/06/Patents_on-new-GE.pdf

7 www.testbiotech.org/wp-content/uploads/2023/07/Testbiotech_-2023-_-CRISPR-Patents.pdf, and www.no-patents-on-seeds.org/en/report2023

5 Solutions to stop patents on plants:

What can be done?



Two proposals have been put forward so far to alleviate the detrimental effects of plant patents on innovation in plant breeding, agricultural production and consumer choice. First, in February 2024, the European Parliament proposed changes on the patentability of NGT processes and plants in the EU Biotech Directive in its position[8] at first reading on the **proposed new EU regulation on NGTs.** Second, the seed industry is promoting voluntary schemes.

Neither of these proposals fully address the problems related to plant patents. Instead, more far-reaching changes are necessary to ensure that breeders can continue to innovate successfully to ensure future food security and to implement right of farmers to seeds, as recognised in Article 19 of the **United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP)**.

The legislative framework

In theory the 1994 **WTO Agreement on Trade related intellectual property rights (TRIPS)** Agreement (Article 27.3) gives states the flexibility to exclude completely plants from patentability. In Europe this flexibility has not been used fully, notably due to the prior existence of the **1973 European patent convention (EPC),** and the subsequent **EU Directive 1998/44 on the legal protection of biotechnological inventions (EU Biotech Directive)**.

The EPC is an international treaty regrouping more countries (39) than the EU, but in which all EU Member States participate. It does not allow the patenting of plant varieties and essentially biological processes, for example crossing and selection, for the production of plants or animals (art. 53b). Plants obtained exclusively through essentially biological processes also cannot be patented[9].

The EU Biotech Directive has transposed into the national legislation of the 27 EU Member States. It has also been incorporated into the Implementing Regulations

8 www.europarl.europa.eu/doceo/document/TA-9-2024-0325_EN.html
9 Decision G3/19 of the Enlarged Board of Appeals of the EPO, May 2020, www.epo.org/en/boards-of-appeal/decisions/g190003ex1.

of the EPC, which provide more detailed guidance to patent examiners than the general provisions of the Convention. It addresses both the question of what is patentable, and which rights are awarded to patent owners, with provisions that considerably expand the reach of the monopoly.

The first and more sustainable solution to withstand the test of time is to **operate changes to the applicable law.** In Europe, this means adapting the EPC and/or the EU Biotech Directive to the needs of plant innovation in agriculture, by making changes to what is actually patentable, and/or what prerogatives accompany patents that have been granted on plant processes, plants themselves, or information (sequences) contained therein.

Some changes have already been adopted in Europe. Firstly, rules on patentability have been further developed through EPO case-law and the adoption of **Rule 28.2 of the EPC Implementing Regulations** that now prohibit the patenting of products obtained exclusively by essentially biological processes. This change closed the loophole created by the practice of not patenting the non-technical breeding process (crossing and selection), but rather the product of such process (such as a genetic sequence or trait). The EPO also attempted to act on the extension of patent protection to 'native traits' by adopting the practice of the **'disclaimer' that is inserted in the patent claims**, which detail (and thus limit) the rights of patent owners. This practice intends to limit the extent of the monopoly so that it does not reach into plant material obtained by crossing or selection, or which already existed in nature. In essence, it is disclaimed that the patent will not bear its effects in certain cases, i. e. when the plant existed in nature beforehand. The intention of the legislator is however tainted by the wide scope of protection given to patents, and the fact that the burden of proof falls with subsequent users who need to show that they have not used the patented invention.

Despite these changes, patents on NGT and techniques used in conventional breeding (especially random mutations) and the resulting plants continue being granted by the EPO.

Proposal by the European Parliament February 2024

More far-reaching changes were proposed by the European Parliament (EP) in its position[10] on the NGT proposal at first reading in February 2024. The amendments adopted by the EP suggest making numerous changes to the EU Biotech Directive both with regards to rules on patentability, and on the scope of protection granted to patents covering NGT plants. To become EU law, there needs to be a compromise between the European Commission, the European Parliament and the Council of Agriculture ministers. As of August 2025, there is still no majority for a compromise on this file. Moreover, such a change of the EU Biotech Directive would need to be followed by the longer and more complex process of changing the EPC as well.



What can be patented (Patentability requirements)?

The EP proposes to **not allow patents on plants obtained by NGTs**, as well as "**NGT process features"** that are found in the plants. It also aims to forbid the granting of **product-by-process claims** (where the use of an NGT technical process opens the door to control over the whole plant and some of its characteristics) should the patented plant not be distinguishable from those existing in nature or obtained only through essentially biological processes, without using the patented process.



What rights do patents give (Scope of protection)?

The EP proposes to limit the scope of all patents on plants, but does not introduce a full breeders' exemption. Breeders would no longer require authorisation from the patent holder or need to pay license fees if they develop (or have developed) a variety with the same characteristics, provided they have not used the patented process and they use essentially biological processes such as crossing or selection (but not exclusively).

In the same spirit, **farmers** who multiply or propagate a variety with the same characteristics as the patent claim but obtained without using the patented process may also do so without authorisation from the patent owner. The EP proposal also aims to redress the issue of 'native traits' that have the same characteristics as the patented plants, but have been present in fields (or gene banks or conservation networks or breeding pools) long before the existence of the patent, which can continue being used and circulated without authorisation from the patent owner. This would apply to both product and process patents in the case the existing plant material cannot be distinguished from the patented one. Since the amendments do not touch on the burden of proof, it still remains the duty of breeders or farmers who wish to use the invention, that they have not done so. Patent holders continue to benefit from what is called 'absolute patent protection'.

10 www.europarl.europa.eu/doceo/document/TA-9-2024-0325_EN.html

Proposal by the Council of EU Agriculture Ministers March 2025

Discussions in the Council of EU Ministers on the NGT file were stalled for many months due to the issue of patents. Surprisingly, contrary to some proposals made by State representatives on this pressing topic during negotiations to reach a consensus, its final mandate agreed upon in March 2025[11] includes only minor transparency measures regarding patents. Companies requesting the release of NGTs must submit a written statement concerning patent claims on the NGT plants. This information is not subject to verification and has only declaratory value. While this statement may slightly improve transparency for breeders and farmers, it will not address the existing power dynamics and monopolisation of the seed sector. The Council further proposes that the Commission conduct a study on the impacts of patents following the entry into force of the NGT regulation. This study is currently being conducted by external contractors, meaning any follow-up actions to mitigate the detrimental socio-economic impacts of widely patented NGT plants will occur long after their deregulation and entry into the EU market.



What can be patented (Patentability requirements)?

The Council does not propose any changes to the patentability. NGTs as well as some conventional plants (e.g. produced by random mutations or including naturally occurring genetic variations) and their products would still be patentable.



What rights do patents give (Scope of protection)?

The Council does not propose changes to the scope of protection. Breeders who want to work with patented NGT processes, plants or products must negotiate a licence with the patent holder. Worse, breeders using essentially biological processes in sectors and crop species where NGTs are likely to develop, will face a higher risk of infringing on patents by developing varieties that incorporate traits featured in patent claims, regardless of whether they have used the patented NGT technology or not. This may discourage their involvement in those sectors and would severely hamper their freedom to operate. Likewise, farmers who are involved in breeding activities, or who multiply or propagate a variety with the same characteristics as those mentioned in a patent claim will continue facing legal uncertainty.

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

Changes on national level

National patent laws in EU countries have two functions:

First, they **set the rules for national patents**, which are only relevant in the respective Member State. Such patents are quite rare in the field of agricultural biotechnology, where most patents are applied for on European level. National patents and applicable national legislation still have an important symbolic value, especially in controversial domains such as patents on plants and animals.

Second, they **implement the EU legislation into national law** and thus show how these rules are interpreted by national experts and policy makers, both at the level of patentability requirements and protection scope. This can also have an effect on the interpretation by European institutions. For example, in the infamous EPO pepper decision G3/19, national laws were quoted as a reference to show how member states interpreted the exception to patentability.

Austria amended its national patent law in 2023 to make clear that the **ban of patents on "essentially biological processes" also entails patents on random mutations and gene variants**[12]. Regarding patentability, such national interpretations only apply to national patents, and beyond that have only symbolic value, as rules on patentability for European patents are established by the EPC and the EU Biotechnology Directive. But on **patent protection scope**, there is a **direct impact**, as "classic" European patents (not Unitary ones) are implemented according to the rights and prerogatives delineated in national patent laws. The EPC is indeed concerned with patentability, merely linking patent protection to the claims listed in the patent and leaving their interpretation to national laws. The importance of national laws will also persist in the new Unitary patent system, where the scope of protection will be determined by the country in which the applicant resides, in line with the minimal provisions of the UPC agreement (which include for instance a limited breeders' exception).

Therefore, legislative or judiciary changes at national level can have **symbolic yet minor impacts** at European legal and political level, but they will not solve the legal uncertainties and loopholes around patents on plants and animals, especially their patentability.

Non-legislative and voluntary approaches

Non-legislative and voluntary approaches do not address the core issues of patentability, nor the scope of patent protection, but focus on providing **facilitated or less complex access to patented technology, whether products or processes**. These solutions may in some cases mitigate some of the negative effects of overlapping and extensive patents by providing easier access to the patented material

12 www.ris.bka.gv.at/eli/bgbl/I/2023/51

or process, but they do not tackle the underlying problem of plant patents. They also fail to provide comprehensive, legal certainty to breeders and farmers, as not all patent holders will participate and the rules can change at any time.

Some schemes focus on **easing the access to patented inventions.** *Patent pools* are collaborative patent licensing models where multiple patent holders put together their titles, designing a 'one-stop-shop' to obtain a license for the use of all inventions that have been pooled. To be efficient, they require the participation of the main actors of the patent landscape, which is quite difficult to foresee in the case of NGTs due to the legal battles that have already shaken the field. *Licensing platforms* are similar, yet more flexible structures where the license negotiation aspect is taken out of the equation for those who wish to use the patented invention. Despite their efforts, these approaches remain out of reach for smaller operators such as farmer-breeders who engage in participatory breeding programmes, as they require the existence of human and financial resources to engage in these legal and administrative processes.

In addition, nothing prevents patent holders from **forfeiting to enforce the rights and prerogatives that accompany a patent for certain types of uses.** (For example, the Dutch Wageningen University allows for non-commercial research for all their Crispr-Cas9 patents without royalty payments or prior authorisation.) Such a solution was presented to EU Member States by the Belgian Presidency in early 2024 in an attempt to solve the disagreement on patents on NGT plants. Without questioning the existence of patents or the requirements to be met to obtain a monopoly, the proposal simply conditioned the grant of NGT1 plant status only if and when existing patents on the plants would not be enforced.

None of these solutions will address the problem at its core, which remains the patentability of plants and the extended prerogatives that accompany patents. However, changes to the rules on patentability at the level of the EU Biotech Directive and the EPC would be necessary. These changes require a revision of the EPC text itself, through the convening of an international conference with the presence of at least three quarters of the 39 signatory States to the EPC, with a three-quarter voting majority of present States (art. 172 EPC). If only the interpretation of the EPC is changed (e.g. only banning patents on random mutations), the Implementing Regulations can be changed with a three-quarter majority, provided at least a majority of the 39 States are present (art. 33 (1) c EPC). If the EPC is brought in line with EU legislation following an amendment of the EU Biotech Directive, unanimity is required at the EPO Administrative Council, both in presence and voting (art. 35 EPC). However, since the scope of patent protection is not defined in detail in the EPC, EU institutions and its Member States can act on this level independently of the EPO. At EU level, this would require a proposal from the European Commission and adoption by the EU Council and Parliament, following respective law-making procedures. The current legislative process on the proposed new EU regulation on NGTs can be used to achieve this, followed by a change of the UPC. These lengthy processes could easily take a decade to be adopted and bear their fruits.

Additional challenges related to plant patents outside of the world of NGTs are the current reach of patents into the world of conventional breeding through the EPO interpretation of the notion of "technical process" that opens the doors of patentability, and the issue of retroactivity. These problems must be urgently solved, as they are blocking organic and conventional GMO-free breeding. Any solution drawn up with regards to NGT patents, especially regulatory ones, will also face the ghost of existing patents granted in accordance with past rules, which will continue to be enforceable.

6 ARCHE NOAH Conclusions

Which changes are needed?



Long-term: Overhaul of patent laws needed

ARCHE NOAH recommends a full overhaul of the European patent legislation to exclude patents on all seeds/plants, as well as the genetic information contained therein. This will be a complex and lengthy process requiring revisions of the EU Biotech Directive and EPC, but is necessary to once and for all put an end to legal loopholes that can be exploited by resource-rich seed giants and patent lawyers to gain monopoly rights over the plants and seeds that are the starting point for our food security.

Short-term: Stop patents on conventional breeding

In the interim, urgent action should be taken at the level of the EPC Implementing Regulations and the EU Biotech Directive to ensure (i) a full and effective implementation of the exclusion from patentability of all seeds and plants derived from essentially biological processes and all products there of, (ii) limitations of the scope of patents granted on NGTs/GMOs, and (iii) applying fair proportionate rules on the burden of proof – so that breeders, farmers, and food processors who do not work with NGTs have the freedom to operate and to innovate without concerns of patent infringement. This is necessary to ensure that conventional breeders do not fall under patent protection, which was the intention of the European patent laws.

As a transition measure, consider using systems such as patent pools and clearing-house mechanisms solely to provide easier access to methods and/or material that have already been patented (not to create legal certainty, which should be provided through the law itself). These should be mandatory and accessible for all users, going beyond the provision of transparency and information on existing patents.

Patents on Seeds – The Legal Framework

Annex 1



At international level

1970 Patent Cooperation Treaty (PCT)
One of the earliest treaties of international IP law, the PCT is in its essence a **treaty focusing on procedure, and aims to facilitate the granting of patents[13] in different patent offices** of the world. It helps patent applicants by allowing them to file an international PCT request for an application in any participating patent office. This triggers an international search for prior art and will often generate non-binding "PCT patentability information" that is communicated to applicants and other PCT patent offices. Applicants may then choose the countries where they want to pursue protection, following the national patent pathway (with all applicable fees and translations) for each country where they want to enforce their patent, with extended deadlines and other procedural benefits. It is **not an automatic recognition of a patent granted in another PCT jurisdiction**, yet filing a PCT application buys applicants **significant time** as it extends the deadline to apply for national patents to 30 months instead of 12 months after the priority date.

With 157 signatory States, the PCT is also the IP treaty with the widest geographical scope and is managed by the World Intellectual Property Organization (WIPO), although PCT patents are always granted by national patent offices, or regional ones such as in Europe (EPO) or Africa (ARIPO).

Patentability requirements?
None, the PCT does not regulate conditions of patentability, so it does not decide if and under which conditions patents on plants can exist or not. It eases the burden of regional or national patent offices by providing them with a *preliminary patentability assessment and prior art search* done by the patent office where the PCT application is made. All assessments will continue to be done by each competent patent office according to national (or regional) law.

13 www.wipo.int/en/web/pct-system/texts/articles/atoc



Scope of patent protection
None, patents are granted with the rights and prerogatives established in national or regional legislation

1973 European Patent Convention (EPC)
Adopted as early as in 1973, the European Patent Convention ("EPC") is an international Treaty that binds 39 countries (including but not limited to all EU Member States[14]) and is managed by the European Patent Office ("EPO"), which grants European patents in line with the EPC rules. Together with its Implementing Regulations, which are regularly updated by participating States to adjust to legislative changes[15] (such as the inclusion of the EU Directive 98/44 on the protection of biotechnological inventions into Part II, Chapter V of the EPC Implementing Regulations)[16] or to adjust to judiciary decisions (such as the landmark broccoli and tomato cases G 2/12, 2/13 and 3/19), the EPC contains all rules to be followed by the EPO. The EPC is based on the fundamental principle of a general entitlement to patent protection for any invention in all technical fields (art. 52§1).



Patentability requirements
European patents are granted for any inventions in all technology fields, provided they are new, involve an inventive step and are susceptible to industrial application (EPC, art. 52.1) They cannot be granted for scientific discoveries.

The EPC Implementing Regulations mirror the provisions of the EU Biotech Directive 98\44 that will be detailed further below. Especially, the new rules 28(2) clarifies that plants and animals obtained exclusively through essentially biological processes cannot be patented.

The EPO still considers only plants and animals derived from crossing and selection as not patentable, while treating processes that concern the selection without crossing or random mutations as patentable inventions.

Exceptions to patentability?
European patents cannot be granted for individual plant or animal varieties or essentially biological processes for the production of plants or animals (but they are granted to microbiological processes or their products). There is however no clear definition of what essentially biological processes are in the text of the Convention.

14 www.epo.org/law-practice/legal-texts/epc.html
15 https://new.epo.org/en/legal/epc/2020/regulations.html
16 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044



Scope of patent protection
European patents granted by EPO give the *same rights that would be conferred by a national patent* granted in that State. The true extent of the patent powers will be determined by the *claims* made by the applicant, as amended by the EPO and its examiners (art.69).

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 (art. 64 EPC)*.

Exceptions to scope?
None are formally included in the EPC text, which is more concerned with what is patentable and how European patents are granted. This leaves a lot of margin to its signatory states to determine the extent of prerogatives attached to a European patent in their national laws.

1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) adopted in 1994 has set out the **minimum standards** for intellectual property (IP) protection in countries that are members of the World Trade Organisation (WTO)[17]. Building on the practice of the main patent offices around the globe and the needs of central players of international trade, the TRIPS Agreement has imposed the **general principle of patentability of all technical inventions,** whether products or processes, no matter their contextual applications, which already existed in the EPC, to the vast majority of the globe. The TRIPS Agreement nonetheless allows States to **adopt a general exception to not allow patents on plants or animals, or on the smaller segment of essentially biological processes, provided there is an efficient system to protect plant varieties**. While affirming the main prerogatives that States need to attach to product or process patents in general, the TRIPS Agreement accepts that they provide exceptions to these prerogatives, which need to be reasonable and not conflict or cause prejudice to patent rights, just as those mentioned in the EPC.



Patentability requirements

New inventions in all fields of technology, which involve an inventive step and are capable of industrial application

Article 27 of TRIPS states that "*patents shall be available for any inventions, whether products or processes, in all fields of technology, as a rule of thumb*"

Exceptions to patentability

Art. 27 paragraph 3 allows States to exclude "*plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes*"

The only obligations for countries that want to limit patents on plant is to provide protection to plant varieties, either through patents or an effective 'sui generis' plant variety protection system (like the UPOV Convention system adopted in the EU, or another effective system).

17 www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm



Scope of patent protection

Product patents shall at minima give their owners the right to prevent third parties not having the owner's consent from the acts of: *making, using, offering for sale, selling, or importing the product* for these purposes (art. 28§1)

Process patents shall at minima give their owners the right to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes *at least the product obtained directly by that process* (art. 28§2)

Exceptions to scope

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do *not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner,* taking account of the legitimate interests of third parties.



What happens if a country violates TRIPS?

WTO Dispute Settlement Body competent to oversee cases of violation of the TRIPS Agreement by a country. Complaint by another WTO member.

To this day, only 44 consultations have been launched (only 2 are active, both involving China), and none have touched upon patentability requirements or their exceptions. **The TRIPS Agreement provisions are nonetheless clear: patents on plants can definitely be completely prohibited, as long as plant varieties are protected in an efficient manner.**

At EU level

EU Biotech Directive

The European Union (EU) and its Member States have enacted additional legislation implementing and complementing the TRIPS Agreement and the EPC. The most prominent tool in that respect is the EU Directive 98/44 on the protection of biotechnological inventions[18], which addresses both patentability and protection scope issues.



Patentability requirements

New inventions, which involve an inventive step and are susceptible of industrial application if they concern *a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used* (art. 3§1).

Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention, even if it previously occurred in nature (art. 3§2).

This means that patents on plants are absolutely not prohibited in the EU, rather they must be granted by patent offices even if the invention can be found in fields, gardens, gene banks or breeders' gene pools.

Exceptions to patentability

Plant and animal varieties (patents can only be granted if the invention is not confined to a single variety, but apply throughout different varieties). **Essentially biological processes** cannot be patented either as well as their products, as shown by an Interpretative notice published by the European Commission in 2017.



Scope of patent protection is defined in great detail in the Directive

Patents on **products** that contain or consist of genetic information give control over *all material where the product is incorporated, containing the genetic information,* and where it *performs its function* (art. 9)

Patents on **processes** to produce biological material or processes that give certain characteristics to biological material (such as disease resistance) give control over

- the use of *material produced with the patented process* (product-by-process protection), and

18 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044



- the use of *material "derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics"* (art. 8§2). The last half of the sentence goes further than what is required by TRIPS.

Exceptions to scope

A **limited farmers' privilege,** mirroring the provisions of EC Regulation 2100/94 on the Community Plant Variety Protection regime, is included in the Directive. This means that, under conditions to be determined by national law, farmers who have bought seeds or plants from the patent holder (or its licensee), may multiply and propagate biological material containing the patented invention without asking for consent once again, or paying full priced royalties.



What happens if a country violates the EU Biotech Directive?

The consequences of non-compliance of an EU Member State (in its national patent law or in the practice of its national patent office) are dealt with in the founding Treaties of the European Union. Both the European Commission and European Court of Justice have key roles to play in this context.

EU Unitary Patent System

The Unitary Patent System comprises a set of different legal instruments: one international convention to be ratified by EU states (the 2013 Agreement on a Unified Patent Court)[19], and two EU Regulations that apply following such ratification (Regulation 1257/2012 creating the unitary patent[20], and Regulation 1260/2012 which deals with the language regime of the system[21]).



Patentability requirements

The UPC system is not concerned with patentability, as it only deals with the issues of national validation of European patents granted by the EPO, their scope of protection and potential litigation.

Patentability rules, including exceptions (essentially biological processes and their products) continue to follow the rules of the EPC and the EU Biotech Directive**.**



Scope of patent protection; slightly different rights for patent holders?

The general principles of absolute patent protection are not changed by the UPC system and most of the rights given to patent holders by the EU Biotech Directive and national patent laws remain applicable. These can still prevent the direct and indirect uses of the invention by third parties during the time of the monopoly.

However, **limited breeders and farmers' exception,** has been adopted in the UPC system in article 27 of the UPC Agreement, which limits the effects of the patent. The use of the plant (and its patented characteristics) for **breeding, discovering and developing varieties** is permitted without the consent of the patent holder. However, the **commercialization of a new variety does not completely fall under the exception,** and should the patented genetic sequence still be found in the new variety, royalties will be due. In a similar vein, the use of the plants by farmers will not require authorisation if they are the product of their own harvest and they are propagating on their own farm. This possibility may still require the payment of royalties in certain conditions, mirroring the approach of plant variety protection rules in the EU.

19 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2013_175_R_0001_01
20 https://eur-lex.europa.eu/eli/reg/2012/1257/oj/eng
21 https://eur-lex.europa.eu/eli/reg/2012/1260/oj/eng

European Parliament position on NGT patents and suggested changes to the EU Biotech Directive



Patentability requirements

'*NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable*'

"*Plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.*" (Changes suggested to article 4 of the EU Biotech Directive by the EP on COM proposal on NGTs)

"*By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.*" (Changes suggested by the EP to article 8 of the EU Biotech Directive)[22]



Scope of patent protection

"*2. By way of derogation from paragraphs 1 and 2, the protection conferred by a* ***patent on a biological material*** *possessing specific characteristics as a result of the invention shall not extend to biological material possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such material through propagation or multiplication.*" (Changes suggested by the EP to article 8 of the EU Biotech Directive)

"*3. By way of derogation from paragraph 1, the protection conferred by a* ***patent on a product*** *containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.*

4. *The protection conferred by a* ***patent on a technical process*** *that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.*"
(Changes suggested by the EP to article 9 of the EU Biotech Directive)

22 www.europarl.europa.eu/doceo/document/TA-9-2024-0325_EN.html



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