The ban on patenting of NGT plants?

On February 7, 2024 the European Parliament voted on the first reading in favor of the proposal for a regulation on plants obtained by certain new genomic techniques (NGT) and their food and feed. This method involves breeding plants by introducing specific changes to the DNA; in many cases it does not require the use of foreign genetic material from species that cannot interbreed naturally. NGTs exhibit numerous scientifically proven benefits: unlike classic techniques such as seed selection and crossbreeding, they allow for faster, more targeted, and precise results.

What is particularly important, it is currently possible in the EU to obtain a patent for NGT plants — the draft regulation, which has been sent for further legislative work, excludes this possibility. In this Legal Report, we look at the proposals for new EU rules and consider the consequences that their implementation may entail.

The context: the initiative of the European Commission

In July 2023, the European Commission (EC) presented a new proposal of a regulation on plants produced by certain new genomic techniques. **The critical aspect of the proposal is the recognition of two categories of NGT plants: NGT plants that are considered equivalent to naturally occuring or conventional plants and other NGT plants with more complex modifications. Different legal regimes would apply to placing plants of particular categories on the market.** In the case of NGT plants equivalent to naturally occurring or conventional plants, they would only be subject to a notification requirement. Plants in the second category will remain sub-

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ject to the stricter process set out in Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. So far, the strict regime for GMOs has been uniformly applied to all NGT plants. It shall be noted that despite the relaxation of the requirements for placing the first group of NGT plants on the market, these plants would still be prohibited in organic production, and their seeds would have to be clearly labeled.

Undoubtedly, the EC's motivations in developing this project are reasonable. NGTs used in plant cultivation allow the development of plants that are more resistant to extreme climatic conditions or require less fertilizers and pesticides. Facilitating the placing on the market of plants obtained by this method could actually contribute to improving the sustainability of the EU's food supply (reducing the EU's dependence on agricultural imports). The EC project on NGT plants should be seen as part of a wider package of measures being developed under the European Green Deal for a more sustainable use of natural resources (see: here).

What is especially noteworthy is that **the original proposal of the regulation did not provide for the ban on patenting of NGT plants.**

The current state of law

The provisions of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions in their current shape **do not prohibit patenting of NGT plants.** Art. 3 of the Directive specifies how the patentability shall be understood for its purposes: the criteria of novelty, inventive step, and industrial application are listed. They can be fulfilled even if the invention concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material is defined as “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system”.

The patentability is ruled out in the case of plant and animal varieties, and essentially biological processes for the production of plants and animals (Art. 4(1)). Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety (Art. 4(2)). **It should be emphasized that NGT plants are not included in the exclusions.**

In the preamble of the Directive it is underscored that when it comes to the protection of biotechnological inventions, “the rules of national patent law remain the essential basis for [their] legal protection”. The purpose of this instrument was predominantly harmonization so as to “take adequate account of technological developments involving biological material which also fulfil the requirements for patentability” (recital 8). Furthermore, the Directive was aimed at clarifying uncertainty regarding the protection of biotechnological and certain microbiological inventions that has

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been created by certain national laws based upon international patent and plant variety conventions (recital 9). The drafters of the Directive were aware that "the patent system should be used to encourage research" (recital 10). **It appears that this time the members of the European Parliament adopted a drastically different (and wrong) perspective, according to which patents lead to restrictions on innovation.**

What is in the EP's proposal of the Regulation

New items have been added by the European Parliament to Article 4 addressing the exclusions from patentability:

> "c) **NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) …/…**
>
> d) 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."

The second items includes thus a reference to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Annex I B to said Directive excludes from the scope of its application mutagenesis and cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding method (on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of those techniques/methods).

In other words, **in the new state of law NGT plants and those obtained using plant cell mutagenesis and fusion techniques are not subject to patenting.**

At the same time, some changes are being proposed to the provisions of the Directive that define the scope of protection. In Art. 8, paragraph 3 is being added, according to which 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. Art. 9, in its new wording, provides that 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 (para. 2). Moreover, 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 incorpo-

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rated 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 (para. 3). The same applies to protection conferred on a technical process that enables the production of such a product (para. 4).

The justification presented by the EP

What was the EP's rationale behind introducing the ban on patenting all NGT plants, as well as those obtained using mutagenesis and plant cell fusion techniques? The press release mentions briefly **the need to avoid legal uncertainties, increased costs and new dependencies for farmers and breeders.**

The elaboration of this justification can be found in the proposed preamble as amended by the EP. The newly added recital 1a provides that the lack of such a ban would strengthen multinational seed companies. We can read that in a situation **"where large companies already have a monopoly on seeds and increasingly control natural resources, this would deprive farmers of all freedom of action by making them dependent on private companies".**

Recital 45a underscores that **it is necessary to ensure that patents do not restrict the use of NGT plants by breeders and farmers.** It is indicated that the Community Plant Variety Rights (CPVR) system that is already in place provides for the sufficient protection of inventors (see: Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights). The proposal mentions that in order to avoid a scenario where patents are being granted or patent applications are being submitted between the date of the entry into force of the Regulation and its application, **the plant material shall be excluded from patentability from day one —** the day of the Regulation's entry into force. What is more, in the case of patents already granted and the patent applications already submitted, the need for their further limitation is suggested. **The EC is called upon to carry out a study on patenting plant material that would lead to the proposal of further necessary adjustments.** The adjustments in questions, not thoroughly addressed, would serve to strengthen the position of breeders, farmers (increasing the availability of material for plant reproduction, seed diversity, ensuring affordable prices) and small and medium-sized enterprises (supporting their innovation). Art. 30(5a) of the proposed Regulation obligates the EC to submit such a report by June 2025.

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Controversies regarding the proposed direction of changes

A number of doubts may arise in the context of the discussed draft regulation that the EP has voted in favor of. Organizations associating IP professionals have raised several objections to the planned solutions. Among others, epi (Institute of Professional Representatives before the European Patent Office) even before the vote called on the EP to reconsider the project and return to the EC's original proposal, which did not provide for a patent ban. In this context, we especially encourage you to read the position paper by the AIPPI (International Association for the Protection of Intellectual Property), which is very critical of the proposed regulation.

First of all, the AIPPI's position paper states that **a total ban on patenting NGT plants will negatively impact innovation in this sector.** At the same time, it will certainly not solve the problem of monopolies of large agricultural corporations. The paper states that the EP acted under a misconception that patents are instruments used by international corporations to expand their spheres of influence, which harms small and medium-sized enterprises and harms the general interest. Meanwhile, it is quite the opposite, because a properly constructed patent system supports innovation and encourages the widespread sharing of research results, in return offering the inventor a limited period of exclusivity. Moreover, such a system enables the cooperation of interested actors through licensing and cross-licensing mechanisms. Innovation developed in this way contributes to increased productivity and competitiveness, and what is more, it promotes the realization of sustainable development goals. Without a properly functioning patent system in the EU, entities undertaking innovative activities will migrate outside Europe, looking for places where such activities will bring greater benefits.

Another erroneous assumption that the EP was guided by is the belief that inventors are sufficiently protected under the CPVR. However, as AIPPI has rightly pointed out, Community plant variety rights do not provide protection for technical results and, unlike patents, do not provide any incentive to share research results with the public.

Furthermore, under Art. 5(4) of the Treaty on European Union, "the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties". An important objection raised in AIPPI's position is **the lack of proportionality of the patent ban.** It is difficult to disagree that the interests of farmers and breeders are already largely protected by regulations providing for a general research exemption or a breeder's exemption ensuring the ability to freely use protected varieties, without the obligation to obtain the consent of the breeder of a given variety. Moreover, the freedom of action of farmers and breeders is extended by Art. 28(3) of the Implementing Regulations to the European Patent Convention (EPC), according to which European patents are not granted for plants or animals exclusively obtained by means of an essentially biological process.

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An additional problem is posed by the regulation's temporal scope of application. From the moment it enters into force, provisions prohibiting the patenting of NGT plants will come into force, which — as AIPPI has correctly noted — will lead to a situation in which the rights from patents already granted will be largely unenforceable. It is questionable how such a limitation can be reconciled with one of the general principles of EU law, i.e. the principle of the protection of acquired rights.

What is next for the project?

Of course, this is only an early stage of the legislative process. The European Parliament will no longer deal with this project during this term, but work is still ongoing in the Council of the European Union, where Belgium currently holds the presidency. As of this moment, the text of the act that is in development contains the solution that involes a ban on patenting NGT plants of the first category (the second category would remain covered by more stringent regulations regarding GMOs). According to experts, it is quite probable that such a proposal will gain the required qualified majority in the Council. It is worth emphasizing here, however, that **it remains absolutely necessary to develop any solutions in this area in dialogue with all stakeholders, not only representatives of farmers and breeders, in order to gain a full understanding of the consequences of introducing a ban on patenting NGT plants.**

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