



27.02.2024

epi Position Paper on New Genomic Technique (NGT) Plant Patenting Proposal of the European Parliament

About epi

The Institute of Professional Representatives before the European Patent Office (**epi**) is the professional body representing all European Patent Attorneys. Currently the Institute has about 14,000 European Patent Attorneys as members coming from all the 39 Contracting States of the European Patent Convention and who work either in industry or in private practice. European Patent Attorneys help their clients and employers, which include multinational corporations, SMEs and private inventors, to create value from their inventive ideas, thus providing jobs and strengthening the European economy.

epi as an organisation deals primarily with the development and implications of patent law. **epi** is at the forefront of patent law developments and regularly serves public policy leaders by issuing legal opinions and highly specialised advice.

Executive Summary

The Court of Justice of the EU (CJEU) clarified that plants derived from new mutagenesis techniques such as gene editing fall within the scope of the current EU GMO legislation¹. To address and change that situation and as part of its “farm-to-fork” strategy, the European Commission has now proposed a regulation on plants obtained by certain new genomic techniques (NGTs) with the aim to create a special class of plants which can be released and used in farming within the EU under less strict conditions than the GMO legislation². On 7 February 2024, the Members of the European Parliament (MEPs) adopted a proposal³ of the Committee on Environment, Public Health and Food Safety (ENVI) to amend the draft Regulation from the European Commission that had been intended to foster the development of plants obtained by New Genomic Techniques⁴ (NGT Plants) in Europe.

¹ C-528/16 of 25. July 2018.

² Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, COM(2023) 411 final

³ P9_TA(2024)0067.

⁴ Plants obtained through targeted mutagenesis and cisgenesis.

The amendments include a broad new exclusion from patentability for such NGT plants and also plants obtained through classical mutagenesis or cell fusion, as well as “*plant material, parts thereof, genetic information and process features they contain*”.

epi would recommend **to not include any patentability exclusion in the proposed regulation on NGT plants** and has the following remarks on this proposal:

- The impact of a patent ban on innovation in this highly innovative sector cannot be underestimated as the patent system ensures the disclosure of innovations to the public and allows a return on investment in development of new products.
- The Plant Variety Protection (PVP) system⁵ is not a proper substitute for patent protection of NGT traits.
- A broad ban on plant patents will be counterproductive and lead to a lack of innovation in the development of much needed plant traits that can counter some of the issues Europe is facing now and will be facing in the future regarding productivity, sustainability and climate change.
- The extent of proposed patent ban is both disproportionate (in view of existing legislation and industry initiatives) and vague concerning the extent of what is to be excluded from patentability or restricted in scope of protection.
- The proposed patent ban would also impact on non-EU member states of the EPC which are not part of the current legislative process.
- **epi** furthermore questions whether the proposed patent ban is compatible with the obligations of WTO members under the TRIPS Agreement.
- **epi** is very concerned that a broad patenting exclusion is proposed without any systematic impact assessment and a detailed discussion with stakeholders.
- **epi** expressly endorses the proposal by the Commission to compile a much-needed fact-based study into NGTs and the potential impact of patent protection before any legislative steps are taken that will significantly curtail intellectual property rights in this field.

⁵ E.g. by Council Regulation (EC) 2100/94 of 27 July 1994 or under corresponding national law.

Background

On 7 February 2024, the Members of the European Parliament (MEPs), in a first plenary reading, adopted a proposal⁶ of the Committee on Environment, Public Health and Food Safety (ENVI) to amend the draft Regulation from the European Commission that had been intended to foster the development of plants obtained by New Genomic Techniques (NGT Plants) in Europe⁷.

Several of the proposed amendments are aimed at excluding from patentability all NGT plants (i.e. plants obtained by targeted mutagenesis and cisgenesis), but also plants obtained by classical mutagenesis or cell fusion, as well as *“plant parts and plant material thereof, genetic information and process features such plants contain”*.

Furthermore, amendments are proposed that would limit the scope of protection (including for existing patents covering plant-related subject matter) afforded by patents on products containing or consisting of genetic information or by patents on technical processes that enable the production of a product containing or consisting of genetic material. Currently, such protection extends to material in which the product is incorporated and in which the genetic information is contained and performs its function, as well as to biological material obtained through propagation or multiplication. The amendments would exclude from protection *“plant material which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process”*.

The patentability ban and restriction of scope of protection would be achieved by including in the proposed Regulation two Articles (Article 4a⁸ and Art 33a⁹) amending Articles 4, 8 and 9 of Biotech Patent Directive 98/44/EC. The patentability exclusion in these proposed amended articles would apply from the date of entry into force of the proposed NGT Plant Regulation (amendment 70¹⁰).

As justification for the proposed ban on patenting plants and further restrictions on the scope of protection for plant-related patents, the document refers to the risk that *“allowing for new genomic techniques and their results to be patented risks [gives] multinational seed companies even more power over farmers’ access to seeds”* and would *“deprive farmers of all freedom of action by making them dependent on private companies”*¹¹ and that *“it should be ensured that breeders have full access to the genetic material of NGT plants”*¹². To secure the full breeder’s exemption *“NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation*

⁶ P9_TA(2024)0067.

⁷ COM(2023) 411 final.

⁸ Amendment 33 - Proposal for a New Article 4a Exclusion from patentability.

⁹ Amendment 69 - Proposal for a New Article 33a Amendments to Directive 98/44/EC1a.

¹⁰ Amendment 70 to Art 34 -paragraph 2- subparagraph 1.

¹¹ Amendment 167 - Proposal for a New Recital 1a.

¹² Amendment 23 - Proposal for a New Recital 45a.



(EC) No 2100/94, which allows the use of the breeder's exemption ... For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited"¹³.

Following the 7 February 2024 vote on the draft legislation, the matter was referred back for inter-institutional negotiations and the European Parliament now has to start the trilogue with EU member states in the Council and the European Commission on the final law.

Position

As **epi**, we are particularly concerned about these developments.

Biotechnology has been identified as a key technology with significant potential to boost Europe's competitiveness with innovative solutions that also contribute to the EU's sustainability ambitions. NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal and of the 'Farm to Fork', Biodiversity and Adaptation to Climate Change, Strategies to global food security, the Bioeconomy Strategy and to the Union's strategic autonomy.

Europe has always been a pioneer in biotechnology, particularly agriculture-related biotechnology, and the protection of inventions through intellectual property is essential for the survival of many Europe-based innovative companies, spin-offs, SMEs and research institutes active in this sector in a highly competitive global setting.

The impact of a patent ban in this highly innovative sector at this stage cannot be estimated and has in our view the potential to seriously damage Europe's innovation power in this crucial area.

The patent system ensures the disclosure of innovations to the public and allows a return on investment in development of new products.

New technologies such as gene editing and NGTs offer new opportunities. However, they require significant investments. Conditions for commercial access to the foundational patents related to these technologies (often in the hands of academic institutions) include payment of substantial fees on the path towards commercialization. Furthermore, the creation of NGT based traits will require considerable investments in R&D, regulatory compliance and market acceptance. The ability to adequately protect newly created traits with patents is therefore in our view an essential component to secure sustainable investments in the breeding of innovative crops.

Contrary to the common misconception, also expressed in the adopted proposal, that patents are only used by large multinationals to create monopolies to the detriment of SMEs, farmers and the public, patent protection plays an essential role in the cycle of innovation and investment, especially

¹³ Amendment 23 - Proposal for a New Recital 45a.

for the smaller players such as spin-offs, SMEs and research institutes. In exchange for a complete disclosure of technical contributions, the innovator is awarded a time-limited period of exclusivity, after which those contributions enter the public domain and are then free for all to be used. The patent system encourages full and early public disclosure of innovations that could otherwise be kept secret. Patents thus fundamentally allow for important technologies to be made available for the public, in the form of both innovative products brought to market and the contribution to public knowledge that persists in public domain once the respective patents expire. Many inventions may have never been developed in the first place, nor brought to market, had it not been for the temporary exclusivity granted to the original innovators. In other words, in exchange for a brief period of exclusivity, society is granted access to essential technology that may never have existed had it not been for the possibility of temporary patent protection.

PVP is not a proper substitute for patent protection of NGT traits

The proposal, as adopted by the EU Parliament, boldly states that *“NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder’s exemption”* (new recital 45a).

PVP rights, however, only protect specific plant varieties, i.e. a given specific assembly of genetic make-up, including traits, in a single species. A PVP certificate grants the right to exclusively commercialize the protected variety. But PVP rights do not separately protect the genomic modifications leading to the traits within the protected varieties. Through the breeder’s exemption associated with the PVP legislation, breeders can use any commercial variety comprising one or more genomic modifications brought to the market (even when protected by a PVP certificate) for further crossing with their own varieties to introduce these genomic modifications and develop new varieties that contain the NGT-based traits of the original PVP protected variety. The breeder’s exemption allows free commercialization of the newly developed variety without any consideration for the holder of the PVP on the originator variety (save a few exceptions). Once a variety containing a newly developed NGT-trait is marketed, this trait would become available through straightforward introgression breeding for anyone, without compensation for the innovator. PVP rights also do not provide protection against copying innovations on traits by independently recreating mutations linked to a desirable trait. Therefore, NGT-based plant traits (that can be used in many different plant varieties) cannot be effectively protected by the PVP system. Only a generic protection of the newly developed genomic modification leading to a given trait through invention patents, independent from the variety protection, can ensure adequate return on investment.

A ban on plant patents will be counterproductive

A patentability ban would hamper further developments specific to agricultural conditions in Europe, as there would be no adequate compensation for the efforts and investments made. Plant breeding is a highly regional business. For example, seeds produced in the mid-west of the US are often not

well-suited for Europe or Latin America. Should there be no adequate patent protection, it is hard to see who would develop and work on specific regional solutions for Europe using these new techniques. This will lead to a lack of innovation in much-needed traits that can counter some of the issues Europe is now and will in the future be facing regarding productivity, sustainability and climate change. The objectives of the European Green Deal and “Farm to Fork” Strategy that are in part relying on the development of new (NGT) traits hence risk being totally missed.

The extent of proposed patent ban is both disproportionate and vague

The proposal as amended by the EU Parliament refers to exclusion from patentability not only for the NGT plants themselves but also to *“plant parts and plant material thereof, genetic information and process features such plants contain”*.

The term *“genetic information ... such plants contain”* could potentially encompass the complete genomic information of the envisaged plants, which obviously goes well beyond the intended scope of the NGT regulation as well as the gist of the current EU Biotech Directive 98/44/EC.

Also the term *“process features such plants contain”* is totally unclear and lacks any definition in the proposal. Is it intended to exclude from patentability the methods and tools used, such as CRISPR/Cas proteins or TALENs and the like when applied to plants? This potentially endangers the patentability of a whole field of genome editing technology and goes well beyond the ambit and the original objective of a Regulation on NGT plants. A clarification is thus urgently suggested by **epi** to avoid misinterpretations when applying the ultimate Regulation as part of European Union’s secondary law.

Furthermore, the proposal additionally suggests amending Articles 8 and 9 of the EU Biotech Directive 98/44/EC. Article 8 is proposed to be amended to exclude from the scope of protection all *“biological material”* (i.e. not limited to plants, but also eukaryotic cells, viruses, micro-organisms, etc.) *“obtained independently of the patented biological material and from essentially biological processes”*. The proposed amendment to Article 9 aims at limiting the scope of protection afforded by the EU Biotech Directive 98/44/EC to a patent on a biological material containing genetic information or to a patent on a process for such product to be produced as extending to biological material derived therefrom through propagation or multiplication, by excluding from such protection plant material obtained or which can be obtained by an essentially biological process.

It should be noted that, contrary to Rule 28(2) of the European Patent Convention, these exclusions do not refer to **“exclusively** obtained by essentially biological processes”. As such, it can be questioned whether these exclusions from the scope of protection would also apply to the progeny of plant material which would remain patentable (e.g. transgenic plants) obtained through crossing and selection.

Finally, the ban on patentability is disproportionately broad in that it would ban patents not only for NGT plants but also for plants obtained through (classical) mutagenesis and cell fusion, whose regulation is not at all affected by the current draft NGT plant regulation.

The proposed patent ban seems disproportionate to the perceived concerns of farmers and breeders organisations, which are already largely addressed by existing mechanisms that have been carefully crafted in view of those concerns and with proper consultation with the full range of stakeholders.

Specifically, farmers and breeders enjoy a general research exemption in EU patent law. In addition, breeders' exemptions are implemented by many EU Member States and the recently implemented Unified Patent Court Agreement introduced a breeder's exemption for patents¹⁴.

Furthermore, under the current EU Biotech Directive 98/44/EC, farmers are already entitled to save seeds under the same conditions as for plant variety protection.

It should also be noted that the EPC already excludes from patentability plants or plant material if the claimed product is exclusively obtained by means of an "essentially biological process", as well as excluding from patentability essentially biological processes as such¹⁵.

Apart from these legislative measures, several voluntary initiatives have been launched over the last years across the crop sector, intending to address concerns raised by some stakeholders with regards to access to genetic material, particularly by small market participants, and to facilitate access to patented materials.

Impact on non-EU member states of the EPC

Since the EU Biotech Directive 98/44/EC is explicitly referred to in the European Patent Convention (EPC), these changes could also affect non-EU member states of the EPC which are not party to the current EU legislative proceedings.

An amendment of the EU Biotech Directive 98/44/EC would require EU Member States to amend their national patent systems accordingly to appropriately implement the amendments. However, a majority of the patents in Europe are granted under the European Patent Convention, and any amendment of the EU Biotech Directive 98/44/EC through this regulation would not automatically apply to the EPC, as it is an intergovernmental agreement, but would require an amendment of the EPC itself.

epi warns against hasty adaptation of the EPC since it would hamper the rights of non-EU members states as well.

¹⁴ See Art. 27 lit. c) And i) UPCA.

¹⁵ See e.g. Enlarged Board of Appeal opinion G 3/19 of 14. May 2020.

Further, **epi** warns against hasty parallel amendment of the EU Biotech Directive 98/44/EC in the context of the legislative process primarily aiming at arriving at a Regulation of NGT plants.

Is the proposed patent ban in line with obligations of WTO member states under the TRIPS Agreement?

Article 27.3b TRIPS allows member states to exclude from patentability “*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*”. However, when looking at the proposed amendments to the Biotech Directive, the exclusions on patentability would extend to genetic information, process features and even to all “biological material” obtained by essentially biological processes, which seems to be in conflict with the TRIPS agreement.

Would the legislative process for amending the Biotech Patent Directive withstand scrutiny?

epi questions whether amending the Biotech Directive through a regulation on environmental safety of NGT plants is appropriate. Indeed, the NGT regulatory framework aims to regulate and protect human and animal health and the environment, and therefore provides no legal basis for regulating IP rights, let alone installing a complete broad patent ban on NGT plants.

Even the rapporteur of the ENVI committee suggested that, although she acknowledges the concerns of breeders and farmers, the issue of patents for plants obtained through NGTs should be addressed in a separate piece of legislation to prevent the proposal from exceeding its scope¹⁶.

In addition, amendments to the Biotech Directive in this way pose a genuine risk for other technological sectors, as similar legislation or amendments to the Biotech Directive could be simply introduced without re-opening profound discussions on the Biotech Directive. In this context, it is important to point towards the final report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973) of 17 May 2016, commissioned by DG Grow of the European Commission, wherein none of the Experts recommended amending the Biotech Directive.

epi agrees with the need for a thorough study on any potential IP issue as proposed by the European Commission and the EU Parliament

The original proposal of the NGT regulation by the European Commission of July 2023 included a suggestion to carry out a study on the potential impact of Intellectual Property Rights around NGT plants.

¹⁶ A9-0014/2024, page 46.

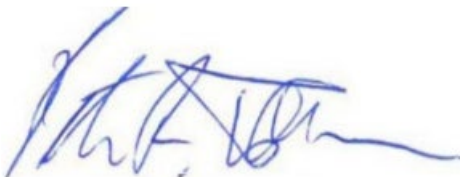
The proposal amended by the European Parliament contains the following paragraph 5a to be added to Article 30 of the proposed Regulation: *“By June 2025 the Commission shall submit a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and, in particular, on opportunities for SMEs. The report shall assess whether further legal provisions are necessary in addition to those provided for in Article 4a and Article 33a of this Regulation. Where appropriate to ensure breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, the report shall be accompanied by a legislative proposal to address further necessary adjustments in the intellectual property rights framework.”*

This seems to imply that even more severe restrictions on plant IP rights are to be envisaged than the ones already proposed. **epi** notes that again here, the reference to *“opportunities for SMEs”* is important since it seems to imply that SMEs would lack opportunities due to the existence of patent rights on plants. This should probably be changed into *“missing opportunities for SMEs in absence of effective IP protection”*.

epi endorses the proposal by the Commission to timely initiate and compile a much-needed fact-based impact study into NGTs and the potential impact of patent protection before any legislative steps are taken that will significantly curtail intellectual property rights in this field, to avoid a negative effect on the European market.

In any case, any impact study should additionally engage with representatives from the full breadth of industry stakeholders, including the many Europe-based start-ups, SMEs, and research organizations active in the plant- and agricultural-biotechnology fields as well as experts in the field of Intellectual Property, in particular patents, to reach a reasonable and balanced consensus between all stakeholders. **epi** would be happy to provide corresponding expertise in the field of plant patents and their effect on innovation in the plant and breeding sector.

Yours sincerely



Peter R. Thomsen

President