



28.04.2025

Update on the status of the legislative process towards a regulation on plants obtained by certain new genomic techniques and their food and feed, and the implications for patenting of plant products in the EU

The Institute of Professional Representatives before the European Patent Office (**epi**) is the professional body of all European patent attorneys. Currently, **epi** has about 14,400 members from the 39 Contracting States to the European Patent Convention (EPC). European patent attorneys mainly work in private practice patent law firms or in industrial patent law departments. They represent a wide variety of users of the European patent system, from individual inventors to multinational corporations, from all parts of the world. European patent attorneys represent patent owners, opponents and interveners in opposition and opposition-appeal procedures.

On March 14, 2025, the Committee of Permanent Representatives achieved a significant milestone in the legislative process of the EU towards a “Regulation on plants obtained by certain new genomic techniques and their food and feed” (“NGT plant regulation”). With a qualified majority, they approved the latest proposal of the Council of the European Union, developed under the Polish Presidency. The EU Council endorses a mandate for negotiations with the European Parliament, allowing the start of the trilogue negotiations between the Council of the EU, the European Commission and the European Parliament, to arrive at a final text for the Regulation. As a reminder, the Regulation aims at providing a framework for deliberate release and marketing of certain plants obtained by new genomic techniques (NGTs) that enable more targeted, precise and faster changes in the genetic characteristics of plants, as compared to conventional breeding techniques. Plant products developed by these new techniques have the potential to enhance the EU agricultural sector’s competitiveness and contribute to the innovation and sustainability objectives of the EU level strategies on “European Green Deal”, “Farm to Fork” and “Biodiversity”,

On July 5, 2023, the EU Commission had adopted a new legislative proposal, laying down conditions under which particular plant products obtained by NGT, not containing any foreign DNA and which could also be obtained by conventional breeding techniques, including random mutagenesis, plant occurring naturally (so called Class I NGT products) could be considered as not falling under the existing EU GMO legislation. All other NGT products (Class II NGT products) would remain regulated as GMO’s as previously decided by the Court of Justice of the European Union, in its judgement C-528/16. While being focused on the regulatory aspects, the Commission proposal did include concerns amongst some stakeholders (mainly smaller breeders and farmers) on a perceived negative impact of invention patents covering such NGT products, by ordering a study on the impact of patents on access to germplasm for breeding purposes, potential reduction of choice of crop varieties for farmers, and risk of monopolization of the agricultural industry. The European Parliament adopted later amendments to the proposal after analysis of the EU Commission’s proposal by the Parliament’s Committee on Environment, Public Health and Food

President • Peter R. Thomsen

epi Secretariat · Bayerstrasse 83 · 80335 Munich · Germany
Phone +49 89 242052-0 · Fax +49 89 242052-220
info@patentepi.org · www.patentepi.org

Direct Phone: +41 79571 0076
president@patentepi.org

Safety (ENVI) and the Committee on Agriculture and Rural Development (AGRI). That amended version included a new prohibition of patents for NGT plants, but also for plants obtained by random mutagenesis - currently exempted from the EU GMO regulation - and for methods for obtaining such plants, as well as genomic information contained therein and products derived therefrom.

epi welcomes that the current Proposal of the Council of the EU does not contain any general provisions for a ban on patenting of (NGT) plants, or methods, products thereof or genetic information contained therein. **epi** further welcomes that the previously proposed provisions have been deleted to make the applicability of the regulatory allocation of plants to NGT Class I dependent on the condition that no patent applications/patents “covering” such NGT1 plants had been filed, or in the case such patents did exist, were subject to a declaration by the patent owners that they would not enforce such patents.

The current Proposal does contain provisions “*aiming to increase the level of transparency regarding patents on NGT plants, encourage licensing on equitable conditions, and assist operators in navigating the plant intellectual property landscape*” which **epi** considers a positive development, subject to additional clarification.

Concerning transparency, Recital 16 states in the current version that “*requesters should submit declarations describing the extent to which a plant for which the verification of NGT 1 status has been requested benefits from **any type of patent protection**. Requesters should make such declarations to the best of their knowledge, providing any relevant information of which they are aware*”. Although this recital refers to “any type of patent protection”, Art 6, 3x and Art 7, 2x appear to limit the declaration to identifying “*patents claiming **modifications of biological material of the NGT plant resulting in particular traits**, or published applications for granting such patents, or declaring the absence of such patents or published applications for granting such patents*” thus excluding any patents on (generic) methods on technology for genomic modifications. However, Art 27 request the Commission to “*adopt implementing acts... on the content of the patent information [to be provided]*” and **epi** would warn against an overly broad interpretation to request inclusion in the patent information of patents or patent applications only directed at such (generic) method claims which could potentially also cover gene editing technologies in general. In addition, **epi** also would like to warn against applying said patent information requirement in an overly strict manner since it could result in an undue burden for the party trying to bring an NGT plant trait to the market. Indeed, in many cases, said party would not necessarily be the patent holder and/or may not have a complete overview of all patents and patent applications that could be seen as covering said NGT plant trait.

epi also welcomes that the Commission shall establish and maintain a database listing the category 1 NGT plant status decisions, including the provided patent information, (Art 9) and thereby enhancing transparency. However, **epi** would like to caution that the obligation to update the patent information provided “*expeditiously*”, albeit to “*the best of their knowledge*”, (Art 9§3) creates an additional/undue burden on requesters/developers, particularly when they are not the


actual patent owners. Indeed, the scope of patent applications may change during prosecution, usually in the sense that patent applications initially claiming modifications of biological material of the NGT plant resulting in particular traits may no longer contain such claims at the grant stage of the application. Also, new patent applications may have been filed by third parties, even after the initial request, to interfere with marketing of NGT1 plants, and while such patent applications would likely not be compliant with novelty requirements of the EU patent systems, it may require patent offices a long time to reach final conclusions on such patent applications.

With regard to the encouragement of “*licensing on equitable conditions*”, **epi** appreciates that the provisions in the proposal to encourage “*license declaration(s) by patent holders announcing their willingness to license their patent under certain terms and conditions*” remain on a voluntary basis. Patents do remain an IP asset, allowing to exclude third parties from exploitation of the claimed subject matter without a license. Furthermore, **epi** would have preferred the retention of the well-established term “*fair, reasonable and non-discriminatory terms in the Union*” contemplated in previous proposals, rather than the less defined “*equitable conditions*” currently recited.

epi endorses the recommendation in the Council’s proposal to conduct a comprehensive study (and establish an NTG patent expert group) on the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders’ access to plant genetic material and techniques and on farmer’s access to plant reproductive material while evaluating the overall competitiveness of the EU plant breeding industry (Arts 30 and 30bis). **epi** firmly believes “*Measuring is knowing*” and any future actions to be taken regarding patented NGT plants should be grounded in factual evidence, rather than on emotional or non-evidence based concerns. **epi** is hereby offering any assistance it may be able to provide to both the proposed study and NTG patent expert group activities.

As mentioned before, the legislative process is now entering into the trilogue negotiation phase between the European Commission, the Council of the EU and the EU Parliament. Likely, the patent exclusion on (NGT) plants adopted by the European Parliament will be discussed again, and **epi** refers to its [previous position paper](#) on the matter for arguments opposing such a patent ban as being counterproductive for stimulating innovation in the NGT plant sector in the EU.

Yours sincerely,



Peter R. Thomsen
President