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ANALYSIS

IP

NGT plant patenting: betwixt and between regulatory continuity and expectations

'Position (EU) No 6/2026 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their products' does not introduce any substantial changes in the field of patents, focusing instead on transparency and monitoring measures. Overall, lawmakers have taken a cautious approach, pending an assessment of the new framework's actual impact.

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1. Genetically modified organisms and the proposal for a regulation on plants obtained by certain new genomic techniques

1.1. To date, the concept of a *genetically modified organism* (GMO) is defined in EU law 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 ('Directive 2001/18'), which defines it as any biological entity capable of replication or of transferring genetic material (with the exception of human beings) "in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". This directive imposes a series of strict obligations on genetically modified organisms regarding authorisation, monitoring, and labelling.

Category 1 NGT plants are considered equivalent to conventional plants and are exempt from the legislation applicable to genetically modified organisms

However, the development of so-called new genomic techniques (NGT), which allow the genome of an organism to be altered without incorporating exogenous DNA and do so with much greater precision than existing procedures, raised the question of whether products or organisms resulting from the application of these new techniques fall within the legal definition of *a genetically modified organism* and, consequently, whether the obligations and controls established in Union legislation regarding such organisms apply to them.

This question was examined by the Court of Justice in its Grand Chamber judgment of 25 July 2018, *Confédération paysanne et al.*, C-528/16, (ECLI:EU:C:2018:583), in which the Court held that organisms obtained by means of techniques/methods of mutagenesis that had appeared or have been mostly developed since Directive 2001/18 was adopted constitute legally genetically modified organisms within the meaning of that directive and are not to be excluded from its scope. Consequently, following this judgment, it became clear that organisms or products obtained by new genome editing techniques such as CRISPR-Cas9, Talen, etc., were subject to all obligations applicable to genetically modified organisms. By contrast, products resulting from random mutagenesis — conventionally used in a number of applications and with a long safety record — did not come within the scope of that directive.

The Court of Justice's equating of transgenic products with those resulting from the application of *new*

genomic techniques — though based on legal arguments and having earned the applause of some legal scholars — has sparked significant criticism, with the following main arguments against it:

a) it lacks scientific basis;

b) it bases the distinction between organisms on the method of mutation used — whether random or directed/targeted — rather than on biological criteria;

c) it is not possible to distinguish whether an organism has been obtained through random or targeted mutation, which creates uncertainties and difficulties in the application of the legislation;

d) in reality, the risk of targeted mutagenesis applying new molecular techniques is much lower than that of transgenesis (where undesirable effects are more frequent due to the introduction of a foreign gene) and even lower than the risk of conventional random mutagenesis, where thousands of mutations occur in the recipient organism's genome.

1.2. This critical reaction against the classification of products obtained through new genomic techniques ('NGT plants') as genetically modified organisms explains why a current of opinion in favour of amending Union legislation on genetically modified organisms gained momentum, which led the Council to present, on 5 July 2023, the 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[1] (the 'proposed regulation').

Contrary to the Court of Justice's interpretation, the proposed regulation is based on the exact opposite principle and establishes two distinct categories of plants obtained using new genomic techniques:

1) 'Category 1' NGT plants, which are all those that can also be obtained naturally or produced using conventional plant breeding techniques, as well as their progeny obtained by such techniques;

2) 'Category 2' NGT plants, which are all others, as they feature more complex sets of modifications to the genome.

On that basis, the proposal considers that Category 1 products "should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related

[1] Document COM(2023) 411 final.

requirements in sectoral legislation". Conversely, category 2 products will remain subject to the legislation applicable to genetically modified organisms.

1.3. On 8 April, 'Position (EU) No 6/2026 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625' (the 'Council's position' or the 'position') was made public. This position is very important because it reflects the political agreement reached between the Council and the Parliament, an agreement that also enjoys the support of the Commission[2] .

The Council's position — and, consequently, the aforementioned interinstitutional agreement — retains the general structure of the Commission's proposal and the distinction between the two different categories of plants obtained by new genomic techniques, confirming that NGT plants classified in Category 1 are exempt from the restrictions imposed by Union legislation on genetically modified organisms (Article 5 of the text of the regulation adopted by the Council). However, recommendations and provisions regarding patents are introduced, which we address below.

2. Plants obtained by new genomic techniques and patent law

2.1. The position upheld by the Court of Justice in the aforementioned Grand Chamber judgment of 25 July 2018, did not affect the regulation of biotechnology patents. And, along the same lines, the proposed regulation presented by the Commission does not address in any way the issue of the patentability of this type of plant.

2.2. However, the emergence of new genomic techniques led to various proposals aimed at excluding from patentability organisms whose genome is subject to targeted mutation without the addition of foreign genetic material, so that only those organisms in which the new techniques are used to generate transgenics may be patented.

In this vein, the European Parliament, at first reading, adopted several amendments to the Commission's text, including the introduction of an article (Article 4*a*) into the proposed regulation, stating that "NGT plants, plant material, parts thereof, genetic information and the process features

[2] As stated in the Communication from the Commission to the European Parliament pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the position of the Council on 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(2026) 151 final.

they contain shall not be patentable"[3]. And, in parallel, another amendment was approved[4] to incorporate Article 33*a*, amending Directive 98/44/EC on the legal protection of biotechnological inventions, to add to Article 4(1) of that directive two new prohibitions on patentability, according to which "NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in [the] Regulation" on plants obtained by certain new genomic techniques and their food and feed, shall not be patentable, nor "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".

2.3. However, these provisions are absent from the Council's position, and what is included — as the Council itself states in the explanatory memorandum — is a series of safeguards that address concerns regarding the potential adverse impacts of the patenting of NGT plants and of related licensing and transparency practices, for example, on breeders' access to plant biological material and techniques, and the risks of market concentration.

Thus, the text of the regulation adopted by the Council does not alter the patent system or introduce changes to the current regulation of biotechnology patents. However, it is based on the general principle (Recital 26) of the need to maintain effective protection of invention and stimulation of research and development on the one hand and wide access to varieties serving the development of new varieties on the other hand.

In this context, in response to concerns that patents relating to NGT plants might limit the access of breeders to those plants for the purpose of developing other plant varieties or might give rise to "unintentional" acts of infringement, the recitals of the regulation emphasize three issues:

1.st It is recalled (recital 63) that patents are not to be granted in respect of plants exclusively obtained by means of an essentially biological process; therefore, for a plant obtained by technical processes, the part of the patent claim defining exactly what is to be protected is required to specify that the patent does not include plants produced by essentially biological processes.

2.nd Member States are invited (recital 62) to incorporate the breeder's exemption into their national legal systems, as already provided for in Article 27(*c*) of the

[3] Amendment 33.

[4] Amendment 69.

Agreement on a Unified Patent Court, according to which the rights conferred by a patent shall not extend to the use of biological material for the purpose of breeding, or discovering and developing other plant varieties.

3.rd It is stated (recital 65) that, when assessing a possible infringement of a biotechnology patent, consideration must be given to situations where the unintentional or accidental presence of patented biological material of NGT plants occurs during agricultural activity by farmers, as a result of natural self-replication through cross-pollination. Such situations may imply the absence of infringement. However, even if it is concluded that a patent infringement has occurred, Directive 2004/48/EC lays down the framework for the enforcement of intellectual property rights and requires, inter alia, that measures, procedures and remedies provided by Member States be proportionate and applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. That requirement is to apply when determining the appropriate enforcement measures, procedures and remedies in such situations.

2.4. Beyond these mere statements (which, *per se*, are not of a legislative nature), the regulation introduces some specific measures:

1.st *Transparency regarding patents and licenses*

It is provided that, when applying for a declaration of category 1 NGT plant status, the requester shall submit information, to the best of its knowledge, on patents or published patent applications including one or more claims on the biological material of the NGT plant, or declare the absence of such patents or published patent applications (Art. 6(5)).

Furthermore, if the plant material is covered by patents or patent applications, the verification request must indicate whether the patent holder is willing to license the protected subject matter under fair and reasonable conditions (FRAND) and whether the holder is, or intends to become, a member of relevant and appropriate licensing platforms (Art. 6(6)). However, this patent information and these licensing declarations shall not be subject to verification and shall have only declaratory value (Art. 6(7)). And, of course, it does not affect the classification of the plant as category 1, which is contingent solely on compliance with the technical criteria established in the regulation.

This information on patents and licenses will be included in the database of decisions declaring category 1 NGT plant status, which, according to the agreed text of the regulation, must be

established and maintained by the Commission.

The text of the regulation (in Art. 29(3)) also provides that the Commission shall publish, and thereafter review and update if needed, guidance for the purpose of assisting operators, in particular breeders and farmers, on matters relating to plant intellectual property, and shall include information on the following aspects:

a) plant licensing platforms;

b) public organisations that have the purpose of assisting plant breeders with intellectual property-related questions;

c) databases allowing operators to identify the intellectual property rights which apply to a given plant;

d) basic information on intellectual property rights relevant to plants, including on conditions for obtaining protection, rights conferred and their limitations, as well as compulsory cross-licensing.

2.nd *Code of conduct*

The Commission is also tasked (in Article 30) with drawing up, in cooperation with the Member States, a code of conduct at Union level to enhance the transparency of information relating to patents on plant biological material, to facilitate breeders' access to such material and to enhance legal certainty for breeders and farmers. The Commission will invite the owners of patents relating to NGT plants, representatives of voluntary platforms for the licensing of patents on plant biological material, plant breeder and farmer organisations as well as other civil society organisations and other interested parties to participate on a voluntary basis in the drawing-up of the code of conduct.

In drawing up the code, the Commission will aim to include the following commitments by patent owners:

a) the provision of clear, comprehensive and publicly accessible information on patents and patent applications covering biological material incorporated in plant varieties placed on the market in the Union;

b) arrangements for the licensing of patents under fair and reasonable conditions;

c) the amicable settlement of patent disputes involving breeders which are SMEs, or involving farmers in the case of unintentional minor presence of patented biological material in their fields.

And, with regard to voluntary platforms for the licensing of

plant biological material, the Commission will aim to include in the code of conduct the following commitments:

a) cost-attractive fees for participation in the platforms to facilitate participation in the platforms by breeders which are SMEs;

b) standard license agreements;

c) fair and impartial mechanisms for settling disagreements on licensing fees.

3.rd *NGT plant patent expert group and the assessment on the impact of NGT plant patenting*

Article 31 of the regulation provides that the Commission shall establish an expert group on the effect of the patenting of NGT plants, which shall assist the Commission in its periodic assessment of the impact of the patentability of such plants, as well as in surveying the patent licensing practices for the breeding and marketing of NGT plants protected by a patent, ongoing patent application procedures concerning NGT plants and patent enforcement practices; it will also analyse the effects of all of this within the Union with regard to the following aspects:

a) innovation in plant breeding;

b) breeders' access to patented plant biological material, traits and techniques, and breeders' ability to conduct experimentation;

c) farmers' access to plant reproductive material, including the price of available products and other available propagating material, as well as their rights to use farm-saved seeds and propagating material;

d) the risk of litigation involving farmers or breeders in situations where patented plant biological material may appear in their crops or products due to accidental presence or similarity, without intentional use of such material;

e) competition in the plant-breeding sector, particularly from the perspective of small and medium-sized breeders, while considering the potential risks of market concentration;

f) transparency and legal certainty regarding patented plant biological material.

If this assessment reveals significant barriers to access to patented plant biological mate-

The Council removes the ban on patenting NGT plants proposed by the Parliament

rial, undue restrictions on experimentation, negative effects on breeders and farmers, increased market concentration, reduced diversity in seed supply, insufficient transparency, or other evidence that the system is not functioning smoothly, the Commission shall, where appropriate, submit legislative proposals to set up mandatory conditions or safeguards.

3. Conclusion

In short, the text of the Regulation on plants obtained by certain new genomic techniques (NGT), resulting from the Council's position and the agreement reached by the Union's institutions, consolidates a significant shift in approach with respect to the case law of the Court of Justice, by differentiating between categories of plants and making the treatment of those NGT plants that can be considered equivalent to those obtained by conventional methods more flexible. However, in the area of patents, it does not make any substantial changes to the current legal regime, limiting itself to incorporating transparency measures, guidelines, monitoring and assessment mechanisms, as well as references in the recitals to preserve the balance between innovation and access to plant material. Rather than establishing strict rules or prohibitions, the European lawmakers opt for a cautious and gradual approach based on observing how the system functions and on the possibility of future interventions if significant negative effects are detected.