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GMO patents: is it possible to break the deadlock?

Par

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In July 2023, the proposal to deregulate GMOs obtained using new genetic modification techniques (known as "new genomic techniques" - NGTs) highlighted a sensitive issue that is still under discussion: patents. Patents are fiercely criticised for their many negative effects on the rights of farmers and traditional seed producers, as well as on biodiversity. A report commissioned by The Green/EFA addresses this issue and suggests ways out of the impasse.



Photo de Sippanont Samchai

In Europe, patents are causing problems for various players in the agricultural sector. This is the conclusion drawn from current discussions on the European Commission's proposal to deregulate GMOs/NGTs. Patents create difficulties, in particular:

- access to plant genetic resources, since a patent means that reproduction is prohibited without payment of royalties;
- legal uncertainty, as it is currently impossible for breeders and farmers to know whether there are patents on a plant they could use;
- and, more generally, the widespread appropriation of living organisms.

In December 2024, The Greens/EFA published a reportⁱⁱ commissioned from Axel Metzger, a law professor at the University of Berlin. This document analyses the legal options for resolving these problems, taking into account international law (Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS)ⁱⁱⁱ, the European Patent Convention (EPC) and European law (Directive 98/44/EU).

Different solutions, different difficulties

This report therefore analyses the possible options for excluding certain elements from patentability or limiting the scope of the protection conferred by patents. These options vary in complexity.

• Ban patents on plants and genes?

According to the report, it is unrealistic to hope for a rapid ban on patents on plants and/or their components derived from technical processes, such as the new techniques of genetic modification (NGTs). Such a ban would require amendments to the European Patent Convention (EPC), and therefore the unanimous agreement of the 39 signatory states, not all of which are members of the European Union. A condition that seems impossible to meet within the timeframe of the legislative discussions currently underway on the possible deregulation of GMOs derived from NGTs.

The report refers to a proposal put forward by Belgium when it held the presidency of the Council of the European Union (from January to July 2024), aimed at making the deregulation of GMOs/NGTs1 (presented as "similar" to what nature or traditional breeding can do) conditional on the renunciation of patents. This proposal was recently taken up by Poland, the current President of the Council of the EU, but Metzger believes it raises legal objections, in particular because of the principle of proportionality (Article 5(4) TEU^{IV}). According to this principle, the legislator may not refer to considerations extraneous to the subject matter - in this case patent law - as a basis for regulatory measures that are not supported by a risk assessment. This is undoubtedly why Poland is proposing, as an alternative, a labelling requirement indicating that so-called "category 1 NGT" seeds are patented.

Through the Euroseeds organisation, the multinationals have proposed excluding from patentability plants obtained by what Euroseeds calls "random mutagenesis", an expression that has no legal definition. For Axel Metzger, this proposal is open to debate. Excluding such plants without amending the text of the EPC does not seem feasible to him. He adds that while an amendment to this effect to Directive 98/44 by the European Union could influence the EPC's implementing regulation, the EPO's Enlarged Board of Appeal's support for this change remains uncertain. Axel Metzger therefore remains sceptical about such a reform without a revision of the EPC. It should also be remembered that, in order to avoid any subsequent abuse of semantics, such an approach would first require a precise definition of "random mutagenesis", as the expression currently has no legal basis and is of no use.

A. Metzger therefore believes, in summary, that prohibiting or rapidly restricting the scope of these patents on plants and/or their components derived from technical processes, such as NGTs, is unrealistic because of the legal and institutional obstacles.

Preventing the granting of patents on naturally occurring elements

On the other hand, according to the report, it would be legally possible to prevent patents being granted on naturally occurring plants and on genetic sequences present in such plants (the author refers to "genetic sequences", not "genetic information" or "biological material"). This would be compatible with TRIPS, but would require an amendment to Rule 27 of the Implementing Regulations of the EPC, which declares patentable "biological material isolated from its natural environment or produced by means of a technical process, even where it existed in a natural state". Such an amendment does not require unanimity among the 39 members of the EPC, but only a decision by the Administrative Council of the EPO with a three-quarters majority, and without ratification by national parliaments. In order to obtain such a majority, however, it would be necessary to amend European Directive 98/44 beforehand, since rules 26-34 of the EPC Regulation derive directly from it.

Another option analysed would be to impose systematic disclosure of the origin of biological material in patent applications, in line with the theoretical obligations of international treaties on genetic resources. Although it has been analysed that these recent obligations can easily be circumvented. Axel Metzger believes that, on paper, these measures would provide breeders with greater legal certainty, theoretically eliminating the risks of litigation and the costs associated with exploiting patented resources. The rapporteur points out that these obligations could also be introduced by decision of the EPO Administrative Council, as there is a basis for this in recital 27 of EU Directive 98/44.

To sum up, A. Metzger considers that preventing the patentability of natural plants is possible, but would require a reform of the EPC implementing regulation, or even an amendment to European Directive 98/44.

• Limiting the scope of current and future patents

According to the report, there are ways of limiting the scope of existing and future patents. For example, it would be possible to specify explicitly in Directive 98/44 that "the protection conferred by a patent on a product consisting of or containing genetic information shall not extend to plant material in which that product is incorporated and in which the genetic information is contained and fulfils its function, but which is not distinguishable from plant material obtained or which can be obtained by essentially biological process". This new Article 9.3 was proposed in February 2024 by the European Coordination Via Campesina (ECVC) to the European Parliament, which adopted it in its amendments to the European Commission's proposal for the deregulation of GMOs. Axel Metzger points out that this will make it possible to exclude from patent protection NGT plants considered to be "equivalent" to those derived from conventional breeding. But isn't that the elephant in the room: equivalent (according to certain criteria and not others) does not in fact mean identical.

Metzger's report also proposes a change to the rule on the burden of proof in cases of alleged infringement - which would then rest solely with the patent holder - for products derived from specific NGT processes. These clarifications would help to reduce - not eliminate - breeders' and farmers' fears of potential disputes arising from the use of plants containing traits similar to those patented.

A. Metzger therefore considers that it would be possible to restrict the scope of patents, in particular by clarifying their scope and reversing the system of the burden of proof.

Extending the breeder's privilege

Another possible option is to extend the breeder's privilege, allowing breeders not only to continue breeding on the basis of patented varieties, but also to market the new varieties obtained. But Axel Metzger believes that a complete exemption for breeders is difficult to implement, as it may be incompatible with Article 13 of the TRIPS Agreement (limitations and exceptions for rights holders). In his view, such a reform of breeders' privilege would require amendments to both Directive 98/44 and TRIPS, which could pose legal challenges that are unattainable in the short term.

Increasing the transparency of existing patents and forcing their holders to take out patents

A final possibility analysed by A. Metzger is the adoption of measures aimed at increasing patent transparency and limiting abuses by rights holders, without however being able to exclude them completely. For example, the European legislator could make it easier to obtain compulsory licences, along the lines of the Swiss model, and introduce a compulsory transparency register for patents on plants (other than the Pinto database, which operates on a voluntary basis), their varieties and the techniques used. It would also be possible, in his view, to restrict the rights of patent holders in the event of blocking or delaying the provision of necessary information to other breeders.

A. Metzger argues, in short, that increasing transparency and regulating patents would make it possible to limit certain abuses without eliminating them altogether.

The position of the organisations

At a round table organised by The Greens on 9 December 2025^{VI} on the Metzger report, ECVC reiterated the importance of appropriate regulation to prevent patent abuse. However, ECVC highlights a shortcoming in the report, which fails to address a key point: the removal of any obligation on GMO producers to provide detection and identification procedures enabling products obtained using new techniques to be traced. In ECVC's view, the only way to restrict abusive patent claims in the first instance is to maintain such an obligation under current GMO legislation. The organisation also deplores the fact that the report does not propose any concrete solutions - other than the *disclaimer* provided for by the EPO, which it considers ineffective VIII - to counter the abusive extension of patents to natural plants or plants derived from farmers' or traditional selections.

The European coalition No Patents on Seeds (NPOS) also welcomes the Metzger report in its analysis of the patent issues surrounding NGT-derived products. However, it criticises the report for not making a sufficiently clear distinction between "genetic engineering" and "conventional breeding". According to NPOS, this could limit the opportunities for prohibiting patents on plants obtained by essentially biological processes. NPOS, which, like Euroseeds, includes "random mutagenesis" (without defining it) in these processes, believes that there is sufficient room for manoeuvre at EU level to implement such a ban. The coalition adds that such a ban would be left to the interpretation of the EPC, which would not therefore need to be amended, something Metzger doubts.

NPOS and ECVC have on several occasions expressed their differences on, in particular, the patentability of "random mutagenesis", for which there is no legal definition. ECVC refutes the position of NPOS, which considers it to be an essentially biological process (EBP). The two organisations are currently at odds over the strategy to be adopted to break the legislative

deadlock on the issue of patents. While NPOS is essentially focusing its position on changing the legal status of "random mutagenesis", which it wants to see classified as an EBP, ECVC would like to amend Directive 98/44 with a minimum provision: making it compulsory to publish the identification and detection procedures for patented products in order to trace them and avoid abusive prosecution of small seed producers and farmers, failing which the validity of the patent would be called into question.

While the proposed deregulation of GMOs/NGTs continues to generate intense debate, the issue of patents remains a major obstacle to balanced reform. The Metzger report highlights the legal complexities and differences of approach between stakeholders, illustrating the tensions surrounding fair access to genetic resources. While solutions do exist to regulate these patents and limit their effects, they require strong, concerted political decisions to ensure that this deregulation does not work to the detriment of farmers and biodiversity.

- <u>i</u> Denis Meshaka, <u>"Les brevets : une réponse insatisfaisante"</u>, *Inf'OGM, le journal*, n°175, April/June 2024 (in french).
- ii Metzger, A., "Legal options for changing the patent protection of plants in Germany, Europe and in international law", 4 December 2024.
- <u>iii</u> TRIPS, or the Agreement on Trade-Related Aspects of Intellectual Property Rights, aims to define minimum protections for intellectual property rights in member countries of the World Trade Organisation (WTO).
- iv Article 5(4) TEU: "In accordance with the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties. The institutions of the Union shall apply the principle of proportionality in accordance with the Protocol on the application of the principles of subsidiarity and proportionality".
- <u>v</u> However, there are loopholes in this obligation that allow it to be circumvented. K.M. Gopakumar, "WIPO opens more widely the door to biopiracy", *Inf'OGM*, 31 October 2024.
- vi Martin Häusling, <u>"Freier Zugang zu Saatgut Für ein krisensicheres Ernährungssystem"</u>, 9 December 2024.
- <u>vii</u> ECVC, <u>"European Commission proposal on "new GMOs": Towards the appropriation of all</u> seeds by the patents of a few multinationals", 18 July 2023.

<u>viii</u> NPOS, <u>"What can be achieved at EU level against patents on seeds? The Green parliamentary group in the Bundestag presents an expert opinion", 9 December 2024.</u>

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