

## **SC Biotechnology and Plant Varieties**

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

#### **Summary/bullet points/headnotes:**

- The International Association for the Protection of Intellectual Property, known as AIPPI, is the world's leading non-profit association dedicated to the development and improvement of laws for the protection of intellectual property. It is a politically neutral, non-profit organisation, with over 8000 members from over 110 countries.
- AIPPI has issued resolutions in favour of the patentability of biologics and genes, as well as plants (cf. Q114 -1994; Q159 – 2001; Q259 – 2017).
- On February 7, 2024, the Members of the European Parliament (MEPs) adopted, by way of plenary vote, a position supporting a proposal of the Committee on Environment, Public Health and Food Safety (ENVI) to ban patents for all plants obtained by New Genome Techniques (NGT plants), plant material, parts thereof, genetic information and process features they contain.
- AIPPI, through its thematic Standing Committees on Biotechnology and Plant Varieties and on Patents, has identified the following concerns regarding said proposal:
  - AIPPI finds the proposed patent ban on plants disproportionately broad and undesirably vague.
  - Whereas the patent system exists to promote and spread innovation to the benefit of the public, the proposed plant patent ban would put the future of innovation in this critical industry in Europe at risk, and compromise Europe's long-term competitiveness. The proposed ban therefore undermines the aims of the original Commission proposal, which was expressly intended to create "an enabling environment for research and innovation" in the NGT plant sector.
  - Inventors making technical contributions should be able to protect their inventions in return for public disclosure and the investment in

time and resources, especially in highly technological areas, such as NGT plants.

- Plant Variety Rights are not designed, and are not sufficient, to cover such technical contributions, and they contribute neither to the store of public knowledge nor to technological progress and development since they do not require disclosure of the innovation used.
- AIPPI urges the European Parliament, the Commission and the Council of the EU to study the impact of such a patent ban on the full breadth of industry stakeholders in the areas of plant- and agro-biotechnology (and in other industries involving genetic information and processes that may be affected by the proposed ban), including innovators in Europe and innovators elsewhere seeking to enter the European market.
- This AIPPI position does not deviate from earlier AIPPI resolutions.

On 7 February 2024, the Members of the European Parliament (MEPs), by way of a plenary vote, adopted a position supporting a proposal<sup>1</sup> of the Committee on Environment, Public Health and Food Safety (ENVI) to amend a proposal from the European Commission that had been intended to foster the development of plants obtained by New Genomic Techniques (NGT Plants) in Europe.

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. A new Regulation for plants derived by certain NGTs would represent an important step forward in fostering the biotechnology sector in Europe.

However, through the amendments proposed, and as stated in a press release from the European Parliament; "MEPs want a full ban on patents for all NGT plants, plant material, parts thereof, genetic information and process features they contain, to avoid legal uncertainties, increased costs and new dependencies for farmers and breeders. They also request a report by June 2025 on the impact of patents on breeders' and farmers' access to varied plant reproductive material as well as a legislative proposal to update EU rules on intellectual property rights accordingly."

The MEPs' proposal intends to accomplish this by way of a series of **amendments to the EU Biotech Directive** (98/44/EC), which include a broad patent ban of

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<sup>1</sup> 2023/0226(COD), per

[https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2023/0226\(COD\)&l=en](https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2023/0226(COD)&l=en)

uncertain and poorly defined scope. The proposed patent ban seems to go well beyond NGT plants to cover all plants obtained by (classical) mutagenesis or cisgenesis.

The proposed patentability exclusion would **apply from the date of entry into force of the proposed NGT Plant Regulation**, which would render many existing granted patents in the sector potentially unenforceable. Since the EU Biotech Directive is explicitly referred to in the European Patent Convention (EPC), these changes **could also affect non-EU member states of the EPC** not party to legislative proceedings.

This far-reaching amendment came as a complete surprise to the agricultural biotechnology sectors and to the intellectual property community. In the original proposal from the EC of July 2023, it was merely mentioned that: *"Concerns have been expressed by breeders and farmers' organisations on the need to ensure breeders' access to patented genetic material"*.

As the International Association for the Protection of Intellectual Property (AIPPI), we are particularly concerned about these developments. The impact of a patent ban in this highly innovative sector cannot be underestimated. Europe has always been a pioneer in this sector and the **protection of inventions through intellectual property is essential** for the survival of many innovative companies active in this sector in a highly competitive global setting.

The rationale behind the proposed amendment seems to be *"to avoid legal uncertainties, increased costs and new dependencies for farmers and breeders"*. The MEPs also requested a *"report by June 2025 on the impact of patents on breeders' and farmers' access to varied plant reproductive material as well as a legislative proposal to update EU rules on intellectual property rights accordingly"*.

Although AIPPI is sympathetic to the concerns of some of the farmers' and breeders' organisations, we question whether the proposed amendment is in the long-time interests of the European farmers' and breeders' community at large. Agricultural innovation is of paramount importance for farmers and breeders in the EU for several reasons, including increased **productivity** (which is crucial for meeting the growing demand for food in the EU's increasingly populated and urbanized society), **sustainability** (innovation helps to reduce environmental impacts such as greenhouse gas emissions, soil degradation, and water pollution; and to mitigate the effects of climate change), and **competitiveness** (by increasing efficiency and reducing costs, farmers and breeders can produce higher-quality products at competitive prices).

Moreover, we feel that any impact study requested by MEPs should additionally engage with representatives from the **full breadth of industry stakeholders**, including the many European-based start-ups, SMEs, and research organisations active in the plant- and agricultural-biotechnology fields. Similarly, **these stakeholders should be properly consulted** before any legislative steps are taken that will significantly curtail intellectual property rights in this field.

Reading between the lines, it is apparent that the European Parliament is particularly worried about increased monopolisation of the agriculture and food industry. **Although this is of course a genuine concern, a ban on patents will not solve this issue. Rather, the proposed patent ban would have an entirely counterproductive effect in this respect.**

It is an unfortunate but all-too-common misconception that patents are only used by large multinationals to create monopolies to the detriment of SMEs and the public. Such a view is untrue and betrays a lack of understanding of the essential role of patent protection in the cycle of innovation and investment. **The patent system is designed to promote innovation** and to encourage disclosure of technical contributions for the public good by awarding a time-limited period of exclusivity, **after which those contributions enter the public domain and are thereafter free for all to use.** The patent system encourages full and early public disclosure of innovations that could otherwise be kept secret.

Many innovative European start-ups, SMEs, and research institutes (as well as those seeking to enter the European market) rely on the patent system to protect their innovations. This is critical to ensure a return on their significant investments in R&D and regulatory compliance. In fact, it is the proprietary position afforded by the patent system that enables new market entrants to innovate to compete with established players. Patents often serve as a basis for collaboration, licensing, and cross-licensing. **Hence, the patent system levels the playing field between different stakeholders.**

**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.

It is possible that MEPs may believe that plant variety rights can provide sufficient protection in this sector. However, plant variety rights are not designed for, nor are they sufficient to, protect these types of technical contributions. Plant variety rights also do not encourage the sharing of technical contributions with the public, as they do not require disclosure of relevant technological details.

New technologies, such as gene editing and other NGT, offer new opportunities. However, they require significant investment. Without adequate intellectual property protection of the technical contributions made, it can be impossible to bring new, innovative products to market. As a consequence, companies will have no incentive to invest in this technology in Europe, innovation will slow down, and innovative products will not be brought to market for the public's benefit. Companies who would have otherwise invested in the European market will not do so. Ultimately, the EU's goal of fostering competitiveness with stronger biotechnology contributions to help farmers maintain productivity in times of climate change will be put at risk.

In addition, the proposed **patent ban seems disproportionate** to the actual 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 EU Unitary Patent Court Agreement introduced a breeder's exemption for patents.

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 such.

Following the 7 February 2024 vote on the draft legislation, the European Parliament is now ready to start negotiations with EU member states and the European Commission on the final law.

In the interests of due process, and given the far-reaching consequences of the ENVI proposal and the concerns expressed above, AIPPI strongly urges the European Parliament, the European Commission and the Council of the European Union **to consult all stakeholders in the sector** (i.e. not only the farmers and

breeders' organisations) in order to **assess the implications a patent ban will have on the competitive power of the European innovators in a global economy.**