

**12th GRUR meets Brussels Workshop -
New Genomic Techniques and Patents in Plant Innovation**

**(Full) Breeder's exemption and other
restrictions of the patent scope of protection**

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Introduction

*** Patents on innovative plants - controversial for years**

- EPO EBoA Broccoli, Tomato, Pepper: essentially biological processes + plants from these processes not patentable**
- Genetically modified plants, plants from untargeted mutagenesis: patentable to date**

*** Actors and arguments**

- Patent-experienced international agrochemical companies, large and SME breeders, farmers, civil society**
- Arguments in favor of patent protection: plant variety protection does not cover all technical innovations, rapid adaptation of plants required, investment incentive**
- Arguments against patent protection: Plant variety protection sufficient, cheaper, more innovation-friendly (for downstream innovations), concern about concentration**

Window of opportunity

- * Legislative initiatives on NGT plants and patents open a window of opportunity after years of discussion**
- * Changes to the Biotechnology Directive 98/44/EC are possible in the coming months**
 - What restrictions/changes should be made to patent protection for plants: economic and political issue**
 - Which restrictions/amendments are compatible with the requirements of international law (TRIPS, EPC): legal question**
 - What restrictions/changes can be achieved in legislative process: political issue**

Multi-level system of patent law

* International law

- **TRIPS: Patentability and scope of protection**
- **EPC: basis for the grant of patents by the EPO, case law of the Boards of Appeal, no provisions on scope of protection**
- **EPC AO: Implementation of Directive 98/44/EC**
- **UPCA: Treaty of the EU Member States, binding on EU law, scope of protection**

* EU law

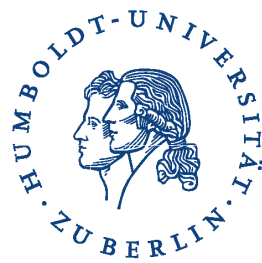
- **Biotechnology Directive 98/44/EC: patentability and scope of protection, binding of EU member states, indirect effect on EPO via EPC AO**
- **Enforcement Directive 2004/48/EU**

* National law

Exclusion from patent protection

- * Exclusions of NGT plants and plants from untargeted mutagenesis (EP Proposal) are compatible with TRIPS but require amendment of the EPC to be effective**
- * Proposal of the Belgian/Polish Council Presidency is compatible with EPC, but doubtful under European law:
→ Art. 5(4) TEU Principle of proportionality**

Restrictions on the scope of protection



*** Restrictions on the scope of protection are compatible with TRIPS and EPC but require a change of the Biotech Directive**

- EP resolution of 7.2.2024 proposes changes to Art. 8, 9 Biotech Directive

- The approach deserves support, but does not go far enough

- Humboldt White Paper of 27.1.2025:

<https://www.rewi.hu-berlin.de/de/lf/ls/mzg/humboldt-white-paper-on-ngt-patents-27-1-2025.pdf>



Whitepaper

Mitigating impact of patents on plants obtained from New Genomic Technique (NGT)

27.1.2025

This Whitepaper Paper is a contribution to the debate on how to ensure that patents on NGT-derived plants will not hinder the further development and cultivation of innovative plants with and without genetic modification. Limitations of the scope of patent rights are seen as the only realistic way to achieve this objective. Limitations to patentability require a complex change to the European Patent Convention (EPC)¹ and would not affect existing patents and patent applications. Requiring applicants to ensure a “patent-free” situation as a requirement for a NGT Cat. I classification is “mission impossible”² in many cases and comes with legal uncertainty. Limitations to the scope of patent rights can be implemented without changing the EPC, through a change of Dir. 98/44 (as proposed below) or directly in the national patent laws of the EU Member States and the UPCA. Such a change would affect all pending patents and patent applications.

Proposed Provision	Explanation
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25.6.2025

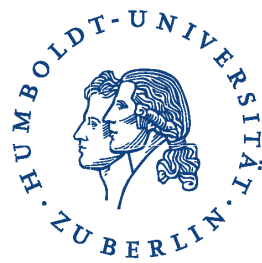
Metzger

Restrictions on the scope of



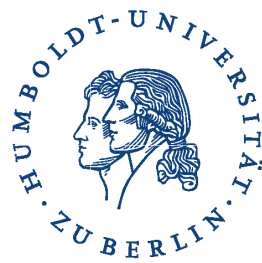
Proposed Provision	Explanation
<p>1. Art. 11 para. 4 (new) „By way of derogation from Articles 8 and 9, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to</p> <p>a) biological material possessing the same characteristics that is obtained independently of the patented biological material³ and from essentially biological processes, or to biological material obtained from such independently obtained material through propagation or multiplication.</p>	<p>The provision follows the proposal of the European Parliament of February 7, 2004. The French and the Austrian Patent Act already contain a similar clarification.⁴ The provision would re-enforce the political intent that plants derived from classical breeding should be excluded from patentability (as expressed by Rule 28(2) EPC by expanding the effect to patents filed before July 1, 2017.</p>
<p>b) the use of that biological material for the purposes of</p> <p>(i) breeding, discovering and developing of a new plant variety for food and agriculture and</p> <p>(ii) the multiplication, offering and placing on the market of that new plant variety, and</p> <p>(iii) using that new plant variety for any purpose in food and agriculture</p>	<p>This provision creates a full breeder's exemption: While the use of a patented process for making of a NGT plant still requires a license, the use of the NGT plants by breeders, who create and commercialize new plant varieties, would not be covered by the patent. The limitation will apply to all existing patents and patent applications.⁵ A “limited breeders’ exemption” is already part of the national patent laws of several EU member states and the UPCA.</p>
<p>2. Art. 8 para. 2 sentence 2 (new): „Sentence 1 does not apply to plants for food and agriculture where the specific characteristics and its underlying genetic change as a result of the invention are not a feature of the claim.”</p>	<p>The provision clarifies the scope of method claims under Art. 8(2) Dir. 98/44. The extension should only be available for specifically defined characteristics which are instrumental for the inventiveness of the patent and are part of the patent claim. General processes should not extend to plants, as it is not possible for third parties to</p>

Arguments for a full breeder's exemption



- * Full breeder's exemption addresses main concern of breeders with regard to downstream innovations**
- * Limited breeder's exemption → dependency on patent owners**
- * Streamlining with PVRs on plants obtained by means of an essentially biological process**
- * Milder measure than exclusion of NGT plants from patent protection: Biotech companies can still use patents against identical copying, as signalling tool for VC etc.**
- * Compatible with TRIPS and EPC**

Restrictions on the scope of protection



<p>3. <i>Art. 11a (new): „A court shall decline the measures, procedures and remedies available to a patent owner under the Directive 2004/48 or under national law unless the patent owner has taken all reasonable efforts to provide clear information in a publicly accessible register on all patents and patent applications covering plant varieties approved for cultivation in the EU prior to said approval.”</i></p>	<p>The provision requires patentees to enable transparency which varieties in the EU market are covered by patents, irrespective whether these are varieties of the patentee, an affiliate, or a licensee. The information needs to be clear i.e., patentees should not list patents or applications which do not cover the variety. The listing can be part of the EU seed catalogue or a publicly accessible database of seed associations.</p>
<p>4. <i>Art. 12 para. 3 sentence 2 (new): „The breeding of a new variety that is eligible for approval under EU seed laws constitutes significant technical progress of considerable economic interest in the sense of lit. b.</i></p>	<p>This provision clarifies the requirement for compulsory cross-licenses. In consequence, for plants which obtained seed market authorization courts only have to decide on a reasonable compensation.</p>

Arguments for a mandatory register

- * Voluntary databases, especially PINTO, have not proven to provide sufficient transparency for breeders**
- * Entry in registers should be mandatory for patent owners**
- * Varieties of the patentee, affiliates, or licensees must be disclosed**
- * Non-compliance → restriction on remedies (injunction, damages, etc. Enforcement Directive 2004/48/EU)**
- * Compatible with TRIPS and EPC**

Conclusion

- * Changes to the Biotechnology Directive 98/44/EC are possible in the coming months**
- * Exclusion from patent protection is not effective without a change to the EPC; it is questionable if it is wise from a political/economic perspective**
- * Restrictions on the scope of protection are possible and sufficient**
 - Exception for biological breedings**
 - Lowering the bar for compulsory licenses**
 - Full breeder's exemption**
 - Mandatory transparency register restriction of claims**