



Whitepaper

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

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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
<p>1. <i>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</i></p> <p><i>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.</i></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><i>b) the use of that biological material for the purposes of</i></p> <p><i>(i) breeding, discovering and developing of a new plant variety for food and agriculture and</i></p> <p><i>(ii) the multiplication, offering and placing on the market of that new plant variety, and</i></p> <p><i>(iii) using that new plant variety for any purpose in food and agriculture</i></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. <i>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.”</i></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>

1 A change of the EPC would require unanimous consent of all 39 EPC contracting states. Further, as plants can be covered by many kinds of claims – often of a very general nature – excepting all claims which may cover plants is a challenge with a high risk of collateral damage.

2 For example, applicants will unlikely be successful to convince third parties to abandon their patents.

3 The term “patented biological material” means biological material made by the patentee or a licensee under the patent.

4 Article L613-2-3 Code de la propriété intellectuelle; Austrian Patent Act, Article 22(1b). § 22. (1b)

5 If this limitation causes a complete loss of protection for existing varieties of the patentee (because the patent was the only IP right), it could be considered to allow patentees within a transition period of 6 month to obtain a PBR for the affected varieties. Such scenario should be rare.

	establish a connection between process and plant.
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>	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.
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>	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.

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