



# Position

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on

## Intellectual Property Protection for plant-related inventions in Europe

### 1. Introduction

ESA is the voice of the European seed industry, representing those active in research, breeding, production and marketing of seeds of agricultural and ornamental plant species. It represents more than 30 national seed associations (and with that more than 1000 seed businesses in the EU, most of them SMEs) and more than 40 direct company members.

ESA's mission is to work for fair and proportionate regulation of the European seed industry, freedom of choice for customers in supplying seeds as a result of innovative, diverse technologies and production methods and for effective protection of intellectual property rights relating to plants and seed.

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ESA European Seed Association is representing the European plant breeding and seed industry which industry - by creating modern, innovative plant varieties – is contributing significantly to one of the basic needs of society: enough healthy food that is produced at reasonable prices in an efficient and environment-friendly way.

Innovative plant breeding thus has a great impact but it is a time-consuming and costly endeavour. Plant breeders are investing up to 20 % of their annual turnover into the development of new varieties, which is higher than in most other industries focused on research and innovation.

Plant breeding results in biological material, which is particularly easy to copy being generally self-reproducing. Therefore plant breeders require an effective intellectual property protection system. At the same time, access to all forms of plant material including commercially available protected plant varieties is indispensable for a successful plant breeding industry thus ensuring that it will always be based on as much genetic diversity as possible.

The World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights of 1994 (TRIPs) provides certain criteria concerning the availability, scope and use of Intellectual Property Rights and requires Members to set up a legal framework complying with such criteria. Regarding the protection of plant varieties, Article 27(3)(b) of the TRIPs Agreement provides for a choice between patents, an effective *sui generis* protection system or a combination thereof.<sup>1</sup>

Since decades European plant breeders have been benefitting from the *sui generis* intellectual property system of plant breeder's rights (PBR) based on the UPOV Convention which provides effective IP protection for new plant varieties as such and fits the specific nature and needs of the industry.

<sup>1</sup> Article 4(1)(a) and (b) of Directive 98/44/EC and Article 53(b) of the EPC.

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ESA considers the 1991 Act of the UPOV Convention to be the most suitable existing *sui generis* intellectual property system for the protection of plant varieties *per se*: on the one hand it provides for effective protection of plant varieties of all genera and species in order to obtain return on investment; and on the other hand it guarantees the continuous flow of improved plant varieties by safeguarding access to genetic variability through the so-called breeder's exemption.

This breeder's exemption is a key cornerstone of the UPOV PBR system. This compulsory exemption provides that all varieties protected by PBR can be used for further breeding and the resulting variety can be commercialized without any obligation towards the PBR holder. This feature can be regarded as a kind of "open source" system and has always been relied upon by breeders for further improvement on each other's varieties and boosted innovation in plant breeding.

Besides PBR also patents play an increasing and important role in the European seed and plant breeding sector. ESA has always supported the co-existence of all Intellectual Property Rights offering adequate protection for each kind of **inventive** activities in living matter and results thereof. However both the European Patent Convention (EPC) of 1973 and Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions clearly stipulate that plant varieties as such as well as essentially biological processes for the production of plants are excluded from patentability.<sup>1</sup> ESA fully supports these exclusions.

According to the definition in the Community Plant Variety Rights Regulation ((EC) No. 2100/94) – which definition is referred to in both Directive 98/44/EC and the Implementing Rules of the EPC<sup>2</sup> -, a 'plant variety' is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties. A plant grouping, however, which is characterized by a particular gene and not by its whole genome, is not covered by the CPVR and therefore not excluded from patentability, even if it comprises new varieties of plants.<sup>3</sup> This conclusion was also reached in the decision of the Enlarged Board of Appeal of the European Patent Office in the *Novartis case* in 2000<sup>4</sup> and confirmed more recently in the *Sunflower case*<sup>5</sup>.

This implies that while in theory plant varieties as such are excluded from patent protection, in practice – as a result of the specific nature of plant-related patents and of the above described cases – plant varieties often fall under the scope of certain patents. As the current European patent system does not provide for a breeder's exemption this blocks access to biological material for further breeding which material otherwise would be free for such purposes under PBR.

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<sup>1</sup> Article 4(1)(a) and (b) of Directive 98/44/EC and Article 53(b) of the EPC.

<sup>2</sup> Article 2(3) of Directive 98/44/EC and Implementing Rules 26-29 of the EPC which refer back to Directive 98/44/EC.

<sup>3</sup> This is also stated in Article 4(2) of Directive 98/44/EC.

<sup>4</sup> Case G 1/98, OJ 3/2000, 111.

<sup>5</sup> Case T 1854/07 of May 12, 2010.

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## 2. Safeguarding access and freedom-to-operate in the field of crossing and selection

To safeguard the necessary access to genetic variability for the development of new, improved plant varieties ESA is of the opinion that the following principles should apply:

**1. Free access to all plant genetic material for further breeding has to be safeguarded. In this respect plant genetic material should include commercially available material as well as legally obtained plant genetic material such as material from gene banks.**

**2. Breeding processes based on crossing and selection (i.e. essentially biological processes) are excluded from patentability. This principle must also be applied to biological material resulting from the application of such “essentially biological processes”.**

**3. The effect of any product patent on biological material must not extend to any biological material which has the same properties, but has been produced by means of an “essentially biological process” and independently, i.e. without using the patented material.**

As to the first principle, access for further breeding, ESA points out that this principle has already been implemented in the German and French patent laws (via an extended research exemption)<sup>6</sup> and will also be implemented in the patent law of the Netherlands soon.

As to the second principle, the Enlarged Board of Appeal of the European Patent Office has clarified in its recent decision in the *Broccoli* case<sup>7</sup> that non-microbiological processes containing or consisting of the sexual crossing of whole plant genomes and the subsequent selection of plants are not patentable under Article 53(b) of the EPC. It further specified that this principle does not change even if there are additional technical steps involved in the process where these technical steps serve merely to enable or assist the performance of the crossing or the selection steps.

ESA agrees with and supports the findings of the *Broccoli* decision.

Building upon this already existing exclusion from patentability of ‘essentially biological processes’ (i.e. breeding processes based on crossing and selection) ESA considers that biological material resulting from the application of such essentially biological processes should also be excluded from patent protection. In practice this means that a plant or plant trait should be patentable only if it is produced by a process which is not based on crossing and selection. This would be the case if, for example, a process consisting of genetic modification, technically induced mutagenesis, protoplast fusion or another technical process not based on crossing and selection is used. The decisive question for the patentability of biological material should therefore be the **process** which is used for the production of the biological material.

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<sup>6</sup> In the French *Code la Propriété Intellectuelle* this provision can be found in Article L. 613-5-3 which reads: “*Les droits conférés par les articles L. 613-2-2 et L. 613-2-3 ne s’étendent pas aux actes accomplis en vue de créer ou de découvrir et de développer d’autres variétés végétales.*” (Rights conferred by Articles L. 613-2-2 and L. 613-2-3 shall not extend to the acts performed in order to create, or discover and develop other plant varieties.)

In the German *Patent Gesetz* this provision can be found in Article 11(2a) which reads: “*Die Wirkung des Patents erstreckt sich nicht auf [...] 2a. die Nutzung biologischen Materials zum Zweck der Züchtung, Entdeckung und Entwicklung einer neuen Pflanzensorte [...]*” (The effects of a patent shall not extend to: [...] 2a. the use of biological material for breeding, discovery and development of a new plant variety type.)

<sup>7</sup> Decision in case G1/08 of December 9, 2010.

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“Working methods”, which are methods consisting in technical steps that may enable or assist one or the other steps of a breeding method<sup>8</sup>, can enjoy patent protection by themselves. However, given that such a working method – assisting only the steps of a breeding method - by itself can never result in a product, patent protection of such methods can in no way extend to the biological material.

As to the third principle, in order to fully safeguard freedom-to-operate in the field of crossing and selection, ESA considers that the effect of patents granted on plant-related inventions should not extend to biological material having the same properties as the patented material but produced independently, without the use of the patented material, and by a breeding process based on crossing and selection.

### 3. Patents and commercialization of new varieties

ESA is of the opinion that the commercial use of any new plant variety no longer expressing the function of patented elements should be free. However, the commercial use of new plant varieties expressing the function of a patented element, such as multiplication of propagating material in view of sale of this propagating material, requires the authorization of the holder of the patent right. On the other hand ESA considers that in any case acts required for obtaining PBR and / or listing of a variety should not be considered as commercial use for the above purpose.

In any event, ESA calls upon holders of patent rights to follow FRAND (fair, reasonable and non-discriminatory) conditions in their licensing policies.

### 4. ESA's activities

Besides deciding on a position on IP in the breeding industry, ESA also decided to engage in or continue to be engaged in some activities in order to create more clarity in the field of patents:

#### *4.1 Patent information*

When starting their breeding programs breeders should know whether the biological material they intend to use fall eventually under the scope of a patent application or a granted patent. Since currently there is no transparency on the patented status of biological material breeders might be discouraged to make use of one or the other material which, in the end, may slow down innovation in breeding significantly and constitutes a practical limitation of the breeder's exemption.

In order to improve transparency of patent information ESA proposes the setting up of a web-based database allowing breeders better information and thus a more informed decision regarding the material they use. Therefore, ESA calls upon patent holders to put information on the patented status of their varieties in a public database available on their own company websites at the moment when the relevant patent application is published. Furthermore, ESA proposes and will actively support the creation of a portal containing links to all relevant company websites for facilitating access to information to breeders.

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<sup>8</sup> Such as for instance the use of DNA-based markers for the selection of plants.

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#### *4.2 Raising the bar*

In order to make sure that the needs and specificities of the seed and plant breeding industry are taken into account and respected in the practice followed by patent offices and that the bar applied to the assessment of patentability criteria is sufficiently high ESA is engaged in regular bilateral exchanges of views with patent examiners of the European Patent Office and is of the opinion that such dialogues shall be organized at least once per year.