



BUNDESVERBAND DEUTSCHER PFLANZENZÜCHTER e.V.

BDP Position on the Principles for Patent Protection in Connection with Plant Breeding

BDP Requests the Limitation of Patent Protection to Technical Inventions

Plant breeding and new plant varieties are the essential basis for securing the food supply for a growing world population in times of climate change. The plant breeding industry in Germany – more than 100 mostly medium-sized companies – is a very innovative branch to which agriculture owes the wide selection of plant varieties they can choose from, an important asset for keeping their competitive edge.

Plant breeding is time-consuming and cost-intensive. The resulting commodity – seeds – is self-replicating and easy to copy. Effective protection of intellectual property rights is therefore vital to ensure the necessary return on investments.

Plant breeding is based on the continuous re-combination of genetic elements to combine the best features of already existing plant varieties into new, innovative and improved plant varieties. This re-combination of natural properties of a plant is the result of crossing two plants with each other. This means that the work of plant breeders builds on the achievements of others before them, and accordingly, plant breeders need to have access to plants and their genetic diversity.

There is potential for conflict between the needs to protect intellectual property on the one side and to access genetic material on the other side. It is imperative that this issue be addressed by an effective and balanced protection system. Such a system has already been created in form of the current plant variety protection legislation. The plant breeding exemption to the plant variety protection rights allows plant breeders to freely use protected plant varieties for breeding purposes – including the free marketing of the newly developed varieties. This system accelerates plant breeding progress and is the primary form of intellectual property protection for plant varieties.

The basic principles of the plant variety protection scheme are to be preserved; they must not be undermined.

However, plant variety protection does not cover any technical inventions in the fields of plant breeding or molecular biology. These technical inventions are of increasing importance; they need adequate protection under patent law.

A system of intellectual property rights that is optimized to promote innovation in plant breeding will require a balanced and clear definition of the interface between plant variety protection and patent protection.

In principle, the legislator has acknowledged this issue. There are a number of provisions in the so-called European Biopatent Directive 1998/44/EC and in the European Patent Convention (EPC) that are designed for regulating patents on biological material and the relationship between plant variety protection and patent protection.

The EU Biopatent Directive has adapted patent protection so as to accommodate biological issues, but mainly in view of technical processes, in particular genetic engineering (see Recital 2 of the EU Biopatent Directive). In recent years, however, new techniques have enabled a more precise description of the naturally existing genetic properties, including the sequencing of entire genomes, and on this basis, an increasing number of applications for patents on natural genetic traits have been filed and granted.

The fact that such patents have been granted is liable to create conflicts and to undermine the fundamental principles of plant variety protection, in particular the access to plants, i. e. to genetic diversity. This development is likely to slow down the breeding progress, to reduce the genetic diversity and to increase the dependence on the licensors. These issues could probably be mitigated by suitable tuition for patent officers on the specifics of plant breeding and plant research issues. However, the German Plant Breeders' Association (BDP) is of the opinion that such a measure would not be sufficient to solve the underlying problem.

It must be ensured that access to genetic diversity remains possible for plant breeders not only on paper, but also in practice – which means in a context of legal certainty, and free of discouraging financial encumbrances. We also need an acceleration in the pace of innovation in plant breeding. Therefore, the costs involved in getting intellectual property rights granted or enforced or in opposing them, as well as the costs of IP research, freedom-to-operate analyses, the licensing fees for patent-protected material etc. (i. e. the transactional costs) should be kept at the lowest possible level to free these funds for investments into development and innovation. It will not be sufficient to merely develop standard licence models or to create patent pools.

For these reasons, the German Plant Breeders' Association demands the following:

- 1) According to the decision in the Brokkoli I case (G2/07), no patents may be granted on plant breeding methods that are based on crossing and selection (essentially biological processes). Contrary to the decision in the so-called Brokkoli II case (G02/13), this principle needs to be also applied to biological material that has been created by means of such essentially biological processes. Patents on biological material may only be granted in cases where the biological material has been technically isolated or technically created in the sense of Article 3 of the Biopatent Directive.**

The decision in the Brokkoli I case has made clear that breeding methods which are based on the processes of crossing and selection are of an essentially biological nature and therefore not eligible for patent protection. The same principle should also apply to the biological material bred by means of such essentially biological processes, contrary to the decision in the so-called Brokkoli II case. The legislator has already acknowledged this when drafting the text of the EU Biopatent Directive. Article 3 of the EU Biopatent Directive stipulates that biological material can be patentable even if it previously occurred in nature provided it is isolated from its natural environment or produced by means of a technical process. This means that the isolation and the production by means of a technical process are the decisive criteria to determine whether or not it is a patentable invention.

Crossing neither **technically isolates** biological material from its natural environment, nor is it a form of **technically production** of biological material. The fact that plants are being created by means of crossing therefore cannot warrant the patentability of a process. In November 2016, the EU Commission also clarified this in its Notice (2016/C 411/03) on the Biopatent Directive. If this clarification turned out to be of no legal avail, the Biopatent Directive would need to be amended.

Based on this clarification of the EU Commission, the Administrative Council of the European Patent Office has introduced Rule 28 II into the Implementing Regulations to the Convention on the Grant of European Patents. This rule excludes plants obtained by means of an essentially biological process from patentability. BDP had strongly welcomed this rule. Meanwhile, the decision of the Technical Board of Appeal in the appeal concerning Patent EP2753168A1 has declared this rule to be in contradiction to Article 53 b) of the European Patent Convention. Therefore, BDP sees the

urgent need to revise Article 53 b) of the European Patent Convention so as to provide for the described exclusion from patentability.

- 2) The effect of a product patent effectively granted according to the principles of the above point 1) must not extend to biological material that has the same properties, but has been obtained independently by means of an “essentially biological process”.**

The protection of product patents for biological material applies irrespective of the means by which the material has been obtained. This so-called absolute substance protection encompasses any biological material with the patented property. Whenever biological material can be obtained in various different ways, e.g.

- 1) by means of a technical process and
- 2) by finding a natural mutation and/or
- 3) by means of crossing biological material that preexisted in nature,

the effect of the patent must not extend to biological material that has been obtained through an essentially biological process and without the use of the patented material. Otherwise, this protection would be in contradiction to Article 3 of the EU Biopatent Directive according to which biological material basically can only be considered as a patentable invention when isolated or obtained from its natural environment through a technical process. In line with the exclusion from patentability laid down in Rule 28 II of the Implementing Regulations to the Convention on the Grant of European Patents, the Administrative Council of the European Patent Office had advised patent officers to grant patents on products obtained by means of a technical process only with a so-called “disclaimer”. This disclaimer prevents that the patent protection also extends to products with the same properties that have been obtained by essentially biological processes. However, in its decision in the proceedings on patent EP2753168A1, the Technical Board of Appeal repealed this recent, reasonable improvement in the delimitation between patents and plant variety.

- 3) Patents granted in line with the principles under points 1 and 2 that extend to biological material should not restrict access to breeding purposes. The possibility to use patented material for breeding purposes as provided for in the German and French Patent Acts should apply throughout Europe. The marketing of patent-protected biological material, however, should still require the consent of the patent holder.**

The function/effect of genes is only expressed when it is a part of a living cell / a living organism. This means that their commercial exploitation is not possible except in form of an organism. Hence, a patent granting substance protection for individual genes will always indirectly entail a protection title on the cell/the organism where the gene takes effect.

As a result, there are restrictions for the use of such an organism in breeding. The German legislator has acknowledged this fact and has introduced the research exemption into the German Patent Act. Under this exemption, it is possible to use plants with patent-protected properties in breeding. If the patent-protected property can still be found in the newly developed plant variety, a licence of the patent holder will be necessary before placing it on the market. In this respect, the research exemption of the patent legislation is not as wide as the breeding exemption in plant variety protection. France and Switzerland have included similar provisions into their patent law. However, on Community level, no such research exemption exists, but should be created.

BDP is of the opinion that an amendment of Article 53 b of the European Patent Convention and possibly a revision of the European Biopatent Directive would be needed to comply with this request. With the revision of the national Patent Act, the German legislator has already clarified that patent protection is limited to technical inventions. What is now urgently needed is that Germany

presses for the introduction of a corresponding harmonised provision on the European level to ensure a balanced intellectual property regime that promotes innovation in plant breeding.

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