CIOPORA

UNITING BREEDERS
PROTECTING INNOVATION

CIOPORA POSITION ON PATENTS FOR PLANT-RELATED INVENTIONS

August/September 2017

NTERNATIONAL COMMUNITY OF BREEDERS OF ASEXUALLY REPRODUCED ORNAMENTAL AND FRUIT PLANTS

CIOPORA POSITION ON PATENTS FOR PLANT-RELATED INVENTIONS

as approved by written procedure in August/September 2017

KEY STATEMENTS

- **It is the opinion of CIOPORA that, as a matter of principle, plant related inventions should not be treated so differently that they are essentially deprived of patent protection.**
- **CIOPORA supports the view that the mere discovery in nature of existing plant material with interesting characteristics would not, as such, be patentable.**
- **It is the position of CIOPORA that technical processes containing technical steps, even when combined with biological steps, are patentable, particularly if the technical step constitutes the essence of the invention, provided the processes are new and inventive**
- **CIOPORA is of the view that the so-called "new plant breeding techniques" of inter alia oligonucleotide directed mutagenesis (ODM), zinc finger nuclease (ZFN) technology, transcription activator-like effector nucleases (TALENs), CRISPR/Cas systems, cisgenesis, intragenesis and reverse breeding are all processes which contain a technical step that by itself (i.e. without crossing) introduces or modifies a trait in a plant's genome and are therefore not essentially biological processes.**
- **A DNA sequence from a plant that is publicly available, such as in its natural environment, shall not be considered to be novel as such. However, the use of such DNA sequences isolated from their original plant genome for a given novel function can in principle be patentable.**
- **CIOPORA is of the opinion that patent protection should be available for novel traits, biological material and plants comprising such traits, provided that the further requirements for patentability are fulfilled. The use of DNA sequences isolated from their original plant genome for a given function can in principle be patentable.**
- **CIOPORA is in favor of a breeders' exemption, both in plant variety rights and patent law, allowing plant breeders to use protected plant material for the purpose of breeding or discovering and developing a new plant variety. However, the subsequent commercialization of a plant comprising the patented invention should require the authorization of the patent holder.**
- **It is important for ornamental / fruit breeders to secure quick and efficient access to patented technology under fair, reasonable and non-discriminatory ("FRAND") terms. To this end, CIOPORA supports the establishment of a licensing platform and dispute resolution mechanism.**

Full Text:

Plant breeding in the fruit and ornamental sectors is tantamount to constant innovation, both in terms of breeding methods and of plant material with unique characteristics resulting from said methods. The means used to achieve such innovation are not limited to traditional plant breeding based on crossing

and selecting. Innovation is also increasingly achieved through the use of biotechnology and advanced breeding techniques based on DNA markers or genome editing.

Whereas our industry has, for decades, relied on the availability of *sui generis* plant variety rights under the UPOV Convention or similar protection mechanisms such as the U.S. Plant Patent system, investments into modern breeding technologies and the ever-increasing use of sophisticated biotechnological tools call for an effective protection of inventions in that area, in order to add value to the entire chain. Neither of the aforementioned systems, however, are designed to fully protect such inventions, as their scope is limited mainly to the protection of propagating material of plant varieties, respectively asexually reproduced plants, and therefore do not cover any plant related inventions beyond the plant variety / plant level. In general, the (utility) patent system can effectively protect such inventions.

CIOPORA is, however, of the opinion that an inevitable rise in the use of patents to protect plant related innovations beyond the variety level should not negatively affect the access to and availability of protected plant material for further breeding purposes. This principle has been inherent to our industries from the outset under the so-called "breeders' exemption" and should continue to apply, regardless of the means of protection chosen. However, CIOPORA is adamant that a sufficient incentive is vital to foster innovation.

1. Patentable subject matter

a) Patent protection should be available for plant related inventions, as it is for other inventions

CIOPORA has always supported the strong protection of industrial property in all fields of research including biotechnology[1]. CIOPORA, therefore, is of the opinion that in general all inventions which fulfill the requirements for patentability (novelty, industrial application, non-obviousness / inventive step) should be patentable.

This position resonates with the universally acknowledged principle, enshrined in the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS"), that patents should be available for any invention, whether products or processes, in all fields of technology, without discrimination as to the field of technology, provided that they are new, involve an inventive step and are capable of industrial application.

It is the opinion of CIOPORA that, as a matter of principle, plant related inventions should not be treated so differently that they are essentially deprived of patent protection.

b) Inventions should have technical character to be patentable

CIOPORA supports the basic principle underlying the patent system that, for something to be considered an "invention", it must have some form of technical effect or character.

For the ornamental and fruit breeding industries, the most relevant effect of this principle is that mere discoveries and aesthetic creations are not considered to have technical character and therefore are not considered patentable.

DISCOVERIES

[1] See e.g. the CIOPORA Green Paper, page 52.

CIOPORA supports the view that the mere discovery in nature of existing plant material with interesting characteristics would not, as such, be patentable. This is similar to the situation under PBR laws, where protection is only open to varieties that have (at least) been "discovered and developed"; mere discovery is not enough.

However, as soon as the biological material in question is isolated from its natural environment or if it can be produced by means of a technical process, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ("Biotech Patent Directive") allows it to be patented.

Decisions from Australian[2] and US[3] courts in the so-called Myriad cases have cast doubt on that principle, as it was held that DNA sequences isolated from naturally occurring biological material are not patentable subject-matter, as the mere fact that they are isolated from their natural surroundings does not take away the fact that they are essentially a discovery.

CIOPORA acknowledges the existence of these decisions and their effects in Australia and the US. CIOPORA also acknowledges the common European Patent practice in that genetic material, removed from its natural environment, should have a described function to be patentable.

CIOPORA is of the opinion that DNA sequences isolated from naturally occurring biological material as such are to be considered discoveries and therefore not patentable subject-matter. The use of DNA sequences isolated from their original plant genome for a given function can in principle be patentable.

CIOPORA is of the opinion that plants, that contain such DNA sequences by nature, i.e. without human interference such as crossing and selection, should not be patentable, but be regarded as discovery.

AESTHETIC CREATIONS

It is CIOPORA's position that the mere fact that a plant serves an aesthetic purpose does not render such plant unpatentable.

It is CIOPORA's position that, to the extent that plants are produced by means of a technical process, which links the aesthetic effect to a technical effect, such plants should not be excluded from patentability

c) Breeding methods and essentially biological processes

A process consisting solely of crossing and selecting plant material is generally considered to lack any technical teaching and therefore is not considered patentable. In that regard, TRIPS provides the possibility to exclude from patentability so-called "essentially biological processes for the production of plants … other than non-biological and microbiological processes".

In Europe, under the European Patent Convention ("EPC"), this principle was confirmed by the 2010 decisions from the European Patent Office's Enlarged Board of Appeal in cases G1/084 ("Tomato I") and G2/075 ("Broccoli I"). CIOPORA supports the findings of that Board that pure breeding processes consisting of crossing and selection are excluded from patentability.

[2] D'Arcy v Myriad Genetics (2015) HCA 35.
[3] Association for Molecular Pathology v Myriad Genetics 135 S. Ct 2107 (2013).
[4] EBoA 9 December 2010, G1/08.
[5] EBoA 9 December 2010, G2/07.

It is the position of CIOPORA, however, that technical processes containing technical steps, even when combined with biological steps, are patentable, particularly if the technical step constitutes the essence of the invention (e.g. if a human-technical intervention or step enables or assists the crossing or selecting), provided the processes are new and inventive, it being understood that when a process contains the steps of crossing and selection, the mere fact that the selection step is inventive, does not make the process a technical one. Providing patent protection only for the technical step is in most cases insufficient because the scope of protection does not cover the breeding process and breeding result and the technical step in many cases can easily be circumvented.

It is CIOPORA's opinion that, as far as the EU is concerned, this is in line with both the EU legislator's definition of an "essentially biological process" as a process consisting **entirely** of natural phenomena such as crossing or selection[6], and the Commission's initial intention[7] to provide patent protection for processes in which human intervention consists of more than selecting an available biological material and letting it perform an inherent biological function under natural conditions.

In any event, CIOPORA is of the view that the so-called "new plant breeding techniques" of inter alia oligonucleotide directed mutagenesis (ODM), zinc finger nuclease (ZFN) technology, transcription activator-like effector nucleases (TALENs), CRISPR/Cas systems, cisgenesis, intragenesis and reverse breeding are all processes which contain a technical step that by itself (i.e. without crossing) introduces or modifies a trait in a plant's genome and are therefore not essentially biological processes within the meaning given to that term by the Enlarged Board of Appeal in the Tomato and Broccoli I cases.

d) Patentability of plant material

The value of innovation in the plant breeding sector manifests itself most ostensibly in the plant material resulting from the application of the chosen breeding method. Innovation can e.g. reside in the development of a new plant variety, the identification and introgression of new specific characteristics or traits or the fabrication of gene construct to carry foreign genetic material.

GENETIC MATERIAL/DNA SEQUENCES

A DNA sequence from a plant that is publicly available, such as in its natural environment, shall not be considered to be novel as such. However, the use of such DNA sequences isolated from their original plant genome for a given novel function can in principle be patentable.

TRAITS

The presence of a specific trait in a plant can e.g. be the result of genetic modification, mutations (induced or naturally occurring) or the identification of existing traits in different environments (native traits). Traits often constitute the main component of innovation and considerable investment is made in the area of trait research. However, once a variety with such a trait is made available on the market, the trait may be relatively easily transferable to other varieties[8].

Accordingly, sufficient protection for trait innovation should be in place. Such protection is currently only available under the patent system. However, in many countries the availability of patents for plant product innovations is made dependent, by either legislators, courts or administrative bodies, on the

[6] Article 2(2) of the Biotech Patent Directive.
[7] 1988 Commission Proposal for a Council Directive on the legal protection of biotechnological inventions
[8] With the transfer to a different genetic background, even if PVP protection for a variety comprising the trait is in place, the trait itself escapes the protection provided by the PVP today.

manner in which the traits in question were created (GM, man-made traits, native traits).

CIOPORA is of the opinion that patent protection should be available for novel traits, biological material and plants comprising such traits, provided that the further requirements for patentability are fulfilled. The use of DNA sequences isolated from their original plant genome for a given function can in principle be patentable.

CIOPORA takes note of the 1 July 2017 changes to the EPC Implementing Regulations excluding from patentability plants and animals exclusively obtained by an essentially biological breeding process.

It is the opinion of CIOPORA that, legally, the binding Tomato II / Broccoli II decisions[9] of the European Patent Office's Enlarged Board of Appeal provide the only correct interpretation on this matter, as was also confirmed by the Dutch court of The Hague in the radish cress case.[10]

To the extent that products obtained from essentially biological processes were to become unpatentable in the future, CIOPORA calls upon the legislator to strengthen the plant variety rights system so that such products, provided they are plant varieties, at least receive sufficiently strong protection under that system.

2. The research and breeders' exemptions

CIOPORA calls for a worldwide harmonized **research exemption** which allows research on the patented invention including for the purpose of improving the invention. The mere use of the patented invention as a research tool (research "with") should not be permitted. The research exemption should apply for plant related inventions in the same way as for any other inventions.

Additionally, CIOPORA is in favor of a **breeders' exemption**, both in plant variety rights and patent law, allowing plant breeders to use protected plant material for the purpose of breeding or discovering and developing a new plant variety. However, the subsequent commercialization of a plant comprising the patented invention should require the authorization of the patent holder. However, any commercial use of a plant variety which no longer contains the patented characteristics should be automatically exempted from infringement.

3. Quality of patents

In order to guarantee high-quality patents, the requirements for patentability must be strictly observed. In fact, a stricter examination and scrutiny must take place in order to avoid that sub-patentable developments obtain patent protection. Particularly, a too lenient approach to the requirement of non-obviousness and inventive step damages the reputation of the patent system.

In order to provide for high-quality, fast, cost-effective and transparent examination and opposition procedures, the patent offices and patent courts must be well equipped in regard to both staff and equipment.

4. Information about and access to patents

For plant breeders, it is important to know whether the material used for further breeding purposes is patented and, if so, which patents relate to which plant varieties. To increase transparency in this area, and in view of the increasing amount of patents in the ornamental / fruit sectors, CIOPORA calls for

[9] Enlarged Board of Appeal decisions of 25 March 2015 in cases G 2/12 and G 2/13
[10] District court The Hague, 8 May 2013, [2013] BIE 276.

the establishment of an online database with as broad coverage as possibly feasible allowing breeders to verify, per variety / trait, whether a patent is in place.

Furthermore, it is equally important for ornamental / fruit breeders to secure quick and efficient access to patented technology under fair, reasonable and non-discriminatory ("FRAND") terms. To this end, CIOPORA supports the establishment of a licensing platform and dispute resolution mechanism.

However, it is crucial that costs for any IP Protection do not prevent breeders and inventors, particularly small and medium sized enterprises, from making use of the protection systems.