

Legal protection of plant biotechnological inventions

P.T. VANHALA, T. PEHU, H.G. GYLLENBERG

*Department of Microbiology, University of Helsinki,
SF 00710 Helsinki, Finland*

Abstract. Within biotechnology, plant production is regarded as one of the most promising adaptations. New plant breeding methods are considered to better fulfil the requirements set on patentability than the traditional breeding methods. In Europe, a plant variety can be protected by special legislation. The present patent laws in Europe are not applied to plant biotechnological inventions. The United States has three systems under which new varieties of plants may be protected. These include The 1930 Plant Patent Act, The 1970 Plant Variety Protection Act and The 1952 Patent Statute. Companies that have specialized in plant breeding and organizations representing the industrial countries recommend improvements to the legal protection. On the other hand, farmers and the developing countries are against better protection.

Index words: plant patent, breeder's rights

1. Introduction

Within biotechnology, plant production is regarded as one of the most promising adaptations. Today, several types of biotechnological breeding methods are used in plant breeding. These new methods are considered to fulfil better the requirements set on patentability than the traditional breeding methods. Against this background, extension of the patent protection to cover also new plant varieties has become a topic of current interest. Because of the fast development of biotechnological breeding methods it has become necessary to apply patent legislation in a very flex-

ible way all over the world. The trend seems to continue also in the future. Therefore, issues on legal protection of plant breeding methods are relatively problematic to deal with.

The purpose of this study is to review the current legal state of the plant breeder's rights and patent legislation in Western Europe and in the United States. The first part of the study examines international agreements and national patent laws, the second part the need to further develop the legal rights from the viewpoints of different interest groups.

The study is a review of literature collected from databanks (DIALOG and DIMDI), international agreements and other juridical publications.

2. The protection of plant varieties in international agreements

2.1. *The Strasbourg Convention*

Unification of European patent laws was started in the late 1950s. Due to the problematic nature of the task, questions concerning the patenting of plant varieties were not discussed at the conference (BEIER and STRAUS 1986). The negotiations led to the Strasbourg Convention which was signed in 1963.

Article 2 of the Convention statute:

"The Contracting States shall not be required to grant patents for:

a. . . .

b. Plant or animal varieties or essentially biological processes for production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

This article has had great significance on the patent protection of plant varieties, since it has been transferred as such to the European Patent Convention of 1973, appearing there as Article 53. Furthermore, the countries participating in the European Patent Convention have adopted this article in the same or essentially the same form in their national patent laws.

2.2. *The UPOV Convention*

When the inapplicability of patenting for plant variety protection was recognized, a new protection procedure was created for that purpose. It was signed as the UPOV Convention (UNION POUR LA PROTECTION DES OBTENTIONS VEGETALES) in 1961.

This convention aims to recognize and to secure the breeder's rights regarding a new

plant variety (Article 1). Each contracting state guarantees the breeder's rights by granting a special title of protection (Article 2).

The holder of the privilege possesses the monopoly of commercial production, supply and trade of propagation material. The term "propagation material" covers, by definition, the entire plant (Article 5). Because the protection applies to propagation material, it does not cover other uses of plant material or harvest. The convention permits the production of propagation material for the farmer's own needs.

The plant variety, for which protection is sought, should be distinguishable from previously known varieties, both morphologically and physiologically. The variety should be sufficiently homogeneous and stable in its essential characteristics through repeated propagation cycles (Article 6).

In principle, the breeder's rights can be applied to all botanical genera and species (Article 4). Yet, due to the shortness of resources for the study of varieties, each decides independently whether or not a new plant family will be included within the scope of protection. Further breeding of the protected variety is permitted, as is the case with commercial utilization of its results (Article 5).

It is decreed by Article 2 of the Convention that a contracting state may protect a variety of a certain family or species, either by a patent or by the breeder's rights, but not by both. With the membership of the United States in 1978 Article 37 was included in the Convention. This article permits double protection in instances where both forms of protection have been granted before a state has joined the Convention, which was the case with the United States.

2.3. *The European Patent Convention (EPC)*

2.3.1. Patentability

Articles 52 and 83 of the European Patent Convention present a list of criteria of patentability of an invention (ANON. 1981).

These are as follows:

1. inventive step
2. industrial application
3. novelty
4. repeatability

Clause 2 in Article 52 determines the instances when patents cannot be granted. These are either abstract or non-technical by character. According to the GUIDELINES FOR EXAMINATION IN THE EPO (European Patent Organisation) 1987, Article 52 presumes an invention to be both concrete and technical by nature (ANON 1985). A plant variety does not meet these criteria because it is difficult to encompass the concept of variety into a concrete definition. In the case of plant material, however, this kind of definition is possible. Inversely, the concepts of plant variety and plant material are difficult to conceive as technical by nature.

According to Article 57, an invention must be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. The Guidelines of the EPO suggest that "industry" should be understood in a broad sense.

The requirement of repeatability is presented in Article 83. It states that an invention can be carried out by the person skilled in the art on the basis of the patent application. As for plant varieties or plant material, the requirement of repeatability can be met by a deposit practice defined in the Budapest Treaty. This treaty concerns the international acknowledgement of the micro-organism deposit practice. The EPC decrees that a patented micro-organism must be deposited in an internationally acknowledged deposit institute (EPC RULE 28). Some institutes have agreed on the acceptance of plant cell cultivations and seeds to be deposited as micro-organism (ANON. 1986).

Article 53a excludes from patent protection inventions which could be contrary to "ordre public" or morality. By the correct interpretation of this point the granting of ethically questionable patents can be prevented.

Article 53b excludes from patent protection plant varieties and essentially biological processes used for the production of plants. The greatest controversy of patent protection of plants rises from this point. Because Article 53b uses the two concepts of plant and plant variety, they must be regarded as different in bearing (LOMMI 1987a).

2.3.2. Plant variety

The rule of excluding plant varieties from patent protection conforms with the prerequisites of patentability, because the concept of plant variety lacks a precise definition. A plant variety is generally defined on the basis of three features, i.e. distinguishability, uniformity and stability. In the decision known as T49/83 CIBA GEIGY the Technical Board of the Appeals of the EPO defines the distinction between plant variety and other plant material. Thereby a plant variety is "a multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle".

Experts in this field tend to support the patentability of plants on condition that this claim does not directly concern plant varieties. In its decision (T49/83 CIBA GEIGY) the European Patent Office made a statement that the items excluded from patent protection are plant varieties solely, not plants in general.

The decision was made in association the EP Application 10588, where the following claims were presented:

"Claim 13: Propagating material for cultivated plants, created with an oxime derivative according to Formula 1 in Claim 1.

Claim 14: Propagation material according to Claim 13, characterized in that it consists of seed."

It was decreed in the decision that propagation material treated with a chemical is patentable with the restriction that the claim does not concern a specific plant variety.

2.3.3. The essentially biological process

The EPC denies patent protection for the essentially biological processes used for the production of plants. It is to be noted that in this context the term plant is used instead of plant variety. This leads to the conclusion that the rule which denies patent protection for plant varieties does not cover plants in general.

The essentially technical processes of plant production are patentable. In the Guidelines for Examination in the EPO, the essentially biological and the essentially technical processes are delineated. According to the guidelines, the amount of technical intervention by man is a decisive factor. If such intervention plays a significant role in the outcome, the process would not be excluded. Thereby, a process of treating a plant to improve its properties or to improve its growth, e.g. a method of pruning a tree, would not be an essentially biological process. Although a biological process is involved, the essence of the invention is technical.

The classical breeding methods based on crossbreeding and selection cannot, according to the instructions, be patented, whereas those using biotechnical processes are patentable since all these procedures require technical intervention by man. Similarly, most of these processes can be classified as chemical.

2.3.4. The microbiological method

According to the EPC, a patent can be granted to a microbiological process or the products thereof. Biotechnical plant breeding processes are either macro- or microbiological by nature, and it is not easy to distinguish between the two. The problems of distinction can be illustrated by the EP Application 122791 in which claims are presented for:

- a DNA shuttle vector comprising T-DNA. . .
- a method for genetically modifying plant cell. . .

- a plant, a plant tissue, or a plant cell produced according to the claimed method.

Both the national patent laws and the international agreements have been avoiding the definition of the term micro-organism. In the international patent classification (C 12, Note 2) items such as viruses, undifferentiated plant and animal cells and protozoa are also included in the concept of micro-organism (ANON 1985). In The Guidelines for Examination in the EPO, microbiological processes include in addition to technical processes using micro-organisms also processes for the production of new micro-organisms, e.g. gene technological processes. The absence of definition of the terminology from patent legislation has led to the practice of using the term "microbiological process" to signify the DNA-techniques and protoplast fusions alongside with microinjections and other gene technological processes (BEIER and STRAUS 1986).

3. Plant variety protection in national patent laws

3.1. The United States

The United States has three systems under which new varieties of plants may be protected:

- The 1930 Plant Patent Act (PPA)
- The 1970 Plant Variety Protection Act (PVPA)
- The 1952 Patent Statute

The Plant Patent Act (PPA)
(35 USC 161—164)

The PPA grants patent protection for asexually propagated plant varieties (Sec. 161). The Act was confined to asexual propagation only, because at that time it was believed adequate uniformity and stability can be maintained only by this reproduction method. Patents are also granted for discoveries that are made from the uncultivated state.

The requirements of the PPA concerning novelties and distinction are in conformity with the General Patent Statute. However, Sec. 162 decrees that, as to description, the requirements of Sec. 112 do not cover plant patent applications. A description of the variety as complete as is reasonable is considered sufficient. Deposit of propagation material is not required. The application cannot contain more than one claim, which should concern the variety to be patented (Sec. 162). A granted plant patent prohibits others from asexually reproducing the plant.

The number of granted plant patents rises to about 6000 at present, with an increase of about 400 patents per year (Van HORN 1987).

The Plant Variety Protection Act (PVPA)
(7 USC 2321—2583)

Growing interest in the protection of plant varieties propagated from seeds led to the enactment of the Plant Variety Protection Act in 1970. This Act provides protection similar to the patent protection for sexually propagated plant varieties. With the entrance of the USA into the UPOV Convention in 1980, this was amended to conform with the UPOV. The plant breeder's rights have now been granted for about 2000 plant varieties in the USA, while the number of new cases is about 200 per year (Van HORN 1987).

The Patent Statute (35 USC 101)

The United States' Patent Statute decrees, in Clause 101, that patent protection can be granted for any new and useful process, machine, manufacture, or composition of matter, or any useful improvement thereof. No industrial application of the invention is not required, nor is its technical character emphasized the way it is in Europe.

A patent case EX PARTE HIBBERD 1985 extended the General Patent Statute to cover also plant varieties that are subject to the PVPA. The item discussed was a variety of maize which produced high quantities of tryptophan. Cell lines with high quantities of tryptophan were selected and regenerated into

whole plants. The claims were made for seeds, cell lines and plants (HIBBERD 1985). The claim concerning the plant was as follows:

Claim 249: "A maize plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight, wherein the seed is capable of germination into a plant capable of producing seed having an endogenous tryptophan content of at least about one-tenth milligram per gram dry seed weight."

It was decided in the course of the process that, although this invention belongs within the scope of the PVPA, normal patenting practice may be applied. Consequently, a patent was granted to this invention (US 4581847).

3.2. *The national patent laws in Europe*

The Strasbourg Convention, which took shape through negotiations on the conformity of patent legislation, did not exclude plant varieties from patent protection. Instead, it left the matter to be decided in each country separately. Among the contracting states, FRG, France, Belgium and Spain have decided for the patentability of plant varieties that are not included in their national legislation on breeder's rights (STRAUS 1987). Consequently, patents have been granted in West Germany for the hybrid to tomato and potato (DE 2842197) and for the tetraploid camomile (DE 3423207).

The definitions of patentable inventions are uniform in the Scandinavian patent legislation on the lines included in the Strasbourg Convention. The Scandinavian countries act in accordance with the patenting practices of the EPO, amending their decrees only when the decrees of the EPC are amended (LOMMI 1987b).

Finland and Norway are in principle more free to interpret of the present patent legislation, because they have not signed the UPOV Convention. In this case, plants appear to be patentable, presuming that they meet the other

requirements of patentability and are not classified as plant varieties (HJELT 1987).

4. The need to improve plant variety protection

4.1 The plant breeder's viewpoint

Plant breeders using the traditional breeding methods appear to be satisfied with the breeder's rights and the protection provided by them. The right to further breed is particularly emphasized by the breeders.

The attitude of small breeding companies is cautiously positive towards improving the plant variety protection by patenting. A patent would provide better protection than the breeder's rights. By a single application, patent protection can be sought for several different varieties and parts of plants. Moreover, it is less costly to apply for a patent than for breeder's rights, at least in the United States (LESSER 1986a).

Statistics from 1980 show that in the United States the number of new wheat, soybean and cotton varieties introduced annually was 3–6 times higher after the enforcement of the breeder's rights than before (BERLAND and LEWONTIN 1986). Private investment in plant breeding was also tripled in ten years since 1970, the year of enforcement of the breeder's rights (BARTON 1982). Hence, the number of new plant varieties launched to the market will be augmented with the protection of varieties. Yet, the real value of breeding work cannot be estimated by this fact, because the varieties introduced by private companies tend to resemble each other closely in their characteristics. Plant breeders fear that such cosmetic breeding would increase if patents are granted for plant varieties. Judging by the effects of the breeder's rights, this is to be expected (LESSER 1986b).

The patenting of plant varieties would prevent the free use of a protected variety for plant breeding. Breeders using the traditional methods stand for the viewpoint that plant varieties should remain free for utilization in

plant breeding, regardless of the methods by which they have been produced (MASTENBROEK 1985). According to this view, a certain gene, for example, could be patented, but when transferred into a plant, patent protection no longer would be applicable (DICKSON 1985).

A more positive view in the question of patentability of plant varieties is taken by those breeders who apply biotechnological breeding methods. They claim that the special characteristics of the biotechnological breeding methods are not adequately appreciated in the protection policy based on the breeder's rights. This is due to the fact that, at the time the breeder's rights were enacted, these techniques were not known. Breeders find it unjust that the results of the work demanding great investment should remain free for any utilization. For example, when plant variety with a certain resistance is developed, protection is sought for all varieties produced by the same invention, i.e. the gene causing the resistance. However, this protection cannot be provided by the breeder's rights.

In most countries where the legal position of plant breeders has been improved, plant breeding is mostly practiced by private companies. The patenting of plant varieties would lead to the disappearance of unprotected varieties from the market. It is suspected that varieties created by public means might eventually fall into private patenting (BARTON 1982). It is an alarming prospect for plant breeders that the generalization of biotechnological breeding methods, together with the tightening protection of plant varieties, might lead to the concentration of all plant breeding activity into the hands of large companies (DICKSON 1985).

The improved protection has benefited plant breeding companies. Private breeding activity in England had met with several difficulties before the enforcement of the law that guaranteed the breeder's rights (BARTON 1982). Previously the Government had a major role in the breeding activity, but the law

has resulted in a significant rise in private breeding activity (ARO 1977).

4.2. *The seed producer's viewpoint*

It is necessary for the seed company to produce seed of adequate quality at lower costs than the farmer does or, alternatively, prevent the farmer from using his own harvest as seed. This can be done by producing sterile seed in the manner of the hybrid varieties, or by patenting the seed. The absence of patent protection has partly contributed to the great rise in the use of hybrid varieties (BERLAND and LEWONTIN 1986).

Plant breeding and seed production usually take place in separate institutes. Where the breeder's rights are applied, the seed producer is obliged to pay royalties to the breeder for the right to utilize the variety. These costs are transferred to the seed price, to be paid by the farmer. However, the market price of the seed must not exceed the limit after which it becomes more profitable for the farmer to produce seed for his own needs.

After the enforcement of the breeder's rights in England, many seed producers went bankrupt. The new law forced them to raise seed prices, which caused them difficulties in marketing the seed. Seed companies tried to evade the law by producing seed from the farmers own harvests, leaving the breeders without royalties. Plant breeders have made efforts to prevent this. In France, for instance, plant breeders managed in 1985 to enforce a law prohibiting this kind of activity (BERLAND and LEWONTIN 1986).

Seed producers are generally in favor of the extension of patent protection to cover also plant varieties. The American Seed Trade Association (ASTA) supports the patenting of plants. It also supports the simultaneous application of patenting and breeder's rights (MURPHY 1987). Patenting is supported by the argument that it would prevent farmers from using their own harvest as seed. This, again, would accelerate the introduction of new varieties and promote breeding activity.

The concentration of seed production into a few large companies is a prevailing trend in the USA. In 1980, the large breeding companies were responsible only for 20 % of all patent applications concerning plants, but now an increasing number of small companies are being fused into large ones (BARTON 1982). Yet, it is difficult to show whether this is due to general industrial trends or to the improved protection of plant varieties.

Companies that have actively invested in plant biotechnology are increasingly purchasing seed companies as a means of effectively launching new varieties to the market (ROSENQVIST et al. 1987). The heavy investments give special weight to the demand for protection. In the United States, large seed companies have presented these demands for several years already (LESSER 1986a). The present European legislation seems to be inadequate especially for the protection of plant varieties.

Companies applying biotechnological processes stand for the view that the breeder's rights do not in any circumstances provide adequate protection for plant varieties in the field of biotechnology. The breeder's rights are only applicable to the traditional breeding techniques for which they were originally designed. The companies claim the right to decide independently on the form of protection. Special dissatisfaction is aroused by the right for further breeding, because a monopoly could easily be evaded by insignificant amendments in a variety.

5.3. *The farmer's viewpoint*

Facing the improving variety protection, farmers are concerned about the rising seed prices. There is also the fear of the number of cultivated plant varieties to reduce as a consequence of the protection. Large homogeneous monocultures are especially vulnerable to crop damage. The patenting arrangement would cause an impoverishment in the choice of varieties through the concentration of seed production. This process leads to the loss of

valuable genetic material through the disappearance of old varieties (BELL 1985).

4.4. *The international situation*

4.4.1. The industrial countries' viewpoint

The OECD report, *BIOTECHNOLOGY AND PATENT PROTECTION 1985*, supports the improvement of plant variety protection by patenting. The report exhorts governments to seek possibilities for better protection of plants produced by the gene technological methods. It is further proposed that breeders be given the right to choose the form of protection between patenting and breeder's rights.

The WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) has delineated the present situation of protection policies within the field of biotechnical inventions. The results have motivated a list of possible solutions for the ambiguous points. Thereby:

- all biotechnological inventions should be considered patentable,
- the patenting of plants should be possible at least as far as plant varieties are not concerned, and
- the protection of living material should cover subsequent generations, too (ANON. 1985).

4.4.2. The developing countries' viewpoint

There has been strong criticism on the part of the developing countries against plant variety protection, in fear that it may promote the monopoly of multinational companies on food production (DIXON 1985).

The UNITED NATIONS FOOD AND AGRICULTURAL ORGANIZATION (FAO) presents the viewpoint that seeds, along with other plant material, are a common heritage of mankind, and should thus be exploitable by anyone. The enforcement of patent protection is assumed to reduce breeding activity

funded by public means which is the form of breeding activity that has the greatest bearing for the developing countries.

5. Results and conclusions

In the United States, where it is possible to protect a plant with a patent or the breeder's rights, the patent law is better adapted to the development of biotechnology than in Europe. As far as EPC is concerned, the patent legislation still seems to be relatively unsettled. The reformation process of legislation appears to be so slow that, in the present situation, the interpretation of the law has to be as flexible as possible.

Efforts have been made to improve the patent protection of plant by a new interpretation of such legal expressions as "a plant variety", "a microbiological method" and "an essentially biological method". For the moment, plant material can be regarded patentable but, on the other hand, there are no precedents to clarify the matter. There are no signs of a reform of the EPC in the near future. However, it is most evident that the patenting of plants will become possible either by reinterpretation of the law or after amendments.

The greatest weaknesses of the plant variety protection provided by the UPOV seem to be the right to further breed protected plant varieties and the farmer's right to use his own harvest as seed. It is evident that the number of UPOV members will not increase in the future unless the protection provided by the Convention is improved. With increasing plant patenting the importance of the UPOV will diminish.

Two interest groups can be recognized: companies specializing in plant breeding and organizations representing the industrial countries. They both recommend improvements to the legal protection and stand for the liberation of plant patenting. The improved protection is assumed to speed up research as it increases the willingness to invest in plant breeding.

On the other hand, farmers in industrial countries and the developing countries are against the improvements of the plant breeders' legal rights. Farmers fear for an increase in seed prices as well as for too much dependence on the producer. The developing countries also feel suspicious about the multinational seed companies whose influence is ex-

pected to increase if plant patenting is made possible.

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Kasvibiotekniikan oikeudellinen suoja

P.T. Vanhala, T. Pehu, H.G. Gyllenberg

*Helsingin yliopisto,
Mikrobiologian laitos*

Keksinnön on täytettävä tietyt ehdot, jotta se voidaan patentoida. Patenttilain soveltamista kasveihin rajoittaa perussääntö, jonka mukaan keksinnön tulee olla sillä tavalla kuvattu, että asiantuntija voi kuvauksen perusteella toistaa keksinnön. Nykyään katsotaan, että tällaista kuvausta ei voida antaa elävästä organismista. Tästä johtuen on kasvilajikkeille kehitetty oma, patenttia vastaava, UPOV-sopimuksessa määritelty suoja.

Yhtenä biotekniikan lupaavimpana sovelluksena pidetään kasvintuotantoa. Kasvinjalostuksessa käytettävien bioteknisten jalostusmenetelmien katsotaan täyttävän patentoinnille asetetut ehdot paremmin kuin perinteisten menetelmien. Tämän perusteella on vaadittu patenttisuojan laajentamista koskemaan myös uusia kasvilajikkeita.

Euroopan patenttisopimuksen piirissä oikeuskäytäntö on vielä vakiintumaton. Lainsäädäntöprosessi vaikuttaa niin hitaalta, että nykyistä lakia joudutaan tulkitsemaan mahdollisimman väljästi. Tällä hetkellä kasvimateriaali näyttää patentoimiskelpoiselta, mutta asiaa selventävät

ennakkotapaukset puuttuvat.

Yhdysvalloissa patenttilainsäädäntö on mukautunut biotekniikan kehitykseen paremmin kuin Euroopassa. Yhdysvalloissa on mahdollista suojata kasveja tuotepatenteilla ja valita suojan muodoksi patentti tai jalostajan oikeudet.

UPOV:in tarjoaman kasvilajikesuojan pahimpina heikkouksina pidetään jatkojalostusoikeutta ja viljelijän oikeutta käyttää satoaan siemenenä. Näiden oikeuksien katsotaan tarjoavan mahdollisuuksia suojan kiertämiseen.

Kasvinjalostustyötä tekevät yritykset ja teollisuusmaita edustavat järjestöt suosittelevat suojan parantamista. Parantuneen suojan katsotaan vauhdittavan alan kehitystä. Sitävastoin viljelijät ja kehitysmaiden edustajat ovat kasvilajikesuojan parantamista vastaan. Viljelijät pelkäävät siementen kallistumista ja liiallista riippuvuutta siementuottajasta. Kehitysmaissa epäillään monikansallisten yritysten vaikutusvallan kasvavan parantuneen lajikesuojan myötä.