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WIPO-UPOV/SYM/02/4
ORIGINAL: English
DATE: October 21, 2002

WORLD INTELLECTUAL PROPERTY ORGANIZATION

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS

organized by
the World Intellectual Property Organization (WIPO)

and
the International Union for the Protection of New Varieties of Plants (UPOV)

Geneva, October 25, 2002

PATENT PROTECTION FOR PLANT MATERIAL

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This paper briefly presents the author's views on the subject of patent protection for plant material. It is a quick review of patent types available to the plant breeder or inventor and then goes into a brief discussion of the application of the "experimental use exemption" as a means of exception to infringement. This review is not meant to be exhaustive, but covers patent practice concerned with protection of plants, in several geographic areas, namely, the United States of America., the European Patent Office (EPO), Australia, New Zealand, and Japan.

PLANT, UTILITY, AND STANDARD PATENTS

United States:

In the United States, there are three main ways in which an inventor or breeder may obtain formal IPR on plant material: Plant Breeder's Rights through the Plant Variety Protection Act (PVPA), patent rights under the Plant Patent Act (PPA), and patent rights (for inventions) as a utility patent, the Utility Patent Act (UPA, under, 35 U.S.C. Section 101 35)[1].

Plant patents are available under the PPA for asexually reproduced, novel plants. The applications must include a cultivar name for the claimed variety. The applicant must clearly identify the novel characteristics of the variety to be claimed by the plant patent application. This must be stated as one claim and often photographs or drawings must be filed to substantiate the claimed difference(s).

U.S. Plant patent would seem to not have a corresponding, "doctrine of equivalents" condition to that afforded directly by such a doctrine for plant material (inventions) covered by a utility patent or indirectly by the "essential derivation" concept of plant variety protection under the UPOV-type of protection.

The applicant must swear that the new plant variety has been asexually reproduced by the applicant and that the plant was found in a cultivate state. Plants found growing in the wild, in an area untended by man cannot be the subject of a plant patent. There have been 777 plant patents (PPA) issued so far in 2002. Approximately 96 of these patents have covered plants used for food and agriculture.

Utility patents may be granted in the U.S. for any new plant in which man has had "a hand" in the creation thereof. This follows from the landmark rulings in the Diamond v. Chakrabarty case and also the Ex parte Hibberd case. In the utility patent application, the applicant must fully disclose how to identify, make and use the claimed invention. When a utility application concerns an invention of a new plant, the public must be informed as to how one can obtain the new plant. Usually, this means that seeds or other propagative material must be deposited in an approved depository, unless breeding lines, cell lines, or other material are generally available to the public or if the plant material can be produced or

[1] Trade secrets have frequently been a method of preventing others from propagating plant material, particularly in situations where hybrid seed is produced from particular inbred parental lines. In such cases the identity of the inbred lines, is closely held. This type of trade secret protection has successfully been defended, as in the case of Pioneer Hi-bred v. Holden, 35 F.3d 1226, 31 USPQ2w 1385 (8th Cir. 1994), where genetic fingerprint data, isozyme analysis and phenotypic comparisons were used to prove trade secret misappropriation.

isolated without "undue experimentation". This availability requirement, either through general availability or by deposit is especially important so that this material will be available to the public, once the patent expires or lapses for other reasons. In the case of hybrid breeding lines, both inbred parental lines must be deposited. Utility patents offer broader coverage, i.e., the protection of a novel plant trait, which embraces more than a single plant variety or cultivar.[2]

A recent Supreme Court ruling in the JEM Ag Supply v. Pioneer Hi-bred case establishes that a plant variety may be the subject of both a Plant Breeder's Certificate awarded under the U.S. PVPA as well as the subject of claims in a utility patent application.

Multiple aspects of a plant invention can be claimed in a utility patent. For example, claims can be made regarding breeding method(s), inbred parental lines, plants and pollen produced by the parents or claimed variety, as well as seeds of the parents or variety, phenotypic characteristics of the claimed variety or inbred parents, plants and seeds produced from regenerative methods. Patent applications for transgenic plants (genetically modified organisms) will have claims covering the transgenic plants, seeds of the plants, novel cloned genes/expression vectors, as well as possibly methods for the production of the transgenic plant. Utility patents are considered to afford "stronger patent protection" than rights obtained with PVP certificates, as the requirements are stricter in order to obtain claims. This results in an awarding of greater rights of exclusion than PVP certificates.

Thus far, in 2002, the United States Patent and Trademark Office (USPTO) has issued 222 utility patents under the U.S. plant classification identifier, with claims to seed. Of these, an initial analysis indicates that 114 had claims directed to novel plant varieties.

European Patent Office - standard patents

In countries that are members of the European Patent Office (EPO), the patenting of plant varieties, per se, is prohibited. Indeed, before a decision by the EPO's Enlarged Board of Appeals on December 20, 1999, it was assumed that no plants could be the subject of a utility patent claim, based on the Directive 98/44/EC of the European Parliament. However, the EPO, Board Of Appeals (BOA) determined that a claim directed to transgenic plants of more than one variety, but that does not claim an individual plant variety, is permissible. Thus, opening the way, for all intents and purposes for the EPO to allow claims to plants.

Japan-Standard Patents

According to the Japanese patent regulations:

> "As to an invention relating to a plant, a claim should be described as follows. In the case of an invention of a plant per se, the plant should be specified by, for example, a combination of any of the species, the distinctive gene of the plant, characteristics of the plant, etc. and may be further specified by the process for creating the plants."

[2] Indeed it is this characteristic of utility patents that has allowed the patenting of novel plants in countries of the European Union, even though the EU Directive, 98/44/EC, forbids the granting of patents for plants.

In addition, there is a separate section in the Japanese code for matter relating to the genetic engineering of plants as well.

Australia-Standard Patents

Australia allows the claiming of protection of plants in standard patents, for plants in general and for specific cultivars. This includes new plant varieties, plant components, reproductive material, products from plant and plant material used in industrial processes.

Australia-Innovation Patents

Plants and the biological processes for the generation of plants are not patentable subject matter for an innovation patent. However, it is possible to obtain an innovation patent on processes that use a plant or parts of plants, but that does not result in the generation of a plant.

New Zealand-Standard Patents

Plant material, especially transgenic plant varieties, are considered to be patentable inventions, under the rules for granting utility patents, in New Zealand.

INFRINGEMENT OF RIGHTS/EXPERIMENTAL OR OTHER USE EXCEPTIONS TO INFRINGEMENT

U.S. Plant Patents:

The U.S. Court of Appeals for the Federal Circuit (CAFC) decision, Imazio Nursery v. Dania Greenhouses, 69 F.3d 1560, 36 USPQ2d 1673 (CAFC 1995) ruled that a plant patent holder must prove that the accused variety was actually derived *asexually*, from plant material representing the patented variety. **Accordingly, most would hold that the variety protected by plant patent can be used without authorization by others as a parent in a commercial breeding program**. Thus, there is a broad, "Breeder's exemption", associated with plant patent practice.

U.S. Utility Patents:

In the U.S., the "Experimental Use Exception" to patent infringement, is a judicially created relief. It is not a part of the patent law. A recent ruling (Madey v Duke University), by the U.S. District Court for the Middle District of North Carolina, reaffirmed a very narrow interpretation of "experimental use", set forth in the prior cases, Embrex v. Service Engineering Corp, (Fed. Cir. 2000), and Roche v Bolar (Fed. Cir. 1984). This prior interpretation holds that a defense of experimental use is limited to actions performed, "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry". In the Madey ruling, the court continued, "Further, use does not qualify for the experimental use defense when it is undertaken in the 'guise of scientific inquiry' but has 'definite, cognizable, and not insubstantial commercial purposes'." The concurring opinion in Embrex expresses a similar view: use is disqualified from the defense if it has the 'slightest commercial implication'."

The Court also narrowed the definition of "commercial". It held that Duke University's use of patented technology without the approval of the patent holder was commercial in the sense that such use gave Duke a competitive edge in recruiting high-quality students and in attracting funding through competitive grants. This interpretation was found, even though Duke had no intention of producing any commercial product or claiming a commercial invention, using the technology in question.

EPO-country members

As a rule, it seems that there is a broader interpretation of the meaning of the "experimental use exception" in EPO-countries. For example, in the UK, there is an experimental use exception to infringement that is part of the patent law (Section 60(5)(b) of the Patents Act, 1977).

Australia

There is an "experimental use" exemption from patent infringement under the Patents Act of 1990, in appropriate circumstances.

Japan

The Japanese Patent Law contains a specific provision that excludes from infringement, acts carried out for the purposes of experiment or research.

New Zealand

There are no provisions regarding experimental use in the New Zealand Patent Act. Courts in New Zealand have adopted an, "experimental use from patent infringement", stance. However, the Courts are particularly concerned regarding advancement in the commercial sector under the experimental use exemption.

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