

INTELLECTUAL PROPERTY PROTECTION FOR PLANTS

Summary

Intellectual property rights in plants may be of several kinds: patents, plant variety rights, trade marks, trade secrets, genetic resource rights. Rights vary from country to country: here we give the position in the European Union.

Patents

In principle, plants generally may be patented if new, not obvious and useful, and one can describe how to produce them repeatably. These are the universal requirements to patent any invention. For example, patents have been granted in Europe for genetically modified (GM) plants. However, "essentially biological processes" for the production of plants, in particular crossing and selection, are not patentable, and recent law changes by the European Patent Office (EPO) have excluded plants obtained exclusively by essentially biological processes from patentibility.

Plant variety rights

Plants that are new but obvious cannot be protected by patents. But they may still be very useful. Breeding new plants is expensive and time-consuming (some may take up to a decade or more). Plant variety rights reward investment in plant breeding. A plant variety is defined by the combination of all its characteristics (present or absent). Protected plant varieties may not be multiplied by third parties, but anyone may use them as starting material for breeding new varieties (the "breeder's privilege").

Trade Marks

Trade marks certify trade origin only. For example, a trader may sell many different types of seed under a single trade mark. Purchasers may sell the seeds on, even under the same mark: or (if they are not otherwise protected) multiply the seeds and sell the progeny under a different trade mark or none.

Trade Secrets

Commercially traded seeds are of two main kinds: "pure lines" and F1 hybrids. "Pure lines" are the progeny of identical pure line parents: F1 hybrids are the progeny of two different pure line male and female parents. In each case, the seeds are uniform, and give uniform progeny. But hybrids differ from pure lines in the second generation. The latter still breed true, but the former do not. So replanting seeds harvested from an F1 hybrid produces a non-uniform crop, of lower quality than the parent. The original parents of F1 hybrids are often not sold, but retained by breeders in-house as trade secrets. Without access to both parent lines, customers and competitors cannot reproduce the F1 hybrid.

Genetic resource rights

Under the Convention on Biological Diversity (CBD), "countries of origin" have rights to control access to their genetic resources. The Nagoya Protocol on Access and Benefit Sharing, a supplemental agreement to the CBD, came into force in October 2014 and gives countries control over research on their genetic resources.

This paper now deals in more detail with patents, plant variety rights and genetic resource rights.



Introduction

Modern agriculture requires improvements in the technology of plant breeding to produce new varieties of plant which yield crops having improved resistance to diseases, pests, and other stresses.

What is a plant variety?

A plant variety is a biological classification, below that of genus and species. Members of the same species can breed with one another, though they may look quite different. Thus, in the animal kingdom, dogs all form a single species and all interbreed, but different breeds of dog are nevertheless clearly recognisable by their appearance and characteristics (Labradors, spaniels, sheepdogs and the like). These breeds have been evolved by selection of their parents. Each has its own characteristic appearance, determined by the genes it has inherited. The concept of plant varieties is similar to animal breeds. Many particular plant varieties are well-known: examples are the rose, Peace, and the eating apple, Cox's Orange Pippin. Peace has a specific colour and scent; Cox's apples have a recognisable appearance and an acid, orange-flavoured taste.

Legally, a plant variety must be **distinct** (have a different combination of traits from all other known varieties), **uniform** (all plants have the same properties when grown under the same conditions) and **stable** (plants can be grown over a number of generations without change in traits). Thus a plant variety is characterised by its specific combination of traits. Changing a single trait (for example, colour, leaf shape, growth habit) can give a new variety.

Plant variety rights

Earlier methods of developing new varieties (so-called traditional breeding methods) were largely restricted to repeated crossing of selected individual plants to enhance or combine desired characteristics. These breeding methods take up much time and resources - for example, using traditional breeding methods it may take ten years or so to breed a new variety of wheat. The resultant seed can easily be multiplied simply by replanting. To justify such an investment in a product that is so easily reproduced requires robust market protection. In the late 1950s, a special system of "Plant Variety Rights" (PVRs) for the legal protection of new varieties was established in a number of countries and regulated internationally by the "International Union for the Protection of New Varieties of Plants" (the "UPOV Convention" of 1961).

The main motivation for devising the special PVR system was that the long-established patent system, intended for the protection of technical inventions, was in several countries and for various reasons not considered suitable for protecting new plant varieties obtained by traditional methods. The criteria for the grant of plant variety rights are quite different from those required for patent protection and the rights available under the two systems is also very different. Plant variety rights are available for new plant varieties that are distinct, uniform and stable. Unlike the patent system there is no requirement for the variety to be inventive. Plant variety protection grants the owner exclusive rights in the reproductive material (seed, bulbs, cuttings, etc.) of the specific new variety. Protected seed which has been acquired for planting may be planted, but the product of the harvest is for consumption; replanting it breaches the breeder's right. However, the plant variety system also contains exemptions which in general:

(a) allow breeders to use protected varieties as a starting point for breeding further varieties (the "breeder's privilege"); and

(b) allow farmers, under certain conditions, to save seed from a crop sown from a purchased protected variety for subsequent sowing on their own farms (the "farmer's privilege").



The original UPOV Convention also prevented signatory States from offering "double protection" i.e. both patent protection and plant variety rights within the same genus or species. This provision accorded with the views of the agricultural industry at that time.

Since then, the advent of modern biotechnology, especially recombinant DNA technology, has made it possible to manipulate the genetic structure of a plant in a directed way at the molecular level, free from the constraints inherent in sexual reproduction. In this way, genes from an unrelated species or even synthetic genes may be introduced. Genetic engineering has allowed the development of plants with new traits that could never have been obtained by traditional methods. The impact of genetic engineering on plant breeding led to a review of the UPOV

Convention. As a result an extensively modified UPOV Convention was adopted early in 1991, and entered into force in April 1998. One of the changes was to allow "double protection". Apart from individual States (over 70 countries are now members), the UPOV Convention is now open to intergovernmental organisations provided that they have their own legislation for the grant of plant variety rights.

The European Union has adopted Regulation 2100/94 on Community Plant Variety Rights. This Regulation establishes a Community Plant Variety Right granted by a Community Plant Variety Office which supplements national offices. Following introduction of the Regulation and the revision of UPOV, the British Government revised the Plant Varieties and Seeds Act 1964. Most provisions of the new Plant Varieties Act 1997 came into force on 8 May 1998.

Patent Protection

Although the UPOV convention now allows "double protection", in Europe, Article 53(b) of the European Patent Convention (EPC) continues to exclude from patent protection plant varieties or essentially biological processes for the production of plants (or animals) - though this exclusion does not apply to microbiological processes or their products. Similar provisions are found in the national laws of the EPC Member States. Restrictions on patentability of plant varieties are not, however, present in the patent laws of some other countries, e.g. the United States, Japan and Australia.

In July 1998, the European Parliament and Council of the European Union approved Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (the "Biotech Directive"), which obliged EU States to amend their national patent laws on biotechnology inventions. Like the EPC, the Biotech Directive prohibits patenting of plant varieties or essentially biological processes for their production, subject to a similar proviso regarding microbiological "or other technical" processes. However, the Biotech Directive further clarifies this prohibition by specifying that inventions which concern plants shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety; and that a process is to be considered essentially biological only if it "consists entirely of natural phenomena such as crossing or selection". The Biotech Directive, being an EU instrument, is not directly applicable to the EPC, although the EPO adopted its main provisions on plant patenting.

In 2000, a case (G1/98) was brought to the EPO Enlarged Board of Appeal, in which the crucial claim in the patent application was directed to transgenic plants (from a range of species) having specific foreign genes which conferred resistance to certain pathogens. The Enlarged Board, clarifying and correcting previous conflicting EPO case law on Article 53(b) EPC, confirmed that a patent may be granted for a transgenic plant provided the claim is not



directed (limited) to a specific variety or varieties: i.e. if the claim is generic in scope as opposed to being directed to an individual plant varieties. The fact that such a claim is broad enough to "embrace" unspecified varieties is no bar to patentability.

However, the Enlarged Board failed to provide further guidance as to when, under the EPC, a process for preparing a plant is to be considered "an essentially biological process" and thus barred from patent protection. The EPO Boards of Appeal have held that processes of preparing transgenic plants by transformation and regeneration are likewise acceptable under Article 53(b) EPC; but questions remained as to what other type of process constitute technical, as opposed to natural, phenomena, and to what extent a process comprising both "technical" and "natural" steps can be allowed.

To resolve these questions, two further cases (G2/07 and G1/08) were referred to the Enlarged Board of Appeal (in 2007/2008). The first case relates to genetic-marker-assisted selection of Brassica species having high levels of anticarcinogenic glucosinolates, and the second case to a method for breeding tomatoes having reduced water content: and the products so obtained. The Enlarged Board decided that breeding processes including a step of "crossing and selection" are

(in most cases) inherently unpatentable. The other steps in the process may be patentable separately. The patentees responded by deleting their process claims, and relying only on product claims. The Technical Board doubted whether this response was adequate: if a process was unpatentable, could the product of the process be protected? That question was referred to the EPO's Enlarged Board in cases G2/12 and G2/13. The Enlarged Board decided that Article 53(b) EPC, which does not allow patents to be granted for essentially biological processes for the production of plants, did not prohibit patents for plants produced by such processes. CIPA produced a Position Paper on this decision explaining why the Enlarged Board's decision was legally correct and reasonable.

However, this was not the end of the story. The EPO appeared to be dissatisfied with the Enlarged Board's decision in G2/13 and G2/13, and set out proposals to change Rule 28 EPC used to interpret the Article 53 EPC exclusions from patentability. The EPO Administrative Council approved a new Rule 28(2) EPC which entered into force on 1 July 2017 and stated that European patents "shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process". Such a provision is not part of the Biotech Directive – potentially putting the EPC at odds with EU law – and contradicts the Enlarged Board's interpretation of the Article 53(b) itself.

A further development arose when an EPO Board of Appeal in decision T1063/18 held in December 2018 that the new Rule 28(2) EPC was indeed contrary to Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13. In accordance with Article 164(2) EPC, the provisions of the Convention Articles prevail if there is a conflict with a Rule. The Board thus concluded that European patents *could* be granted in respect of plants (or animals) exclusively obtained by means of an essentially biological process, contrary to the provisions of Rule 28(2) EPC.

Following the EPO Board's decision in T1063/18, the President of the EPO on 4 April 2019 referred questions to the Enlarged Board of the EPO (case G3/19) about whether Rule 28(2) EPC is in conflict with Article 53(b) EPC. If the referral is deemed admissible (there are doubts about this), the Enlarged Board will hopefully bring clarity to this matter.

Rights in Genetic Resources

The Convention on Biological Diversity (CBD) came into force in

December 1993. Nearly all countries in the world are members, with the significant exception of USA. Its objects are:

- to conserve biodiversity;
- to encourage its sustainable use; and

- to promote equitable sharing of benefits between those who provide biodiversity and those who use it. Biodiversity is a synonym for genetic resources.

It is a principle of the CBD that national sovereignty gives "countries of origin" of biodiversity the right to control access to it. This is not difficult or contentious, as long as the genetic resources remain within the country of origin. But once they are removed from the country of origin, problems arise. Was this done legally? How do you tell? Many countries do not plan to enforce their "genetic resource" rights. It is often difficult to tell which the original "country of origin" was (the CBD defines "country of origin" as the country where the species is to be found growing *in situ*. Often there is more than one such country. It may or may not be possible, in respect of a particular sample, to determine which country housed the plant from which that sample descends). Nevertheless, regardless of these difficulties, the Nagoya Protocol to the CBD (agreed in Japan in 2010) will control research on (*inter alia*) all plant genetic resources. Before conducting research on such a genetic resource, the researcher must: 1) identify the "country of origin" of the genetic resource; 2) if required by the "country of origin", negotiate a benefit-sharing agreement with the appropriate authorities in that country. The Nagoya Protocol may inhibit research on genetic resources and slow down production of useful new plant varieties.

Updated by Michael Roberts, Life Sciences Committee, August 2019

