

Intellectual Property and Plants



Plant breeding is an essential practice for agriculture and horticulture (Box 1). Plant breeders may seek intellectual property rights (IPR) over plant varieties and breeding techniques to protect their investment in research. This POSTnote considers the different IPR approaches available to plant breeders.

Background

The purpose of plant breeding is to provide farmers and growers with distinct varieties possessing favourable traits (Box 1). These sectors are important to the UK economy with agriculture earning £5.4bn in 2014,² horticulture £1.8bn and ornamentals £1.2bn.³ Breeders have traditionally used conventional methods that select plants solely on their physical characteristics or performance (Box 2) to obtain new varieties. However, in the last 20 years they have supplemented such approaches with biotechnology (Box 2) which allows them to select for desirable traits by using plants' genetic information.

This increased reliance on biotechnology has resulted in a change in the types of intellectual property rights (IPR) being sought by breeders. Traditionally plant breeders have relied on plant variety rights (PVR, Box 3), a form of IPR designed specifically for plant varieties, to protect their varieties. More recently, some breeders are seeking to strengthen the IPR granted by PVR with patents (Box 4) to protect their innovations and secure a greater return on investment. PVR give exclusive rights to use or exploit a new variety for 25 years (30 years for potatoes, vines and trees). Whilst a patent holder has exclusive rights to use or exploit an invention, which can be a product or a process, for 20 years. This POSTnote outlines the scope of PVR and patents, examines their pros and cons and describes recent ambiguities in patent law and their potential implications.

Overview

- Agricultural plant breeding is essential to the UK's £90bn food supply chain.¹
- Plant breeders can protect new varieties through patents and other forms of intellectual property rights (IPR).
- The use of modern biotechnology alongside conventional plant breeding techniques is now widespread.
- Recent decisions by the European Patent Office have clarified what is and is not patentable under European patent law.
- Concerns for the future of plant breeding include the balance between different types of IPR, and how this will affect the seed sector and access to genetic resources.

Box 1. Plant Breeding Sectors

- **Agriculture** is the cultivation of plants and animals for food and materials for human need. Traits important for these crops include resistance to stressors, increased yield and nutritional quality.
- **Horticulture** is the cultivation of fruit, vegetables and ornamental plants (decorative plants for the garden, landscape and house, as well as cut flowers). Traits important to horticulturalists include taste, yield and appearance.

Plant Variety Rights

UK plant breeders can secure plant variety rights (PVR, Box 3) through either the UK scheme, administered by the UK Plant Variety Rights Office, or the EU-wide scheme run by the Community Plant Variety Office (CPVO). In practice, most breeders opt for EU-wide PVR; in 2014 only six new varieties were administered under the UK scheme compared to 3,626 through the CPVO.⁴ This reflects the reliance of plant breeders on international trade and the similarity in costs of the two systems. The following sections outline the tests used to assess plant varieties for PVR and exemptions to PVR for farmers and breeders.

Distinct, Uniform and Stable

A new variety must be distinct, uniform and stable (DUS, see Box 3) to qualify for protection under PVR. DUS testing takes between one and three years, depending on the plant species. It involves experts at approved centres growing the varieties and examining their properties. The test is based on the observation of physical properties such as height,

Box 2. Plant Breeding Methods**Conventional Breeding Techniques**

Breeding is the *selection* of plants with desirable traits and eradication of those with less desirable traits over several breeding cycles. Breeding usually involves the *crossing* of closely or distantly related plants to produce a range of variation from which the breeder can select plants with desirable traits from each parent plant.

Mutation breeding exposes seeds to chemicals or radiation to introduce random genetic variation (mutants) with the aim of generating desirable traits. It is an alternative way of producing genetic variation from which breeders select desirable traits.

Modern Technologies

Modern biotechnology gives breeders an insight into the genetic make up of a plant and allows them to make better predictions of those possessing desirable traits.

- Marker assisted selection uses easily identifiable unique sequences of DNA that are closely located to a gene of interest. These markers allows plant breeders to screen thousands of plants for a desired trait. .
- Genetic modification is the insertion of whole genes from the same species (cisgenic), or an entirely different species (transgenic).
- Gene editing technologies enable more precise alterations to genes without the insertion of entire sequences. Use of such methods may be impossible to detect as the changes they create could be achieved naturally through random mutation.

leaf shape and time of flowering, using protocols based on UPOV guidelines (Box 3) tailored to each species.⁵

In practice, the features measured vary from one sector to another. In the agricultural sector, the commercial worth of a plant depends on yield and nutritional value, so these are the traits that breeders select for. However, these traits do not feature in DUS testing and the British Society of Plant Breeders, the body that represents agricultural breeders, suggests that this can make it more difficult to obtain protection rights for a new variety in this sector. For ornamental plants, the commercial value of a plant depends more on visual characteristics that set it aside from other varieties. The body that represents breeders of ornamental and fruit varieties⁶ has suggested that awarding PVR for plants that are only minimally different to existing plants undermines the IPR of existing rights holders. It would like to see distinctness being concerned only with “commercially important characteristics” for a particular species,⁷ and suggests that this will increase the distinctness between varieties and promote innovation. It is in discussion with CPVO about testing the feasibility of new methods.

The recent advent of biotechnology means that it is now possible to devise tests for specific biochemical features such as marker genes or novel proteins. Such tests might prove useful in assessing distinctness and reducing the time taken for DUS tests. However, the International Seed Federation notes that this would require better understanding of the relationship between a plant’s DNA profile and its physical and physiological characteristics.⁸

Exemptions to Plant Variety Rights

While PVR gives the rights holder exclusive rights to the protected variety there is a compulsory breeders’ exemption

Box 3. Plant Variety Rights and the UPOV Convention

Most countries and intergovernmental organisations that have introduced a plant variety rights (PVR) system have chosen to base their system on the International Union for the Protection of New Varieties of Plants (UPOV) Convention. UPOV has 74 members covering 93 countries.⁹ Under the UPOV Convention, plant variety rights are granted where the variety is new, and is:

- distinct (D) – possesses measurable traits that make it distinct from other known varieties
- uniform (U) – produces the same traits in each plant of the variety
- stable (S) – after several growing cycles the traits remain uniform.

The UPOV Convention specifies actions that require the breeder’s authorisation to propagate a protected variety and, under certain conditions, to use the harvested material for example to save seed for planting next season). The rights do not extend to acts done (i) privately and for non-commercial purposes, (ii) for experimental purposes or (iii) for the purpose of breeding other varieties (breeder’s exemption). There is also an optional exemption that allows farmers to save seed (see *The Farmers’ Exemption*).

and an optional farmers’ exemption in the 1991 Act of the UPOV convention (discussed below).

The Farmers’ Exemption

UPOV members can decide to allow farmers to save and replant seed on their own farms without the authorisation of the breeder, for certain crops. Farm saved seed (FSS) is a common practice in many countries for some crops. Depending on the type of crop, 36-60% of seed sown in England and Wales is FSS¹⁰. Farmers who save their seed must pay royalties to the rights holder. These are typically 50% of the royalty that would be paid if the farmer bought new seed. This limits the total earnings obtainable for a variety but is designed to strike a balance between the needs of farmers and breeders.

The Breeders’ Exemption

The Breeders’ Exemption allows breeders to develop further a protected variety in a breeding programme. If a resulting variety is sufficiently distinct from the original and meets the other criteria for assessment (Box 3), the new variety can be protected by PVR and exploited without obligation to the original rights holder. This system allows ‘open access’ to protected varieties, promoting continual development in plant breeding, and has worked well with traditional breeding methods. However, breeders that use new methods to select desirable traits (Box 2), may feel this protection is insufficient particularly when they have produced a novel trait or invested heavily to overcome technical difficulties. As a result some breeders are seeking additional protection through patenting.

Patents and Plants

Patents grant exclusive rights to a claimed process or product. They can be granted at a national level through the UK Intellectual Property Office (IPO) or through the European Patent Office (EPO, Box 4). Both types of patent comply with the European Patent Convention. The following sections examine ambiguities over what can and cannot be patented, opinions on this, the new Unitary Patent System and, issues to do with transparency and licensing.

Box 4. The European Patent System

To be patentable an invention must be novel, non-obvious, inventive and useful. Patents can be granted for plant breeding technologies and processes, plant derived products, isolated plant DNA sequences and plants traits that are not limited to a particular variety. In May 2014, 800 varieties were covered by 22 patents in Europe.¹⁸

A patent granted through the European Patent Office (EPO) can have effect in up to 38 countries (including all EU states) that have signed the European Patent Convention (EPC). The EPO is not an EU institution but contracting states have chosen to align the EPC with EU legislation that governs biotechnology patent law (Directive 98/44¹¹). The grant of a European patent can be opposed at the EPO for a limited period. The EPO's Enlarged Board of Appeal (EBA) is the final decision maker in the interpretation of the EPC.

What is Patentable?

The European Patent Convention (Box 4) excludes from patentability "plant varieties" and what it calls "essentially biological processes for the production of plants...".¹² Until recently, it was not clear if the products of conventional breeding (Box 2) were patentable. The EPO's Enlarged Board of Appeal (EBA) considered two cases to clarify the patentability of such products (Box 5). It ruled that:

- a process for the production of plants is *not* patentable in principle if it involves conventional breeding, irrespective of additional technical steps such as marker assisted selection, which support conventional breeding
- the products of such processes (cross breeding and selection) *are* patentable (e.g. plants with novel traits) provided they also fulfil the criteria for patentability.

Opinions on Patenting Plant Breeding Products

Opinion is divided in the industry over the recent rulings (Box 5). The European Parliament has made it clear that it would like to exclude from patentability all plant products derived from conventional breeding.¹³ However, the EBA's decisions mean that products involving 'plant varieties' (Box 4), fruits and seeds (Box 5) derived from conventional breeding methods are patentable. The civil coalition, No Patents on Seeds, notes that 120 patents involving conventional breeding methods have been awarded to date with around 1,000 more pending.¹⁴ It fears that the EBA ruling means that many more patents of this kind will be granted. However, the global market leaders welcome the decisions and believe that clarification was necessary to promote further investment. They wish to see measures to address perceived weaknesses of the European patent system including variations in national law and the lack of a single court with jurisdiction over all EU member states.

The Unitary Patent System

An agreement to implement a unitary patent court was signed by 25 EU member states in February, 2013. Once ratified, unitary patents will be available (under EU regulations agreed in December 2012) and disputes relating to both unitary patents and classic European patents (Box 5) will be resolved in a new Unified Patent Court, with effect in all member states. The Agreement has to be ratified by 13 states, including the UK, France and Germany. The UK has implemented the agreement via secondary legislation

Box 5. The Patentability of Products and Processes

The EPO's Enlarged Board of Appeal (EBA) has clarified the patent exclusion of "essentially biological processes for the production of plants..." in cases involving two plant patents.

Broccoli and Tomatoes I

These cases involved:

- a method for selectively breeding brassica species (such as broccoli) with increased glucosinolates (anti-cancer substances)
- a method for breeding tomatoes with a reduced water content and a tomato product capable of natural dehydration.

Both cases included claims relating to the breeding method as well as claims to plants themselves. Both patents were granted, but were opposed at the EPO by competitor companies on the grounds that the breeding processes (selection and cross-breeding) were "essentially biological processes".

Broccoli and Tomatoes II

Following the EBA decision, both companies revised their applications to omit claims involving the process of selection and cross breeding. They re-submitted what are known as "product-by-process" claims where no claims are made to the process *per se*, but the plants are defined by the process by which they are produced. In March 2015, the EBA ruled that these claims are patentable. It ruled that the patent exclusion to "essentially biological processes for the production of plants" does not extend to the products of those processes.

under the Intellectual Property Act 2014. A single system will apply to unitary patents harmonising national patent law under the EU regulations and the Agreement.

Transparency and Licensing

A recent report for the European Commission found that the patents market was characterised by two key factors: a lack of transparency in patent information, and high costs of licencing.¹⁵ Many in the agricultural seed industry see addressing these two issues as major priorities and are participating in the following initiatives to address them.

- Databases of patent information such as the European Seed Association's PINTO database. This allows plant breeders access to information about patent rights on varieties to avoid unwitting infringement of patents.¹⁶
- The International Licencing Platform (ILP) for vegetables provides a database of all patents held by its members. It details patents on traits and the varieties covered, and also provides a mechanism whereby parties can reach agreements over licencing. Around 50% of seed suppliers are members¹⁷ of the Platform, including Syngenta, but other large vegetable seed companies such as Monsanto are yet to sign up.

While welcoming these initiatives, some plant breeders and NGOs note that they will not address all the issues with patents on plants. For example, membership of the ILP is expensive – the lowest fee is for small companies at €7,500 per year – particularly for small scale breeders.

The Future of Plant Intellectual Property Patent Reforms?

No Patents on Seeds argues that's the EBA's decisions do not reflect the exemptions to patenting present in current European patent law. It would like to see the law in this area

strengthened.¹⁴ However, making such changes would be challenging. For example, it took 10 years to negotiate the EBD.¹⁸ No Patents on Seeds suggests another possibility is for the European Commission to issue a legally binding interpretation of the EBD, which prohibits patents on plants and animals from conventional breeding.¹¹ The European Seed Association's position reflects this view.¹⁹ However, others in the industry caution against any changes to patent protection on the grounds that it might adversely affect the European seed market and plant breeding research sector.

Access to Genetic Resources

Over the years plant breeding has led to substantial benefits for food security by developing resilient crop varieties with enhanced yields. It is thought that plant variety rights have encouraged such innovation.²⁰ However, the UN estimates that the diversity of cultivated crops has declined by 75% in the past century.²¹ There are concerns that this increased uniformity makes crops more vulnerable to, for example, new plant pests/diseases or climate change. The following sections examine whether:

- the trend towards strong IP protection will result in big companies tying up genetic resources, leading to fewer companies sharing the market (market consolidation)
- the newly agreed access and benefit sharing system (Box 6) will act as a barrier to research in practice.

Market Consolidation

The global agricultural seed market is dominated by large agrochemical companies, notably Monsanto, DuPont and Syngenta, which have increased their market share dramatically over recent years.^{22,23} There is concern that this may lead to higher costs and less choice for farmers. Large companies may be more likely to seek patent protection on varieties to protect their investment in new biotechnology. Any trend towards patenting may restrict access to the genetic resources available to plant breeders driving further consolidation.^{24,25} However, there are other causes of consolidation such as company takeovers and partnerships.

Access and Benefit Sharing Agreements

The recently adopted Nagoya Protocol (Box 6) aims to protect countries' genetic resources from exploitation by providing a framework for sharing any benefits arising from the use of those resources. Plant breeders are concerned about the additional costs of negotiations and royalty agreements, the bureaucratic burden of the requirement to keep records of the genetic material used, and the lack of knowledge about what plants are covered by the Protocol.²⁶ They suggest that the Protocol may act as a disincentive to conducting research to develop new plant varieties. Furthermore, variations in the national laws that implement the agreement has led to wide difference in ease of access to genetic resources from one country to another.

Patents, Plant Variety Rights and Innovation

Proponents of patents suggest that they are essential to justify the high initial investment for plant breeding programmes.²⁷ For example, it has been estimated that the cost associated with the discovery, development and

Box 6. Access and Benefit Sharing (ABS) Agreements

The 1993 **Convention on Biological Diversity** (CBD) aims to conserve biodiversity and ensure access and benefit sharing. The **Nagoya Protocol** (NP) is a supplementary agreement to the CBD that came into force in 2014. It provides a legal framework for the fair and equitable sharing of benefits arising from the use of genetic resources. Anyone using genetic material from another country must obtain prior consent from the country of origin, along with an agreement that details how the country will benefit (for example through royalties, sharing IPR or technology transfer).

authorisation of a new biotechnology-derived crop trait is around \$136 million.²⁸ However, those who oppose patents argue that they favour larger companies and are unattainable for small businesses.²⁹ There are concerns that the recent decisions by the EBA (Box 5) may make it more difficult for smaller companies to access patented traits and therefore will limit their ability to develop new products.

In order to help smaller businesses access patents, the EPO has introduced fee reductions for small and medium sized companies (SMEs)³⁰. Furthermore, the Preparatory Committee of the Unified Patent Court consultation on court fees included measures aimed at SMEs including incentives to reward parties for early settlement, and targeted support for those parties that need it. It has set annual renewal fees that are comparable to the combined cost of renewing a European patent in Germany, UK, France and Netherlands, which is considered attractive for SMEs.³¹ However, the legal costs for a patent attorney and defending any opposition to an application may still be beyond the means of many small businesses.

Proponents of plant variety rights argue that they encourage innovation because they allow plant breeders and researchers access to genetic resources while protecting the rights holder. Breeders' exemptions are also available in German, Dutch, French and Swiss patent law to allow breeders to use varieties that are covered by a patent in breeding programmes. Any new varieties can be commercialised provided the product does not contain the claimed trait. NGOs such as Plantum and No Patents On Seeds are calling for full breeders' exemptions (like that in PVR) under patent law.^{32,33}

Endnotes

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