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Navigating the Maze of Intellectual Property Protection for Plant-related Innovations in Australia and Overseas

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The United Nations Food and Agriculture Organization (FAO) has estimated that by 2050, food production worldwide will need to increase by 70 per cent (FAO, 2009) to feed our growing population. The challenge of developing new innovations and improving current innovations within the agricultural sector will be critical to the future of Australia's food production and global competitiveness.

The Agricultural Biotechnology Council of Australia (ABCA) has sought to support public acceptance of the necessary technologies. Work includes a public information campaign centred around the need for the coexistence of biotechnology with farming as well as The Official Australian Reference Guide to Agricultural Biotechnology and GM Crops; providing factual information about genetically modified crops based on scientific evidence.

Equally important though is the commercial profitability of research in this field, and widespread knowledge of the options for protecting and commercialising these innovations is critical. There are a number of strategies available both in Australia and worldwide, and these are explored in detail below.

OPTIONS IN AUSTRALIA

1. Patents

A patent is the sole, legally enforceable right to sell, make, use, offer to sell or import an innovation within the country in which it is filed. Patents last for up to 20 years from the date the application is filed and are essentially a monopoly on commercially exploiting the full value from the owned intellectual property.

Plant material that may be patented includes:

- the plant itself (e.g., GM plants or Non-GM plants);
- plant genetic machinery such as genes or proteins;
- reproductive materials such as seeds;
- methods of producing a new plant (e.g., breeding) or cultivation of the plant;
- progeny of the plant; and
- products produced by and/or from the plant (e.g., fruit, fibre, oils etc.,) together with methods of producing those products.

Currently in Australia, isolated DNA is patentable subject matter, which includes for example new gene sequences, proteins and peptides from plants.

It may also be desirable to protect new inventions relating to apparatus used during cultivation and production processes of plants, including for example growth containers, harvesters, etc.

It is important to note that a patent cannot be granted for a mere discovery of biological material such as a new plant variety - a new plant variety discovered in a back garden, for example, would not be patentable. There must have been some technical intervention such as genetically modifying the plant which distinguishes it from a mere discovery.

A patent can take up to 3 years to grant, and the application goes through a rigorous process of examination.

However, in Australia there are also innovation patents, which may be used to protect new innovations. Innovation patents have a maximum term of 8 years and reduce the overall cost and complexity of the patenting process as they are granted without substantive examination. Examination is required before an innovation patent can be enforced.

According to Australian patent law, plants and animals, and the biological processes for their generation, are not patentable subject matter for an innovation patent. However, it is possible to apply for an innovation patent on processes that claim use of a plant, or plant part, that does not result in the generation of a plant.

2. Plant Breeders Rights (PBR)

PBRs are a form of intellectual property which grant a limited commercial monopoly to breeders of new plant varieties, which includes both the variety itself and the name. The monopoly excludes others from performing the following acts:

- Producing or reproducing the material;
- Conditioning the material for the purpose of propagation;
- Offering the material for sale;
- Selling the material;
- Importing the material;
- Exporting the material; and
- Stocking the material for any of the purposes described above.

The variety to be protected must be new, uniform, stable and distinguishable from any other variety of common knowledge with respect to its characteristics (e.g., colour, size, growth pattern etc.).

To be eligible to file a PBR, it is important that the new variety has not or has been only recently exploited. In particular, at the date of lodgement, a new variety may have been sold in Australia for up to 12 months, or overseas for up to 4 years (or 6 years for trees and vines). Sales beyond these times will prejudice eligibility.

Plant varieties eligible for protection include all fungi, algae and genetically modified plants, but does not include bacteria and viruses.

New varieties must be assessed by an accredited Qualified Person (QP) as part of the PBR application process. It is vital that a suitable QP is identified with experience in that particular variety. The QP may undertake verification growth trials themselves or may analyse and certify overseas growth trials.

The propagating material of the variety must also be deposited at a Genetic Resource Centre (GRC) in Australia, where germplasm material may be maintained. This could include a part of a nursery suitable for maintaining the variety if no formal GRC is available.

The term of PBR protection in Australia is 20 years from the date of grant for the majority of varieties except trees and vines, which are provided a period of 25 years, as essentially they take longer to grow. The application process takes approximately 3 years unless the plant is a tree or vine or the material is imported.

Applying for plant breeders rights (PBR) protection is very much a team effort which often includes for example; the Applicant, a patent attorney, the QP and the PBR Office. All four parties are required to coordinate the filing, testing and examination of the new variety.

Patent protection and/or PBR in Australia?

Under some circumstances it is possible to apply for protection under both the PBR and the standard patent system if the innovation is a plant variety that meets the criteria for both. Both systems come with different advantages:

Advantages of obtaining a patent:

- can protect more than the variety (e.g., can protect the process, apparatus and the final product); and
- may have a more extensive monopoly right.

Advantages of obtaining a PBR

- much cheaper to apply for and maintain than a patent;
- quicker and easier, if not importing or exporting plant material;
- also protects the variety name; and
- must be new, uniform, stable and distinct from known varieties, does not need to be inventive.

A registered patent attorney, with expertise in PBR, will be able to advise on the best options.

OUTSIDE AUSTRALIA

Summary - Patents for Plant Related Innovations Worldwide

It may be desirable to seek patent protection in countries other than Australia. Protection may be sought through filing patents in each country of interest or filing a PCT application which provides the right to seek patent protection in many countries.

Europe: Plant varieties and essentially biological processes for the production of plants are not patentable. However, transformation processes and transformed plant cells may be protected.

United States: Following the Supreme Court Myriad decision of 2013, naturally occurring nucleic acids, and likely proteins and peptides from plants and plants found in or derived from nature are not patentable.

However, plant cDNA having a nucleotide sequence that is markedly different from naturally occurring plant DNA is potentially eligible, even though the process of making cDNA is routine in biotechnology. Genetically modified or mutagenized plants also meet the requirements for a patentable innovation.

Canada: "Higher life forms" such as plants themselves are not patentable, however, methods for producing plants, the use of those plants, and genetically modified genes or cells of those plants are patentable.

Japan: Plant varieties and essentially biological processes for the production of plants including breeding methods are in general allowable in Japan. Transgenic plants are also allowable subject matter.

China: In China, transgenic plants, plant varieties and propagating material are not patentable subject matter. However, the use of such plants and plant materials including, for example, plant cells, tissues and organs are patentable subject matter in China.

JURISDICTION SPECIFIC OPTIONS
United States

Plant Patents

Unlike most countries, the U.S. has a 'plant patent' for the protection of some plant varieties. These are different from standard US patents, in that plant patents encompass newly identified plant varieties as well as cultivated spores, mutants, hybrids and seedlings, as long as they reproduce asexually (ie, they are not propagated using genetic seeds).

To be patentable:

- the plant variety must have been invented or discovered and, if discovered, the discovery was made in a cultivated area;
- the plant must not be seed reproduced or tuber propagated;
- the person(s) filing the application must be those who actually invented the plant;
- the plant must not have been sold or released in the U.S. more than one year prior to the application date;
- the plant must not have been enabled to the public, e.g., described in a U.S. publication more than one year before the application date with an offer to sale.
- the plant must differ from known, related plants by at least one distinguishing characteristic; and
- the invention must not have been obvious to a skilled person at the time of the invention by the applicant.

Grant of a patent for a new plant variety prevents others from reproducing the plant, and from using, offering for sale, or selling the plant, or any of its parts, throughout the U.S., or from importing the plant to reproduce, or any parts thereof, into the U.S.;

- A plant patent must be limited to one plant or genome per application;
- A plant patent expires 20 years from the filing date of the patent application;
- When the plant patent expires, the variety becomes publically available; and
- An application for a plant patent does not require submission of plant material to a Genetic Resource Centre (GRC).

Plant Variety Protection Rights (PVPR)

PVPR in the United States provides protection for new varieties of plants that are seed reproduced or tuber propagated – i.e. not covered by the requirements for a plant patent.

The requirements for PVPR are that the variety be new, distinct from other varieties, genetically uniform and stable through successive generations.

The Applicant must provide at least 3,000 viable untreated seeds of the variety and for a hybrid variety at least 3,000 untreated seeds of each line necessary to reproduce the variety for submission at a GRC.

A new variety may be considered new for the purposes of PVPR only if propagating or harvested material of the variety has not been sold or otherwise disposed of to other persons for purposes of exploitation of the variety for more than 1 year in the U.S. or 4 years outside of the U.S. The term of protection is 20 years for most varieties.

Europe

Community Plant Variety Rights (CPVR)

In Europe, a CPVR can be granted for a new plant variety only if the variety is novel. The variety will not be novel if it has been sold or otherwise disposed of to others by or with the breeder's consent:

- within the European Union more than one year before the date of application; or
- outside the European Union more than four years for most varieties, and more than six years for trees and vines, prior to the date of application.

A holder of a CPVR is solely entitled to:

- produce or reproduce the variety;
- condition the variety for the purpose of propagation;
- offer the variety for sale;
- sell the variety or other marketing;
- export the variety from the Community;
- import the variety to the Community; &
- stock the variety for any of the above purposes.

The protection extends to harvested material of the variety (e.g., fruit and cut flowers which are imported) where these are obtained through the unauthorized use of variety constituents of the protected variety.

A CPVR does not give protection to the owner from:

- acts done privately and for non-commercial purposes (e.g., growing the variety in your back garden);
- acts done for experimental purposes; and
- acts done for the purpose of breeding, or discovering and developing other varieties.

The application process for CPVR in Europe is extremely strict and requires original documents to be lodged with the Office, which can be difficult when presented with short deadlines. Furthermore, if claiming priority from an Australian application, it is the date when the application is deemed complete by the European Office which is considered the European filing date, not the date of lodgement. Therefore, if claiming priority, it is a good idea to lodge the application in Europe in good time before the 12 month deadline to ensure all requirements are met.

INTERNATIONAL AGREEMENTS

Members of the World Trade Organisation (WTO) are bound by their membership to adhere to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs). While the Agreement allows countries to exclude plants and essentially biological processes for their production from their patent system, it requires them to "provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof".

UPOV (the International Union for the Protection of New Varieties of Plants) is the international organisation concerned with plant variety protection. There are currently over 65 UPOV member countries.

As well as promoting international cooperation, and assisting countries in the introduction of plant variety protection, UPOV also provides the guidelines for undertaking the comparative growth trials, known as distinctness-uniformity-stability (DUS-testing) required by most PBR systems.

PBR registration systems are broadly the same in each of the UPOV member countries. Australia is a UPOV member country and its PBR scheme conforms with the UPOV convention. As such, UPOV member countries are required to treat Australian applicants in the same way as their own nationals with respect to applications for PBR.

CONCLUSION

The process of securing protection for a new innovation in food or agriculture in Australia and overseas can be complex and mistakes at an early stage can be damaging to the eventual outcome. New IP owners should seek the advice of a suitably experienced patent attorney early in the process to ensure the best possible protection in the right jurisdictions.

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