



Shoots, leaves and money trees

Marcelo Pomeranz, Daniel J Knauss and Erich E Veitenheimer explore how counsel and inventors can grow their agri business through IP rights

The US has more forms of legal protection for plant-related inventions than any other country in the world. Innovators wishing to protect their inventions in the US can do so through trade secret law, or through the formal IP protections available for plant inventions: utility patents, plant patents, and Plant Variety Protection Act (PVPA) certificates. Table 1 summarises the characteristics of each IP protection type discussed here. PVPA protection, for example, is only available for varieties that are uniform and stable across generations, and is limited by exemptions, which allow third parties to save seed for future crops and to breed using the protected variety. Plant patents are only available for varieties that can be asexually reproduced, and do not protect against seed propagation of the variety. Utility patents provide the strongest and most flexible protection, but are subject to the highest disclosure standards and face the most rigorous review. A further complexity is that different IP forms have different deposit requirements. Understanding the scope, limits, and rules for each type of protection can help inventors and counsel deploy effective legal strategies for protecting their IP while making the most of their legal budgets.

What is the product and how will it be commercialised?

The choice of which IP type to pursue is partially driven by the invention's expected use and commercialisation strategy. For example, plant patents would likely be effective for protecting asexually reproduced cannabis varieties that lose their desired phenotypes when crossed, but would be far less effective at providing exclusivity for stable seed-propagated plants, such as inbred tomatoes. PVPA certificates, with their "research" and "saved seed" exemptions, would also likely be less valuable for varieties whose primary commercial value was as breeding stock.

Further, PVPA and plant patent protections are limited to the disclosed plants themselves, and do not extend to non-plant aspects of the invention, such as non-naturally occurring compositions derived from the plant (eg, dietary supplement formulations), or transgenic traits that are applicable to other plants or species (eg, herbicidal resistance transgenes). For these types of inventions, utility patents may be preferred. Utility patents are also the only type of IP that can provide inventors with extraterritorial protection against the importation of products produced by patented methods, such as pasta products produced from a protected wheat variety, or new plant varieties produced with patented genetics.

Biological deposits and disclosures

A second consideration in selecting which IP type to pursue is the technical and legal ability to complete biological deposits. All PVPA applications must be accompanied by a deposit of 3,000 seeds of the variety. Utility patents similarly require deposits for plant inventions that

are not otherwise enabled or capable of being described by the patent text alone (eg, for non-transgenic plants that cannot be described by presence of a known, sequenced transgene).

Some plants, such as bamboo, may have flowering cycles that make producing the required seed deposit for a PVPA or utility application difficult. Although utility patents can also be supported by tissue deposits, these can present their own set of challenges, as the applicant must provide tissue that is capable of regenerating the claimed plant after cryogenic preservation, or must otherwise arrange for a depository with the ability to maintain fresh viable tissue over many years. Other legal factors may also limit the ability for an applicant to complete a deposit. Cannabis seeds remain implicated by federal law at the time of the writing of this article, and are therefore not accepted by any PVPA or utility patent US depository facility (a handful of cannabis utility patents are supported by foreign deposits). Plants for which deposits are not feasible may instead be pursued by plant patents.

Biological deposits made in connection with utility patent applications can also raise significant concerns regarding germplasm dissemination. Utility patent rights are territorial (limited to the granting country's borders), but deposits that are included as part of an issued patent are made available to the public worldwide upon grant. This creates significant risk of competitors outside the protected territory incorporating the applicant's germplasm into their products or breeding pipeline. Depending on the scope of US patent protection obtained, competitors may even be able to import back into the US new genetics produced by breeding with those deposited lines outside of the country. PVPA deposits are only released at the expiration of the period of exclusivity, and are therefore of less concern.

Overlapping protection

Innovators can pursue and enforce multiple forms of IP protection simultaneously for new plant varieties. Combining multiple forms of IP covering a single invention permits applicants to leverage strategies for raising aggressive exclusivity barriers, with IP lifecycle management, and minimised technological disclosure. For example, an inventor of a new variety of tomatoes would be permitted to seek utility patent protection for claims on methods of breeding and growing the variety, in order to block competitors from exploiting the breeder's and saved seed exceptions of a PVPA certificate. Alternatively, an inventor holding a utility patent protecting all corn plants with a valuable resistance gene may attempt to extend exclusivity on the technology by securing PVPA certificates for later-developed novel commercial inbred or hybrid lines containing the protected gene. For example, "infra short-day type strawberry plants" are claimed as a distinct plant type in US Patent No 5,444,179, while specific strawberry varieties within the type are claimed in at least eight plant patents: Nos 7865, 7869, 7870, 7876,

Table 1: Summary of plant protection rights in the US

Type of IP	Scope of coverage	Exceptions to coverage	Scope of protection and term	Limits/special requirements
Utility patent	Any useful, novel, nonobvious invention.	Judicial exceptions: laws of nature, natural phenomena, and abstract ideas. USPTO guidelines are helpful.	Exclude others from making, using, offering for sale, or selling the invention in US or importing into US (20 years from filing date). Extra territorial protection for inventions produced by patented methods.	Broad protection defined by claims. Biological deposit necessary if required to enable or describe the invention.
Plant patent	Any distinct and new variety of plant that has been asexually reproduced.	Tuber propagated plant. Plants found in an uncultivated state.	Exclude others from asexual reproduction (20 years from filing date).	Only protects against asexual reproduction.
Plant Variety Protection (PVP)	Any new, distinct, uniform, and stable plant.	Plant not meeting the criteria, and plants not capable of deposit at federal depository.	Exclude others from selling, importing, etc. (20 years from issuance, 25 years for vines and trees).	Research exemption allowing use for breeding to develop a new variety. Farmer's exemption allowing saving of seed for replanting. Deposit of seed required.
Trade secret	Scope of coverage/pros of trade secrets Any technical or business information that is secret and gives the owner an advantage over a competitor who does not have it. Unlimited duration as long as the subject matter is kept secret.		Requirements/limits on protection Owner must show reasonable measures to keep secret, which may be difficult if secret is discernible from commercial product. Protects against theft, but not independent creation.	

7881, 8746, 8747 and 8748.

Innovators may also structure their patent filings to avoid releasing valuable genetics to competitors outside of the protected territory. For example, many biotechnology companies protect platform traits, such as herbicidal resistance, in utility patents based solely on the transgene sequence, and later seek utility patents for commercial varieties by depositing non-transgenic lines and claiming the plants with the added feature of a single locus conversion of the missing transgene. This strategy produces two sets of overlapping claims protecting the final resistant line, without ever making the final product available to the public.

Trade secrets and contractual protections

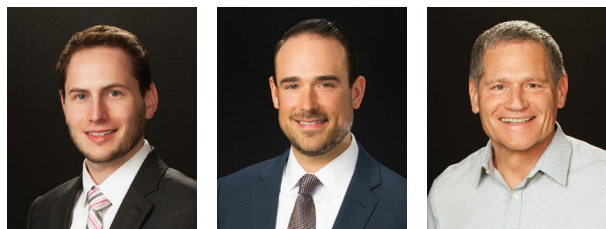
Trade secrets and contractual protections are valuable tools for use in a well-rounded IP strategy. Trade secrets can be used to maintain proprietary technologies in situations where the likelihood of keeping the technology secret is high, and/or where the corresponding ability to police competitors is low. Trade secret protection incurs lower upfront legal costs, and has the potential to provide exclusivity as long as the secret is maintained. Companies relying on trade secrets, however, run the risk that the information will be leaked to the public, or that the technology will be independently developed by a competitor. Although state law often allows for the recovery of damages for trade secret disclosures, collection of those damages can be difficult, and there is often no way to “un-ring the bell” and take back released information.

Many biotechnology companies also rely on contractual protections, such as bag tag agreements, to replace or fill gaps left by formal IP protections. For example, many bag tags prohibit saving seed from a crop in order to prevent growers from exploiting the PVP breeding and saved seed exemptions. Other popular clauses prohibit exporting seed (to avoid germplasm release to jurisdictions without patent protection), or sequencing of the germplasm (to avoid reverse engineering). These contractual obligations not only increase the layers

of exclusivity over a technology, but also provide innovators with the opportunity to control the downstream use of their products.

Innovators should develop an IP plan early in a product's lifecycle that thoughtfully utilizes the overlapping forms of IP protection, trade secret law, and contractual restrictions available in the US.

Authors



Marcelo Pomeranz (left) is an associate at Cooley, his practice focuses on the drafting and prosecution of biotechnology patent applications and Plant Variety Protection applications, as well as assisting in the preparation of invalidity/noninfringement, freedom to operate and patentability opinions. He has extensive technical experience in plant biology, RNA silencing, molecular biology and systems biology.

Daniel J Knauss (middle) is a partner at Cooley, his litigation practice focuses on intellectual property, with an emphasis on life sciences. He litigates patent infringement and contract disputes concerning a variety of technologies, including cancer medicines, antiviral therapeutics, biofuels, agriculture and medical devices.

Erich E Veitheimer (right) is a partner at Cooley and focuses on developing and implementing strategies to enable his clients to procure worldwide protection for their inventions and/or provide them with the necessary freedom to operate. His practice covers a wide variety of technologies including plant breeding, food science and agricultural biotechnology, among others.