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FEATURE

Protecting Plant Inventions

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Interest in protecting intellectual property (IP) for plant-related innovations has grown in view of the merger of high technology and agriculture, the globalization of food sources, the increasing demand for green energy, the rapid emergence of a legal cannabis industry, and the growing public acceptance of plant biotechnology. This article reviews the variety of ways that plant-based inventions can be protected in the United States, and discusses trends and developments in those legal protections.

Forms of IP Protection for Plants

The United States has more forms of government-mandated legal options for protecting plant-related intellectual property than any other country. IP owners filing in the United States may seek formal patent and patent-like protection for their inventions by applying for a utility patent, a plant patent, and/or a plant variety protection (PVP) certificate.¹ In the United States, these forms of legal protection are not mutually exclusive,² making it possible for innovators to obtain multiple formal protections for their new varieties, provided they meet the statutory requirements for each form.

Utility Patents

While many countries have some restrictions on the patenting of living things, almost any conceivable invention involving plants is eligible for patenting in the United States. Utility patents have been issued on a wide variety of plant-related inventions, including: (1) methods of breeding

plants; (2) methods for producing transgenic or edited plants, including using CRISPR technologies; (3) plant parts and products, such as seeds, starches, and gums; (4) herbal medicines and supplements; (5) chemicals made by plants, including formulations comprising flavonoids, cannabinoids, alcohols, and resistant starches; (6) non-naturally occurring amino acid molecules isolated from plants, such as peptides and proteins; (7) non-naturally occurring nucleic acid molecules isolated from plants; (8) plant cells, including individual cells and plant tissue cultures; (9) individual plants, such as inbreds, hybrids, and varieties, whether produced through genetic editing or traditional breeding; and (10) groups of plants, such as open-pollinated populations and synthetics.

Application and Deposit

Utility patents provide inventors with a limited period of exclusivity in exchange for full disclosure of the technology to the public. Patent applications must include sufficient disclosure to enable a person having skill in the art to make and use the invention. For example, utility patents for transgenic crops can be enabled through a description of the nucleic acid sequence of the transgene that is responsible for the claimed phenotype (e.g., the gene providing the plant with glyphosate resistance). Enabling utility patents for nontransgenic plants that are produced via traditional breeding methods can be challenging, as these inventions are less amenable to description on paper.

One way to satisfy the enablement requirement for plant inventions is to supplement the application's written description with one or more biological deposits. The U.S. Patent and Trademark Office (USPTO) permits applicants to deposit seed or other propagation material capable of producing the claimed plants at an internationally recognized depository facility at any time before issuance of the patent.³ These deposits are treated as part of the applicant's disclosure and can satisfy the written description and enablement requirements.⁴

Feasibility of a Deposit

Before filing an application, applicants should carefully consider the feasibility and cost of producing the deposit. Some plants have long or difficult flowering cycles that could prevent the applicant from producing the required 2,500 seed deposit.⁵ Tissue deposits present other challenges, as the applicant must arrange for a depository with the ability to maintain fresh viable tissue for long periods.⁶ Other legal factors may also limit the ability of an applicant to complete a deposit—cannabis seeds, for example, are not necessarily accepted by any U.S. depository facility.⁷

Note, however, that the 2018 Farm Bill removed legal hemp (defined as containing no more than 0.3 percent THC by dry weight) from the definition of “marihuana” under the Controlled Substances Act,⁸ creating the expectation that U.S. depositories should accept deposits of legal hemp seed made in connection with patent applications.

Timing for a Biological Deposit

Applicants should also carefully consider the timing of their deposits before filing the first application to a biological invention. In the United States, applicants may delay submission of biological deposits of disclosed plants until issuance of the patent.⁹ Post-filing deposits in the United States are afforded the same protection as if they had been filed in the original application, so long as the deposit is determined to be for a plant that was specifically identified in the original filing.¹⁰ Most other countries, however, require deposits to be completed at the time of filing, and therefore limit priority claims to applications that already included the enabling deposits.¹¹ For example, the Canadian and European patent offices both require applicants to complete deposits for their inventions before the filing of an international Patent Cooperation Treaty (PCT) application, or before the filing of a national application.¹² Thus, applicants wishing to seek patent protection for their varieties abroad should plan on completing their biological deposits at least prior to the filing of a PCT application, if not earlier.

Risks of Over-Disclosure with Biological Deposits

Applicants should also consider the disclosure implications of their deposit decisions. Once a patent issues, any biological deposits provided therein are made available to the public.¹³ In the United States, the ability to delay the submission of enabling deposits permits applicants to perfectly tailor their deposited material to the issued claims (i.e., applicants can choose to only include deposits associated with claims that were actually allowed). As noted, however, this approach is reversed in many foreign jurisdictions, where applicants must deposit in advance of prosecution. This could result in the applicant having to release all disclosed deposits to the public, even if the issued claims only cover a subset of the disclosed material.

Similar concerns exist for deposited genetics that are patented in one jurisdiction but remain unprotected in others. The rights obtained from an issued patent are territorial, and are thus limited to the granting country’s borders. Deposits, however, become available to the public worldwide, including beyond the territorial scope of the applicant’s IP rights. This fact creates significant potential competitive risk: such deposits are available to competitors outside the

territory protected by the patent, where they may be integrated into a third party's product line or breeding pipeline.

Depending on the strength of patent claims held by the innovator, competitors might seek to import back into the United States the new genetics produced by breeding with the patent owner's deposited lines outside of the country. Utility patent owners, however, are not entirely without recourse in this situation and may still be able to prevent the importation of products produced abroad from their patented genetics. Two provisions under the U.S. International Trade Commission¹⁴ and the patent enforcement statutes¹⁵ prohibit the importation of products made by a process patented in the United States. Thus, applicants with the foresight to patent methods of breeding, or methods of extracting valuable compounds from their patented genetics, may be able to prevent this kind of infringement via importation.

Requests for Additional Information during Prosecution

Another notable development in recent applications for plant-focused utility patents are requests from the patent examiner for "such information as may be reasonably necessary to properly examine or treat the matter."¹⁶ It has now become common for examiners to request information such as detailed family pedigrees, breeding methodologies used to develop varieties, and copies of contracts with growers and field testers. Responding can greatly increase the costs and time necessary to gain protection for new plant varieties, especially those with complex development histories. In addition, any information provided in response to the requests will become publicly available absent filing a petition to suppress its publication online or to expunge the information from the USPTO records after issuance.¹⁷ In rare cases, examiners may deny an applicant's petition to expunge trade secret information if they consider the information to be pertinent to patentability of the case.¹⁸ It then may be more desirable to abandon the application than to have confidential pedigrees and breeding methods become public, or otherwise continue examination to avoid issuance.

Term, First Inventor to File, and Grace Period

The owner of a utility patent can exclude others from making, using, offering to sell, selling, or importing the patented invention into the United States.¹⁹ Patents are not self-executing rights and must be enforced in federal court, where the patent owner will have the burden of proving the defendant's infringing activities during the effective term of the patent.

For applications filed on or after June 8, 1995, the patent term extends 20 years from the patent's earliest effective filing date.²⁰ Patent applications filed after May 29, 2000, are also eligible for patent term adjustment (PTA) that extends the term of issued patents to compensate for USPTO processing delays.²¹ PTA can add weeks, months, or even years to a patent's effective term, but can also be lessened by applicant delays. Patent owners are thus incentivized to respond to all USPTO communications within the initial deadlines in order to preserve as much patent term as possible.

Applications filed after March 15, 2013, are reviewed in the United States under the first-to-file provisions of the America Invents Act. Under this new regime, patent ownership is determined by the first inventor to file on an invention, in contrast to the previous system which afforded protection to the first to *invent*, regardless of which party won a race to file at the patent office.²² The "first-to-file" approach is a marked change to the rules that had operated in the United States for over a century before, but significantly increased the harmony of U.S. IP rules with the rest of the world.

Notably, the transition to the first-to-file regime did not totally eliminate the grace period available for inventor disclosures of an invention. Applicants may file a patent application for their invention up to one year after any disclosure of the invention (by the applicant), including public use or sale of the invention. Applicants should carefully monitor the handling of their inventions before filing a patent application, as even inadvertent disclosures or commercial activity outside of the U.S. grace period may ultimately prevent the applicant from patenting its technology. For example, a grower contract for a soybean variety lacked requirements for secrecy and confidentiality, and "use of the seed" more than one year prior to the earliest application priority filing date was found to bar patentability of the variety.²³

Validity Conditions Limiting Utility Patents

Over the past 15 years, a string of developments in the patent statutes and interpreting case law have, on the whole, narrowed the enforcement power of intellectual property. The changes include an expansion of the rule against patents covering obvious variations on the prior art and a major expansion in the applicability of the rule against patents on "abstract ideas" and "natural phenomenon."

On the issue of obviousness, in 2007, the U.S. Supreme Court decided *KSR International Co. v. Teleflex Inc.*,²⁴ which lessened rigidity in application of the standard for obviousness.²⁵ In response, the USPTO drafted *KSR* training guidelines.²⁶ Accordingly, it is even more important to

provide evidence of patentability in the application with supporting arguments like teaching away from the invention in the prior art, synergistic interactions enabled by the invention, and other unexpected benefits.

On the issue of patentable subject matter,²⁷ the past 10 years have seen a marked uptick in the number of cases finding that patents impermissibly cross the line into unpatentable abstract ideas, laws of nature, and natural phenomenon. Though the law prohibiting such broad patents has existed for decades, courts have increasingly turned to it as a check on broad patent claims—especially in the area of software patents. Biological inventions have not been spared from these developments, however. In a series of landmark decisions, appellate courts have limited the patentability of naturally occurring non-cDNA sequences,²⁸ and treatment²⁹ or diagnostic³⁰ methods based on naturally occurring biological relationships. These holdings, though so far directed at nonplant inventions, may be relevant for applicants considering protecting plant genes or markers, seeking to claim non-GMO plants based on their DNA content, or covering inventions involving the use of microbes to improve plant performance or protecting plants from pathogens.

The overall trend of limiting the patentability of products of nature has not affected the patentability of plants themselves. For example, plants produced via traditional breeding schemes (i.e., non-GMO) continue to be patentable, so long as they are distinct from other naturally occurring plants. Even this requirement, however, is unlikely to have a large impact on the patenting of plants, as the initial burden for determining that a plant is naturally occurring is on the USPTO. This policy effectively gives applicants the benefit of the doubt, and relieves them from having to prove a negative. As the Supreme Court has stated, the mere possibility that an invention may exist in nature is not enough to bar the eligibility of the claim.³¹

Challenges to Patent Validity

In addition to the court decisions on validity, recent years have also seen creation of new procedures at the USPTO for streamlined reexamination of patents.

Since 2012, inter partes review (IPR) has allowed a relatively rapid second look at the validity of issued patents. The proceeding takes place before the Patent Trial and Appeal Board (PTAB), which operates under a statutory mandate to provide a final written decision on patentability within 18 months of the filing of a petition seeking IPR.³² Such petitions can be filed by any party, although a party accused of infringing the subject patent must seek IPR review within one year of being served with a complaint for patent infringement. Furthermore, IPR petitions may only be

based on anticipation and obviousness challenges that rely on patents and other printed publications. The litigation-like “trial” during IPR features dueling rounds of briefs, often supported by expert declarations and depositions, and culminates in an oral hearing before a panel of three PTAB judges prior to the final decision. USPTO statistics show that 65 percent of petitions to institute an IPR are granted, and of those granted 81 percent result in the invalidation of at least one challenged claim.³³ IPRs have invalidated scores of patents, which has triggered reactions from patent owners, both through lawsuits challenging the constitutionality of the IPR procedure as well as calls for statutory reform. While IPR has so far weathered these constitutional challenges,³⁴ expect this area of law to be dynamic and subject to significant change for many years to come. For now, companies facing patent threats should make strategic use of IPR to fend off patent assertions and reduce litigation costs when possible by seeking a stay of any co-pending litigation.

For more recent patent lineages begun under the new “first-to-file” regime, yet another procedure called post-grant review (PGR) is also available.³⁵ These proceedings have many similarities with IPRs, with some important differences—such as the ability to challenge a patent in PGR with invalidity grounds beyond those based on the published prior art.³⁶ Finally, regulations allow third parties to file “observations” relating to ongoing prosecutions of their competitor’s patent first-to-file applications, and allow those observations to be filed with explanatory comments to assist the examiner.³⁷

Plant Patents

This unique form of intellectual property, available only in the United States, provides protection to any distinct and new variety of plant that has been asexually reproduced, other than a tuber propagated plant or a plant found in an uncultivated state.³⁸ This form of protection is not available for tuber-producing plants such as potatoes and Jerusalem artichokes, or for plants newly discovered growing in the wild. Plants found in a cultivated state and subsequently asexually reproduced are patentable, including mutants, sports, and hybrids. While plant patents have been most commonly obtained for ornamentals (e.g., geraniums, petunias, and impatiens) and fruits (e.g., plums, apples, and grapes), they have also been obtained for other types of plants such as perennial corn, sugar cane, cannabis, and interspecific trees.

Plant and Utility Patent Requirements Compared

The requirements to obtain and enforce plant patents are similar to utility patents except for three important distinctions. First, there is a less burdensome requirement to satisfy the written description requirements of 35 U.S.C. § 112.³⁹ In practice, the applicant is usually allowed to supplement the written description of the claimed plant during prosecution if the examiner requests additional information.⁴⁰ Second, plant patents are limited to a single claim directed to one plant or genome.⁴¹ Third, the rules on biological deposits are not applicable to applications filed under the Plant Patent Act—no deposit is required, even if the material was deposited in connection with a utility patent application.⁴² Applicants must provide color drawings or photographs of the plant that show their most distinguishing characteristics.⁴³

Plant Patent Enforcement

The enforcement of plant patents differs significantly from utility patents. The owner of a plant patent can “exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, . . . or from importing the plant so reproduced, or any parts thereof.”⁴⁴ While on its face this exclusionary right seems broad, the law is that “for purposes of plant patent infringement, the patentee must prove that the alleged infringing plant is an asexual reproduction, that is, that it is the progeny of the patented plant.”⁴⁵ It can be challenging in practice to obtain such direct evidence of an infringer’s asexual reproduction where the progeny can be traced back to the original patented plant. Without direct evidence of the theft and/or compelling eyewitness testimony, proof of infringement can be difficult. It is conceivable, however, that infringement could be argued circumstantially where the allegedly stolen plant is shown to have 100 percent genetic similarity with the patented plant. This uncertainty in proving infringement is generally viewed as weakening the value of plant patents, and differs sharply from utility patents, which cover any composition or method within the scope of the claims—even if it was independently derived by an infringer who had no intent to infringe.

Plant Variety Protection

The Plant Variety Protection Act (PVPA)⁴⁶ is the U.S. implementation of the international system of plant variety protection as coordinated by the International Union for the Protection of New Varieties of Plants (UPOV) and administered by the U.S. Department of Agriculture (USDA). The PVPA provides patent-like certificates to the breeder and reproducer of any new, distinct, uniform, and stable sexually or asexually reproduced or tuber propagated plant variety. PVP certificates have been issued for a wide variety of plants, including artichokes, arugula, bentgrass, cauliflower, field corn, lettuce, papaya, potato, rice, sunflower, and zinnia.⁴⁷ Of note, the 2018 Farm Bill

significantly altered the scope of PVP by allowing certification of varieties produced sexually or asexually (previously limited to sexually reproducing varieties).⁴⁸

PVP Grace Periods and Protection Terms

PVP must be applied for within one year after the public dissemination or sale of the variety in the United States, or within four years prior to any such activities occurring outside of the United States. Applications for vine or tree varieties are afforded a longer six-year grace period for activities occurring outside the United States.⁴⁹ These grace periods for varieties originating outside of the United States account for import restrictions/requirements for plants, which can delay actual introduction into commerce. The term of protection is 20 years from the date of issue of the certificate, except trees or vines have a term of 25 years.⁵⁰ Under certain circumstances, the term may be shortened if delays in prosecution are attributed to the applicant.⁵¹

PVP Deposits

PVP applications must also be accompanied by a seed or tissue deposit,⁵² and a declaration committing the applicant to replenish the deposit to maintain stock and ensure viability of the deposit.⁵³ In contrast with deposits for patents, which are handled by private authorized depositories, PVP deposits are submitted according to the USDA's instructions to the National Laboratory for Genetic Resources Preservation (NLGRP) in Fort Collins, Colorado.⁵⁴ Unlike the deposits for patents, PVP seed deposits are not made available to the public until the PVP certificate expires, thus reducing the likelihood of unauthorized use of the applicant's plant.⁵⁵ The 2018 Farm Bill effectively decriminalized legal hemp varieties, clearing the way for the NLGRP to begin accepting legal hemp deposits in support of seed-propagated hemp PVP applications.⁵⁶ Prior to the Farm Bill amendments, PVP was not available for new cannabis varieties since the NLGRP would not accept the necessary deposits.

PVP Scope of Protection

The PVP certificate owner can exclude others from selling the variety, importing or exporting the variety, multiplying the variety for marketing, using the variety to commercially produce a hybrid or different variety, using marked seed for unauthorized propagation, dispensing the variety to another without notice of its protection, conditioning the variety for the propagation, or stocking the variety for any of these prohibited purposes.⁵⁷

There are, however, two very important exemptions to the scope of IP protection provided by PVP. The first, called the “research exemption” or “breeders rights,” permits the use and reproduction of a protected variety for plant breeding or other research.⁵⁸ In an effort to curb perceived abuses of the research exemption, the PVPA was amended in 1994 to extend the enforceability of PVP certificates to “essentially derived varieties” (EDVs).⁵⁹ In doing so, Congress essentially limited the research exemption to use of protected varieties in plant breeding to create new varieties that were so distinct from the PVP variety that they would not qualify as EDVs.

Unfortunately, little guidance is available for breeders or certificate owners regarding the contours of EDV protection. The statute defines an EDV as “a variety that . . . is predominantly derived from another variety . . . or from a variety that is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.”⁶⁰ This definition fails to provide clear morphological or genetic standards for determining whether a plant derived from a protected variety falls within the scope of EDV protection, particularly since the Act defines the distinctness of a variety for the purposes of registration as a difference in “one or more identifiable morphological, physiological, or other characteristics.”⁶¹ This issue is a topic of ongoing discussion in the industry, with various proposals for increasing stringency around the definition of EDV. Proposals offered by the International Seed Federation (ISF) involve the use of a genetic marker test to determine the percentage of genetic similarity between the infringing variety and the protected plant.⁶² These thresholds would vary by variety type. For example, under the ISF proposal for lettuce, in cases where genetic similarity is 96 percent or greater, EDV qualification is presumed and the burden of proof reverses such that it falls on the accused infringer to prove its variety is not an EDV of the protected variety.⁶³

EDVs are themselves eligible for PVP registration. The resulting EDV certificate is narrower in scope, as it does not give the owner any rights against further derivatives of his or her protected EDV (i.e., it will not cover EDVs of the EDV, as this right remains with the owner of the original PVP certificate).⁶⁴ Moreover, registration of the EDV does not take the EDV outside of the enforcement scope of the original certificate. Therefore, the owner of an EDV plant will still need permission from the original PVP certificate holder to commercialize the variety.⁶⁵

The second exemption, often called the “crop” or “saved-seed” exemption, permits one who rightfully obtains seeds of a protected variety to save a limited amount of seed for replanting, but the seed cannot be sold to others for any reproductive purpose.⁶⁶

In addition to these exemptions, PVP rights are subject to the compulsory licensing requirements of the Act. Under these provisions, the USDA Secretary is authorized to grant two-year compulsory licenses where the Secretary determines that such a license would serve the public interest in maintaining an adequate supply of food, fiber, or feed, and the PVP owner is unable or unwilling to supply the public needs at a fair price.⁶⁷

Deciding Which Type of IP Protection to Pursue

Choosing among the Three Forms of Plant IP in the U.S.

Each of the types of available plant IP protection provides a different scope of coverage and includes different limitations to its exclusionary rights. The choice of which protection to pursue will be largely driven by the standards of the industry, and by the type of protection that is desired. Table 1 summarizes the characteristics of each of the three types of IP rights discussed in this article.

Some plant species are not eligible for protection under one or more IP schemes, and this fact alone may dictate what form(s) of protection is available for a specific new plant variety. Where more than one form of IP protection is available, however, there is no prohibition against pursuing and enforcing multiple forms of IP protection simultaneously for a new plant variety.⁶⁸ Furthermore, an inventor may seek utility patent protection for a new class or group of plants and still seek utility patent, plant patent, or PVP certificate protection for individual plants within that class or group.⁶⁹

Combining various forms of IP can provide comprehensive and versatile protection for potentially valuable plant inventions. An inventor of a new variety of strawberries, for example, would be permitted to seek utility patent protection for claims reciting methods of breeding and growing the variety, in order to block competitors from exploiting the breeder's exception and saved seed exception of his or her PVP certificate.⁷⁰ Alternatively, an inventor holding a utility patent protecting all corn plants with a valuable resistance gene may attempt to extend his or her exclusivity on the technology by securing PVP certificates for later-developed novel commercial inbred or hybrid lines containing the protected gene.

Inventors may also leverage the timing of their utility patent and PVP filings to avoid releasing valuable genetics to competitors outside of the protected territory. For example, an inventor could choose to support his or her utility patent for a genus of pest-resistant melon plants with

seed deposits from experimental varieties exhibiting the claimed features, but lacking desirable taste phenotypes, while later seeking protection for better-tasting commercial lines via PVP.⁷¹ Although the seeds from the utility patent would become immediately available upon issuance of the patent, these seeds would be of little value to competitors. Seeds deposited as part of the PVP certificate would not be released until after expiration.

Holders of overlapping IP rights may also benefit from additional enforcement flexibilities. The owner of a broad utility patent application covering a genus of plants could decide to enforce its plant patents claiming the specific commercial lines being infringed. The ability to allege infringement of multiple IP rights may also act as a further deterrent to infringers, who must weigh the cost of multifront litigation against the cost of licensing.

While many factors go into a decision about which forms of IP protection to seek for a new variety, the decision depends primarily on such practical considerations as the cost of obtaining each protection and the scope of protection each provides, while considering the relative commercial value of the variety. In general, the scope of protection and the costs to obtain it are greatest for a utility patent and least for a PVP certificate. On average, plant patents are somewhat intermediate in both regards. Where a plant variety has a perceived or actual commercial value that is far greater relatively than the cost of obtaining a particular protection, the owner will usually seek a utility patent at a minimum and, where available, one or more of the other forms of protection.

For some plant-related inventions, utility patents may be the only form of available IP protection. Plant patents and PVP are both limited to specific plant varieties. Thus, a utility patent is the only form of protection available in the United States for new breeding methodologies, broad new classes or types of plants, DNA isolated from plants, etc.

Relying on Nonpatent Forms of Protection

Alternatively, the owner of such intellectual property may forgo all of the forms discussed in this article and choose to maintain the discovery as a trade secret. This avoids public disclosure, but presents the risk of permanently losing one's monopoly in the event of unauthorized public release.⁷² For example, due to the seed deposit requirement for obtaining a utility patent, a company may decide not to patent the new variety at all or, alternatively, to patent a new hybrid but not to patent one or more of the novel inbred parents, particularly the female. Deciding to forgo a utility patent on an important inbred or hybrid line may be more practical where it is

possible to maintain strict controls over the growing and handling of the inbred and hybrid seed, such as where the company owning the variety increases and crosses all of the inbred plants on property under its direct control. Smaller entities that must enter into joint development agreements or contract for their research or production programs are under significantly greater risks of loss of secrecy and control of their proprietary varieties.

While contracts may also be used to limit allowed activities with specific intellectual property, these generally bind only the parties who execute them, whereas a government-granted monopoly through patent operates throughout the United States and can impact all competitors. Note that inventors may wish to maintain their invention as secret for a period of time in order to test its economic viability before seeking patent protection. Such trial uses, especially if they involve collaboration with third parties, must be carefully controlled and kept secret through properly drafted contracts to avoid creating invalidating prior art uses and sales.

Finally, for completeness in discussing IP protection of plant-related inventions, it is important to mention that other forms of intellectual property could be used to protect the associated aspects of a plant invention. Table 2 briefly summarizes other forms of protection that could be sought to protect new variety names (trademark), instruction manuals for plant breeding schemes or devices (copyright), or trade secret protection of inventions.

[Download PDFs of Table 1 and Table 2.](#)

Endnotes

1. This article does not deal with other forms of IP protection that may be peripherally related to plant inventions, such as brand trademarks, copyrights, trade dress, etc., nor does it deal specifically with IP protections for biological inventions involving yeast, bacteria, or fungi.

2. J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 131–32 (2001).

3. 37 C.F.R. §§ 1.801–.809.

4. *See id.* § 1.802(b); 35 U.S.C. § 112.

5. The USPTO has previously accepted smaller quantities of seed for plants with low seed yield with the applicant's commitment to complete the 2,500 deposit with due diligence. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 2403.02 (9th ed. Rev. 08.2017, Jan. 2018).
6. As of the time of the writing of this article, the American Type Culture Collection (ATCC) facility only accepts cryopreserved tissue cultures. The National Center for Marine Algae and Microbiota (NCMA) accepts fresh culture deposits, which are maintained by facility staff.
7. As of the time of the writing of this article, the National Collection of Industrial, Food and Marine Bacteria (NCIMB) in Scotland is the only facility in the world that is capable of accepting seed deposits for cannabis plants.
8. *See* 7 U.S.C. § 1621; 21 U.S.C. § 802(16)(B).
9. 37 C.F.R. § 1.809(c).
10. *Id.* § 1.809(d)(3).
11. For a complete listing of the deposit requirements of all PCT contracting states, see Annex L of the PCT Applicant's Guide, available at http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexl/anx_l.pdf.
12. *See* Patent Rules, SOR/96-423, § 104(1) (Can.) ("The deposit of the biological material shall be made by the applicant with an international depositary authority on or before the filing date of the application."); Implementing Regulations to the Convention on the Grant of European Patents r. 31(1)(a), Dec. 7, 2006 ("[A] sample of the biological material [must be] deposited with a recognized depositary institution on the same terms as those laid down in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977 not later than the date of filing of the application.").
13. 37 C.F.R. § 1.808.
14. 19 U.S.C. § 1337(a)(1)(B)(ii) (prohibiting the importation into the United States of articles that "are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent").

15. Under 35 U.S.C. § 271(g):

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

16. 37 C.F.R. § 1.105. These can include “any information available regarding the sale or other public distribution of the claimed plant variety anywhere in the world.” *See* *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1280 (Fed. Cir. 2005). In light of the Supreme Court’s recent decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 139 S. Ct. 628 (2019), confirming that secret sales of the invention can destroy patent rights, the USPTO may become more proactive in seeking this information during examination. For a recent discussion of the on-sale and public use doctrines in the context of plant-based inventions, see Daniel Knauss, Sarah Moore & Erich Veitenheimer, *Ensuring a Bountiful IP Yield from Plant Sales*, *MANAGING INTELL. PROP.* (Feb. 8, 2019), <https://www.managingip.com/Article/3857730/Ensuring-a-bountiful-IP-yield-from-plant-sales.html>.

17. 37 C.F.R. § 1.59.

18. *See* MPEP, *supra* note 5, § 724.04.

19. 35 U.S.C. § 271.

20. That is, the first U.S. nonprovisional or PCT international filing date for the case. *See id.* § 154.

21. *Id.* § 154(b).

22. *See id.* § 102(a). Note that an important exception remains to protect true inventors from third parties who “derive” the invention from the work of that inventor and then rush to the patent office to obtain the first filing date. *See id.* § 135.
23. *Ex parte C*, 27 U.S.P.Q.2d 1492 (B.P.A.I. 1992). Indeed, “secret” sales agreements can still constitute invalidating prior sales under certain limited circumstances.
24. 550 U.S. 398, 415–22 (2007).
25. 35 U.S.C. § 103.
26. *See MPEP*, *supra* note 5, § 2141.
27. 35 U.S.C. § 101.
28. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595–96 (2013).
29. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90–92 (2012).
30. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379–80 (Fed. Cir. 2015).
31. *See Myriad*, 569 U.S. at 595 n.8 (“The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.”).
32. *See* 35 U.S.C. §§ 311–319; 37 C.F.R. §§ 42.100–.123; *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136–38 (2016).
33. U.S. Patent & Trademark Office, Trial Statistics: IPR, PGR, CBM (Jan. 2019), https://www.uspto.gov/sites/default/files/documents/trial_statistics_jan2019.pdf.
34. *See Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).
35. 35 U.S.C. § 321; *see also* 37 C.F.R. §§ 42.200–.224.
36. 35 U.S.C. § 321(b).

37. *See id.* § 122(e); MPEP, *supra* note 5, § 1134.

38. 35 U.S.C. § 161; *Imazio Nursery, Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1563 n.2 (Fed. Cir. 1995) (citing ROBERT S. ALLYN, *THE FIRST PLANT PATENTS* 10 (1934)).

39. 35 U.S.C. § 162 (“No plant patent shall be declared invalid for noncompliance with section 112 if the description is as complete as is reasonably possible.”); *see also* *Diamond v. Chakrabarty*, 447 U.S. 303, 311–12 (1980); *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1379 (Fed. Cir. 2017).

40. *See* *Jessel v. Newland*, 195 U.S.P.Q. 678, 684 (Dec. Comm’r Pat. 1977); MPEP, *supra* note 5, § 1605.

41. 35 U.S.C. § 162 (“The claim in the specification shall be in formal terms to the plant shown and described.”). For example, the sole claim of U.S. Plant Patent No. 19,269 reads as follows: “A new and distinct variety of *Ceratostigma* plant named ‘My Love’ as described and illustrated herein.”)

42. *See* MPEP, *supra* note 5, §§ 1605, 2403.02.

43. 37 C.F.R. § 1.165.

44. 35 U.S.C. § 163.

45. *Imazio Nursery, Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1569 (Fed. Cir. 1995).

46. 7 U.S.C. §§ 2321–2583.

47. For a complete listing of PVPA protected varieties, visit <https://www.ars-grin.gov/cgi-bin/npgs/pvp/pvplist.pl>.

48. *See* 7 U.S.C. §§ 2401, 2451; *see also* Daniel Knauss, Chris Holly & Erich Veitenheimer, *2018 Farm Bill Enacted with Important Provisions for Plant IP and Cannabis-Related Business*, COOLEY (Jan. 10, 2019), <https://www.cooley.com/news/insight/2019/2019-01-10-farm-bill-enacted-with-important-provisions-for-plant-ip-and-cannabis-related-business>.

49. 7 U.S.C. § 2402.

50. *Id.* § 2483.

51. *Id.* § 2483(b)(2).

52. 7 C.F.R. § 97.6(d) requires at least 3,000 seeds for plants reproduced via seed, a viable cell culture for tuber propagated varieties, and deposits for each parent for hybrids.

53. 7 U.S.C. § 2422(4).

54. Plant Variety Prot. Office, ST-472, PVP Seed Sample Submission Protocols (Dec. 2018), <https://www.ams.usda.gov/sites/default/files/media/PVPOST472SeedDepositForm021218.pdf>.

55. *PVPO Frequently Asked Questions*, U.S. DEP'T AGRIC., <https://www.ams.usda.gov/services/plant-variety-protection/pvpo-frequently-asked-questions> (last visited June 12, 2019).

56. See Marcelo Pomeranz, Daniel Knauss & Erich Veitenheimer, *USDA Announces Acceptance of PVP Applications for Hemp*, COOLEY (Apr. 26, 2019), <https://www.cooley.com/news/insight/2019/2019-04-26-usda-announces-acceptance-of-pvp-applications-for-hemp>.

57. 7 U.S.C. § 2541.

58. *Id.* § 2544.

59. Jim Chen, *The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy*, 81 NOTRE DAME L. REV. 105, 137 (2005); see also 7 U.S.C. § 2541(c)(1).

60. 7 U.S.C. § 2401(a)(4)(A)(i).

61. *Id.* § 2401(b)(5).

62. See Int'l Seed Fed'n [ISF], *ISF View on Intellectual Property* (June 28, 2012), http://www.worldseed.org/wp-content/uploads/2015/10/View_on_Intellectual_Property_2012.pdf; see also F.A. van Eeuwijk & J.R. Law, *Statistical Aspects of Essential Derivation, with Illustrations Based on Lettuce and Barley*, 137 EUPHYTICA 129 (2004).

63. See Int'l Seed Fed'n [ISF], *Guidelines for the Handling of a Dispute on Essential Derivation in Lettuce* (May 2004), http://www.worldseed.org/wp-content/uploads/2015/10/Guidelines_EDV_Lettuce_2004.pdf.

64. 7 U.S.C. § 2541(c)(1).

65. *Id.* § 2541(c).

66. *Id.* § 2543.

67. *Id.* § 2404.

68. For example, a cultivar of *Guzmania lingulata* named “Ultra” was protected under both U.S. Plant Patent No. 8221 and utility Patent No. 5,453,563. As another example, a corn inbred designated “PHP38” was protected under both utility Patent No. 5,708,189 and PVP Certificate No. 9000250.

69. For example, the “infra short-day type strawberry plants” are claimed as a distinct plant type in U.S. Patent No. 5,444,179, while specific strawberry varieties within the type are claimed in at least eight plant patents. *See, e.g.*, U.S. Plant Patent Nos. 7865, 7869, 7870, 7876, 7881, 8746, 8747, and 8748. Note, however, that inventors should be careful to consider how earlier applications for broad genera of plant-based inventions may affect later attempts to separately patent species from within those genera.

70. The Supreme Court has held that although a farmer may have the right to use seeds from a patented plant as feed, he cannot replicate the technology by planting the seed to create newly infringing plants. *See Bowman v. Monsanto Co.*, 569 U.S. 278, 288–89 (2013).

71. Applicants should keep in mind their duty to disclose the best mode at the time of filing a U.S. utility patent application. 35 U.S.C. § 112.

72. Uniform Trade Secrets Act § 1(4) defines “trade secret” as information that (among other things) derives economic value because it is kept secret. *See, e.g.*, CAL. CIV. CODE § 3426.1(d); D.C. CODE § 36-401(4).

ENTITY:

SECTION OF INTELLECTUAL PROPERTY LAW

TOPIC:

INTELLECTUAL PROPERTY



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This article is for informational purposes only and does not constitute legal or other professional advice.

Type of IP	Scope of Coverage	Exceptions to Coverage	Scope of Protection	Limits to Protection
Utility Patent	Any useful, novel, nonobvious invention.	Judicial exceptions: laws of nature, natural phenomena, abstract ideas. See USPTO guidelines.	Exclude others from making, using, offering for sale, or selling the invention in the U.S. or importing into the U.S. (20 years from filing date). Extraterritorial 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 (DUS) plant. Now covers both sexually and asexually reproducing plants. *Applicability of stability and uniformity may vary for asexually reproduced plants.	Plant not meeting the new and DUS criteria and plants that cannot be deposited at federal depository.	Exclude others from selling, importing, etc. (20 years from certificate issuance, 25 years for vines and trees).	Research exemption allowing use for breeding to develop a new variety. Farmer's exception allowing saving of seed for replanting. Deposit required.

Table 1

Means of Protection	What Can Be Protected	How to Protect	Term of Protection	Owner's Rights
Patent	Any useful, novel, nonobvious invention; design patents can be filed on new, original, or ornamental design; plant patents.	Submit a patent application.	20 years from filing date for utility and plant patents; 14 years from issuance for design patents.	Exclude others from making, using, offering for sale, or selling the invention in the U.S. or importing into the U.S.
Trademark	Words, phrases, and logos (among others) that can distinguish the source of goods and services.	Use or have a bona fide intent to use and apply for a federal registration.	Unlimited duration as long as the mark is in use; renew at USPTO every 10 years.	Right to exclude others from using the mark and other marks so similar they cause confusion.
Copyright	Literary works, software, dramatic works, music, pictures, movies (any tangible medium of expression).	Fix in tangible form; apply for federal registration.	Life of author, plus 70 years.	Right to prevent unauthorized copying or public performance.
Trade Secret	Any technical or business information that is secret and that gives the owner an advantage over a competitor who does not have it.	Keep secret; no registration available; reasonable measures taken given secret type.	Unlimited duration as long as the subject matter is kept secret.	Right to prevent unlawful use.

Table 2