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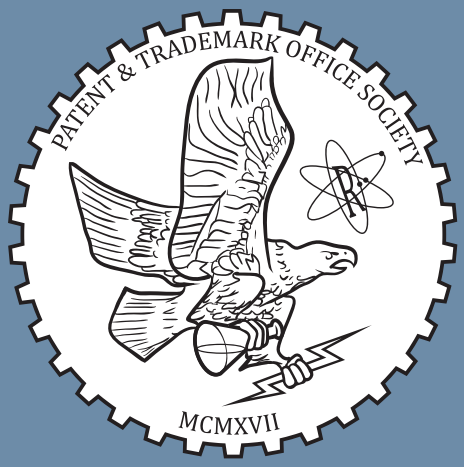

IP Protection for Vegetatively Reproduced Plants: New Paths Forward
– Marcelo Pomeranz, Chris Holly, Daniel J. Knauss, and Erich E. Veitenheimer

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IP Protection for Vegetatively Reproduced Plants: New Paths Forward

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Abstract/Summary—*Intellectual property protections for asexually reproduced plant varieties have historically lagged behind those available for seed-propagated varieties. Seed propagated plants can be protected in the United States via plant variety protection (PVP), utility patents (usually with a deposit of seed of the variety), and plant patents (with evidence that the plant had been asexually reproduced at least once). Asexually propagated plants, on the other hand, were previously statutorily exempt from PVP protection, and were practically prevented from seeking utility patent protection due to challenges in producing acceptable biological deposits.* Per se *protection of asexually propagated plants was thus previously limited to plant patent protection, which courts have narrowly interpreted as only covering asexually-propagated clones of the patented plant. In 2018, Congress tried to address the imbalance in available IP protections by amending the PVP statute to allow for the registration of asexually reproduced varieties. The impact of this statutory change remains uncertain in view of open questions regarding PVP scope and enforceability. This paper briefly reviews the challenges faced by those seeking IP protection for asexually propagated varieties, and proposes new solutions for the industry based on the authors' success in patenting asexually reproduced cannabis varieties.*

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All of the important fruit-crop[2] plants in the United States and many of ornamentals, potatoes, and several nut and forest trees are primarily reproduced through vegetative (asexual) means.[3] Among this group of asexually reproduced plants is the U.S. ornamental flower industry, which in 2019 had an estimated $12 billion in sales.[4] Also included in this category is the booming U.S. cannabis market, which mostly relies on asexual propagation[5] and is on track to hit $15.8 billion in sales in 2020.[6] Despite their economic importance, asexually reproduced plants have suffered from limited access to intellectual property (IP) protections.

The agricultural sector leverages patent and other types of IP protection to establish market exclusivity, fund research, maintain control over key genetic assets, and command significant price premiums for its proprietary products.[7] In this respect, the United States is one of the most ag-friendly jurisdictions, providing more forms of government-sanctioned legal options for protecting plant-related inventions than any other country in the world. IP owners may seek formal patent and patent-like protection for their inventions in the United States by applying for a utility patent, a plant patent, and/or a plant variety protection certificate.[8] Each of these forms of IP registration provides a different scope of protection and includes unique application requirements, while all three may be used in parallel to protect the same variety.

Limited Protection for Asexually Reproduced Plant Varieties

One of the most popular forms of protections for plant inventions is the plant patent.[9] This type of patent, unique to the United States, was introduced via the U.S. Plant Patent Act of 1930 to provide plant breeders with a mechanism for protecting asexually propagated plants.[10] Plant patent applications were

[2] M.E. Ferree and Gerard Krewer, *Propagating Deciduous Fruit Plants Common to Georgia,* UGA Extension Bulletin 818, (Feb. 20, 2015), https://secure.caes.uga.edu/extension/publications/files/pdf/B%20818_5.PDF.

[3] J.R. Magness, *Vegetative Reproduction,* U.S. dept. Agr. Yearbook 1937: 1450-1456, *available* at https://naldc.nal.usda.gov/download/IND43893555/PDF.

[4] Laura Wood, *$16 Billion US Floral Gifting Market-Industry Outlook and Forecast 2018-2023,* PR Newswire (May 22, 2018, 7:00 AM), https://www.prnewswire.com/news-releases/16-billion-us-floral-gifting-market---industry-outlook-and-forecast-2018-2023-300652923.html.

[5] Deron Caplan, Jonathan Stemeroff, Mike Dixon, & Youbin Zheng, Vegetative propagation of cannabis by stem cuttings: effects of leaf number, cutting position, rooting hormone, and leaf tip removal, Canadian Journal of Plant Science, May 4, 2018, at 1126, 1132, available at https://doi.org/10.1139/cjps-2018-0038.

[6] Roy Bingham & Jessica Lukas, *BDS ANALYTICS' Top Ten Cannabis Market Trends for 2019,* BDS Analytics, https://bdsanalytics.com/wp-content/uploads/2019/01/BDS-Analytics-Top-10-Trends-2019.pdf.

[7] Indeed, the average plant variety protected via plant patents commands a 23% price premium over comparable varieties without such protection. See Jennifer Drew, Chengyan Yue, Neil O Anderson, & Philip G. Pardey, Premiums and Discounts for Plant Patents and Trademarks Used on Ornamental Plant Cultivars: A Hedonic Price Analysis, American Society for Horticultural Science, June 2015, at 879, available at https://journals.ashs.org/hortsci/view/journals/hortsci/50/6/article-p879.xml.

[8] For additional information about each of these forms of IP protection, *see* Daniel J. Knauss, Erich Veitenheimer, & Marcelo Pomeranz, *Protecting Plant Inventions,* ABA Landslide, August 5, 2019.

[9] Plant patents in 2010 represented 61% of all varietal rights in the U.S., *see* Jennifer Drew, Chengyan Yue, Neil O Anderson, & Philip G. Pardey, *Premiums and Discounts for Plant Patents and Trademarks Used on Ornamental Plant Cultivars: A hedonic Price Analysis,* American Society for Horticultural Science, June 2015, at 879.

[10] Plant Patent Act, 35 U.S.C. §§ 161-164 (2018).

favored in part because they provided a mechanism for protecting sports (i.e., spontaneous mutations), and other discovered or developed plants, without requiring that every trait be stable (i.e., fixed) across generations. Plant patents also provided a simpler path to protection than traditional utility patents because they only require a detailed phenotypic description of the protected variety in exchange for 20 years of exclusivity without the necessity of making a biological deposit of the plant. This is also in contrast to plant variety protection (PVP), which, until recently, required applicants to submit deposits of stable and uniform seed for each protected variety[11]—a technically challenging requirement for many asexually propagated species.

Plant Patents in Commerce

The emergence of plant patents addressed an imbalance in the economics of the industries for ornamental and other asexually reproduced plants. The development of a new plant variety requires a significant investment of time and resources by breeders, who use their skill and art to develop, identify, and asexually propagate new plants with commercially desirable features. Once developed, however, the new varieties can be easily replicated by nurseries or competing breeder operations, who only need a single cutting from the new variety to generate a limitless supply of clones for resale. Before plant patents became widely adopted, breeders had sought to monetize their new varieties through complex licensing and grower's agreements. These ad hoc exclusivity measures, however, proved difficult to implement and enforce, and also presented the risk of conflict with the anti-competitive provisions of the Sherman Act.[12] The emergence of plant patents addressed these limitations, and created another avenue for breeders to gain a measure of exclusivity over their most valuable varieties.

The evolution between traditional, purely contract-based forms of exclusivity, to ones based on plant patent protection, was reviewed by the court in the *Yoder Bros v California-Florida Plant Corp* case.[13] In this case, *Yoder,* a plant breeder and supplier, sought to enforce several of its chrysanthemum plant patents against a competing plant supplier, who had asexually reproduced and sold the varieties without permission. In its decision, the court reviewed *Yoder*'s commercial history, noting its previous attempts to monetize its breeding program through a series of contractual agreements with downstream plant propagators and distributors. These agreements had proved difficult to enforce, resulting in a significant amount of unlicensed exploitation of *Yoder*'s varieties. A further complication arose in 1970, when *Yoder*'s germplasm exclusivity structure was found to violate the antitrust provisions of the Sherman Act, and was subsequently shut down.

After its antitrust loss however, *Yoder* started shifting its genetic monetization strategies by patenting its new varieties under the Plant Patent

[11] 7 U.S.C. § 2422(4) (2018).
[12] 15 U.S.C. §§ 1-2 (2018).
[13] *Yoder Bros. v. California-Florida Plant Corp.*, 537 F.2d 1347 (5th Cir. 1976).

Act. These patents were then successfully enforced against competitors, who had commercialized *Yoder*'s protected varieties without permission.[14] *Yoder* thus provided an example for how the industry could effectively commercialize its genetics via plant patents.

Plant Patent Scope

The *Yoder* case was also one of the first appellate cases to address the question of plant patent scope and infringement. In *Yoder,* the defendant had argued that it did not infringe the plaintiff's plant patents because it did not allow its asexually reproduced plants to reach floral maturity, and therefore never produced plants exhibiting all the phenotypes described in the asserted plant patents. In its decision, the Federal Circuit clarified that maturing a plant to match the phenotypes described in the plant patent was not a requirement under the Plant Patent Act, and that infringement was complete the moment the defendant took a cutting and reproduced the protected plant.[15] Thus, infringement of a plant patent did not necessarily require the patent owner to prove that the allegedly infringing plant exhibited all of the recited phenotypes of the patent, as long as the plant could otherwise be shown to be an asexual progeny of the protected plant.

The *Yoder* decision also foreshadowed future claim scope disputes through its discussion of the validity of a plant patent in the face of evidence of plants with similar phenotypes. The defendant in the case offered evidence showing that growers had identified related sport plants that exhibited the distinguishing features of *Yoder*'s patented lines. In its decision, the court stated that "[a]n objective judgment of the value of the sport's new and different characteristics—i.e. nutritive value, ornamental value, hardiness, longevity, etc.—*would not depend in any way on whether a similar sport had appeared in the past, or whether that particular sport was predictable*."[16] Although the *Yoder* court never explicitly limited the scope of plant patents to a single variety, its dismissal of the defendant's obviousness arguments suggested that the scope of a plant patent claim may be narrow.

The question of plant patent scope was addressed again by the Federal Circuit in the landmark 1995 *Imazio v. Dania* decision.[17] The *Imazio* case centered around the enforcement of a plant patent to a new variety of *Erica persoluta*, named 'Erica Sunset.' The 'Erica Sunset' variety was commercially successful, in large part, because its early bloom phenotype made it market-ready for the Christmas and Valentine's day seasons. The defendant had created a competing 'Holiday Heather' variety that also exhibited the early bloom phenotype, but was not an asexual progeny of the protected variety.

[14] *Id.* at 1356 (emphasis added).

[15] *Id.* at 1383 ("The district court ruled that the act of asexual reproduction was complete at the time the cutting was taken…We agree with Yoder that it was not necessary to prove that the cuttings actually matured into flowered plants to show infringement.").

[16] *Id.* at 1382 (emphasis added).

[17] *Imazio Nursery, Inc. v. Dania Greenhouses,* 69 F.3d 1560 (Fed. Cir. 1995).

In court, the defendant argued that its variety had been independently produced, and should therefore fall outside the scope of Imazio's plant patent, which was "not intend[ed] to afford plant patent protection to a range of plants, but intended only to protect a single plant" (i.e., the 'Erica Sunset' plant developed by Imazio).[18]

In determining the proper scope of a plant patent, the court looked to the text of the Plant Patent Act, and its corresponding legislative history. The court noted the emphasis that these documents placed on the requirement that protected varieties be asexually reproduced. The relevant Senate Report for example, described protectable varieties as a "specimen" of which only one could exist "except through asexual reproduction."[19] This Senate Report also described plant patent protection as protection meant to encourage "those who own the single specimen to reproduce it asexually and create an adequate supply."[20] In view of these statements, and the consensus among legal commentators, the Federal Circuit ruled that plant patents are limited to "only a single plant, i.e., reproduction from one original specimen."[21] The court further held that independent creation was a valid defense to infringement of a plant patent, because such an independently created plant would, by definition, not be an asexual cutting from the protected variety.

Under this interpretation of the Plant Patent Act, even plants that shared all the phenotypic features of the patented variety would fall outside the scope of protection—unless the patent owner could prove that the infringing plant was an asexual clone of the plant described in the patent application (e.g., through direct evidence of asexual reproduction, or perhaps with the aid of modern techniques, by showing that the infringing plant was genetically identical to the described plant).

Limited Protection for Asexually Reproduced Plants

By limiting the scope of plant patents, the Imazio decision placed vegetatively propagated plant inventions at a marked disadvantage compared with their sexually propagated counterparts. An inventor of a new variety of a sexually propagated plant could protect their investment by seeking a PVP certificate or utility patent claiming the new variety. The resulting PVP certificate would protect not only the precise plant described in the application but also any "essentially derived variety," encompassing plants that were "predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes

[18] *Id.* at 1565.

[19] *Id.* at 1566 (citing S. Rep. No. 315, 71st Cong., 2d Sess. 3 (1930)) (emphasis added).

[20] *Id.* at 1567 (citing S. Rep. No. 315, 71st Cong., 2d Sess. 3 (1930)) (emphasis added).

[21] Imazio 69 F.3d at 1566; see also Id. at 1568 ("In view of the statutory language, the legislative history, the caselaw, the views of the commentators, and a review of relevant provisions of the PVPA, we conclude that the scope of a plant patent is the asexual progeny of the patented plant variety. Variety as used in section 161 encompasses a single plant, the plant shown and described in the specification.").

of the initial variety."[22] The potential protection offered by the utility patent would also be broader than a plant patent, as the claims of the utility patent could be written to protect not only the disclosed plant but also its plant parts,[23] its progeny,[24] other plants with the same morphological characteristics as the disclosed plant,[25] methods of breeding[26] and genetically modifying[27] the disclosed plant, and "equivalents" of all those protected claims. Until recently, however, neither PVP nor utility patents were available for non-true seed producing, asexually reproduced plants, as both required seed deposits as part of the application process.[28]

Another disadvantage of plant patents and PVPs when compared with utility patents, is the lack of guiding caselaw delineating the exact contours of protection. Indeed, very few plant patent and PVP infringement cases make it to final disposition, with even fewer proceeding to the appeal stage. As a result, holders of plant patents and PVP certificates operate in a relative legal vacuum when compared to utility patent holders. The legal uncertainties from the lack of court guidance decrease the value of these rights, and might leave the door open for third parties to avoid royalty payments by operating under untested potential infringement scenarios.

Lobbying for a Legislative Solution

To address this disparity in available IP protection, industry groups for vegetatively propagated plants, including the Society of American Florists, lobbied Congress for a solution.[29] In 2018, these efforts bore fruit with the enactment of the Agriculture Improvement Act, colloquially known as the 2018 Farm Bill. The new farm bill amended the Plant Variety Protection Act[30] so that PVP was expanded to cover asexually reproduced varieties. It also established asexual reproduction of a PVP-protected variety as an act of infringement.[31] New regulations implementing these changes were recently published by the U.S.D.A., leaving the door open for the first round of applications to be reviewed.[32]

The expansion of the PVP program, however, has already raised important questions regarding the scope of protection that applicants could expect. A primary goal of opening up PVP certificates to asexually reproduced plants

[22] 7 U.S.C. § 2401(a)(4)(A)(i) (2018).
[23] U.S. Patent No. 10,306,860 (Issued June 4, 2019) at claim 5.
[24] *Id.* at claim 12.
[25] *Id.* at claim 7.
[26] *Id.* at claims 8, 11, and 12.
[27] *Id. at* claim 13.
[28] Utility patents do not explicitly require seed deposits, but deposits are often required to meet the written description and enablement requirements for claims reciting plants produced via traditional breeding techniques.
[29] Mary Westbrook, *Proposed Farm Bill Offers More Protection for Flower Breeders*, Soc'y Am. Florists (June 13, 2018), https://safnow.org/2018/06/13/protection-act-proposed-farm-bill/
[30] 7 U.S.C. § 2401 (2018).
[31] 7 U.S.C. § 2541 (2018).
[32] 7 C.F.R. § 97 (2020), published final rule available at https://www.regulations.gov/document?D=AMS_FRDOC_0001-1987.

was to expand the protection of asexually reproduced varieties to also include the PVP Act's protection for Essentially Derived Varieties (EDV). The contours of the added protection that PVP holders can expect, however, remains unclear.

EDV Scope for Seed-Propagated Varieties

The scope of EDV protection for seed-propagated varieties has remained a topic of ongoing debate for decades. The concept of an EDV was initially introduced into the PVP statute to curb perceived abuses of the research exemption of the PVP Act, which permitted the use and reproduction of a protected variety for plant breeding or other research.[33] In doing so, Congress essentially limited the research exemption to the creation of new varieties that were sufficiently distinct from the protected variety so as to no longer qualify as EDVs. The scope of EDV protection however, has never been reviewed by a U.S. court, leaving other organizations to try to fill the vacuum.

The International Union for the Protection of New Varieties of Plants (UPOV), of which the United States is a member, has defined EDVs as varieties which are i) predominantly derived from an initial variety, or from a variety that is itself 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.[34] An EDV must also be ii) clearly distinguishable from the initial variety, and iii) except for the differences which result from the act of derivation, should conform to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.[35] This proposed definition, though helpful in contextualizing the concept of an EDV, fails to provide clear guidelines for settling disputes in a consistent and predictable manner. For example, the determination of whether a new variety qualified as an EDV under UPOV's definition necessarily involves several qualitative and quantitative value judgments regarding i) which phenotypes should be considered the "essential characteristics" of the initial variety, and ii) whether the new variety in question shares a sufficient number of those essential characteristics to qualify as an EDV. Despite these limitations, UPOV's definition of EDVs has been highly influential, and has been adopted by many of its member states, including the United States,[36] the European Union,[37] and Australia.[38]

[33] Research exemption, 7 U.S.C. § 2544; see also 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).

[34] International Convention for the Protection of new Varieties of Plants, Dec. 2, 1961 at art. 14(b) (revised on Nov. 10, 1972, Oct. 23, 1978, and Mar. 19, 1991) [hereinafter UPOV] *available at* https://www.upov.int/upovlex/en/conventions/1991/w_up911_.html.

[35] *Id.*

[36] 7 U.S.C. § 2401(a)(4) (2018).

[37] Council Regulation (EC) No. 2100/94 at art. 13 (July 27, 1994) ("A variety is classified as an EDV "when: (a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety; (b) it is distinct in accordance with the provisions of Article 7 from the initial variety; and (c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety.").

[38] Plant Breeder's Rights Act § 4 (1994) ("A plant variety is taken to be an essentially derived variety of anoth-

Other non-governmental associations have also weighed in on the concept of EDVs. The International Seed Federation (ISF), for example, has published a series of helpful guidelines for handling disputes related to EDVs across a variety of different species. ISF guidelines propose objective DNA percentage-identity thresholds for EDVs based on analyses of genetic distances of large populations of existing varieties. For example, in maize, the ISF proposes a SNP-based EDV threshold based on a Roger's distance of 91% or higher.[39] For perennial ryegrass, the ISF proposes a SSR-based EDV threshold of a Jaccard coefficient of 0.6 or higher.[40] For lettuce, the ISF proposes an AFLP-based EDV threshold of a Jaccard coefficient of 0.96 or higher.[41] These guidelines are lauded by many for providing science-based objective measures for settling disputes involving EDV protection. U.S. Courts, however, have yet to rule on the matter, leaving the exact scope of EDV protection uncertain, even for sexually reproduced varieties.

Existing EDV Guidelines May be Challenging to Apply to Asexually Propagated Varieties

Current official guidelines and third-party proposals for EDV protection in the United States were all designed for PVPs of genetically stable sexually propagated plants. The guidelines assume that protected varieties have been demonstrated to be distinct,[42] uniform,[43] and stable[44] as part of the PVP application process. For example, the proposed genetic distance cutoffs from the ISF are based on comparisons of genetic variations present within—and between—recognized and stable varieties of each plant species, which then serve as endpoints in the gradient of possible EDV claims. These assumptions regarding the rigor of the application process and the genetic stability of the resulting protected variety, however, may not apply to PVPs for asexually reproduced plants.

PVP applications for asexually reproduced varieties still have to establish distinctness of the protected variety. The evaluation of uniformity and stability, however, is not based on test grows of sibling and progeny seed, as is the practice for sexually propagated plants, but is instead based on the analysis of asexual clones of the subject plant (i.e., from testing genetically identical clones of the initial variety).[45] This difference in the evaluation of the variety makes

er plant variety if:(a) it is predominantly derived from that other plant variety; and (b) it retains the essential characteristics that result from the genotype or combination of genotypes of that other variety; and (c) it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.").

[39] *ISF Guidelines for Handling Disputes on Essential Derivation of Maize Lines*, International Seed Federation (May 2014), https://www.worldseed.org/wp-content/uploads/2015/10/ISF_Guidelines_Disputes_EDV_Maize_2014.pdf.

[40] *Guidelines for Handling a Dispute on Essential Derivation in Ryegrass*, International Seed Federation (Nov. 2009), https://www.worldseed.org/wp-content/uploads/2015/10/Guidelines_EDV_Ryegrass_Nov_2009.pdf.

[41] *Guidelines for the Handling of a Dispute on Essential Derivation in Lettuce,* International Seed Federation (May 2004) https://www.worldseed.org/wp-content/uploads/2015/10/Guidelines_EDV_Lettuce_2004.pdf.

[42] i.e., different from other known varieties.

[43] i.e., share morphological characteristics among siblings of the same seed batch.

[44] i.e., conserve phenotype across generations.

[45] Personal communication from USDA (April 13, 2020).

it substantially easier to obtain PVPs for newly developed lines, because the applicant only needs to identify and clone a plant with a desired phenotype, as opposed to genetically fixing that phenotype through several rounds of breeding. These technical differences in the composition and evaluation of the protected varieties, however, may affect how EDV protections are applied to certificates for asexually propagated plants.

Strictly speaking, the asexual reproduction of a plant (e.g., through cuttings) would not be expected to generate new plants within the definition of an EDV. This is because the resulting progeny from asexual cuttings would be genetic clones of the parent, and would thus likely share all of the morphologies of the initial plant. Asexual propagation would thus only be expected to cover limited types of EDVs, such as those that could be created by the introduction of a single, known transgene (e.g., for herbicide resistance) into a protected variety. Excepting for the variants that could be generated through artificial or natural somatic mutations, asexual reproduction of a protected variety would thus most likely only create plants within the immediate scope of a PVP, without the need to consider any additional theoretical scope for EDVs.

The story may be slightly different for asexually reproduced plants that are also capable of sexual reproduction. For these plants, asexual PVP may be preferred over the corresponding sexually propagated PVP because of the relative difficulty in sexually reproducing the plant,[46] or because of the relatively easier uniformity and stability tests that are imposed on asexual varieties during the PVP application process (i.e., using clones to establish stability instead of having to produce a genetically stable line). In both cases, it is likely that plants within this category will not have fully stable genomes, or be capable of breeding true to their parents. Were it otherwise, they would (or could) have been protected via a traditional seed-propagated PVP.

For these plants with unstable genomes, even the seed-generated progeny from a selfing of the protected variety would be expected to exhibit significant morphological variability that would likely disqualify it from even the most permissive phenotype-based definitions of an EDV. The lack of genetic variability within a protected asexually propagated variety may also make it difficult to establish scientifically sound marker-based measures for EDVs, as even small amounts of genetic variation could statistically be considered sufficient to define a new variety. Thus, for genetically unstable (i.e., not true to type) asexual varieties, the theoretical added EDV protection of PVP certificates may be difficult to define and enforce. Without additional guidance from the courts, PVPs may thus end up providing little added scope over corresponding plant patents.

An Alternative Solution for Protecting Asexually Propagated Plants

As noted above, utility patents provide the broadest scope potential out of any of the IP protections available for plant and plant-related inventions.

[46] Some species of bamboo have long life cycles and only flower once every 40-120 years. Janzen, DH., *Why Bamboos Wait so Long to Flower,* Annual Review of Ecology and Systematics, 1976 at 347-91.

Until recently, however, this type of IP was largely out of reach for asexually reproduced varieties. The primary limiting factor was the applicant's ability to produce and submit the appropriate biological deposits to meet the patent statute's written description and enablement requirements.[47] Although American Type Culture Collection (ATCC), one of the U.S. Patent and Trademark Office-approved depositories, had started accepting asexually reproduced deposits as early as 1990, it had accepted only a single type of material and required applicants to provide a protocol for regenerating the plant.[48] In the face of these challenges, few, if any, utility patents were issued based on tissue culture deposits.

A solution to this problem came from a relatively new player to patent filings: the cannabis flower industry. Authors of this paper worked together with the Bigelow National Center for Marine Algae and Microbiota (NCMA) depository to develop tissue culture deposits to support utility patent claims for novel, asexually reproduced cannabis varieties. On May 9, 2017, U.S. Utility Patent No. 9,642,317 (hereinafter "the '317 cannabis patent") was issued with claims reciting a cannabis plant, or an asexual clone thereof, supported by "cellular cultures representative of said plants" that were deposited at the NCMA facility.[49] Taking advantage of a utility patent's coverage beyond the specific disclosed plant, the issued utility patent also included claims to a variety of products derived from the claimed plants and methods of growing, cloning, and breeding the disclosed plant.[50] This utility patent directed to cannabis thus inadvertently overcame the technical and legal limitations that had troubled the vegetatively reproduced plant industry for nearly a century.

The ornamental industry was the first to take advantage of this new development. On November 6, 2018, just over a year after the issuance of the '317 cannabis patent, Sakata Seed Corporation became the first applicant to receive an issued utility patent with claims to an asexually reproduced ornamental plant using cryopreserved apical meristems as the deposit.[51] Since then, dozens[52] of other cases have followed suit, each leveraging tissue deposits from the NCMA to secure broad utility claims that had previously been available only for sexually reproduced plants. U.S. utility patent No. 10,258,015, for example, issued with claims reciting i) the disclosed Petunia plant,[53] ii) parts of the disclosed plant,[54] iii) tissue cultures of the disclosed plant,[55] iv) methods

[47] 35 U.S.C. § 112 (2018).

[48] *Making a Patent Deposit,* American Type Culture Collection, https://www.atcc.org/services/deposit_services/patent_depository/making_a_patent_deposit.aspx (last visited April 27, 2020).

[49] *See* U.S. Patent No. 9,642,317 at claim 1 (issued May 9, 2017).

[50] *Id.* at claims 11-12 for methods; *id.* at claims 13-16 for products.

[51] U.S. Patent No. 10,117,392 (Issued Nov. 6, 2018).

[52] *See e.g.,* U.S. Patent No. 10,149,452 (issued Dec. 11, 2018); U.S. Patent No. 10,149,453 (issued Dec. 11, 2018); U.S. Patent No. 10,154,641 (issued Dec. 18, 2018); U.S. Patent No. 10,219,478 (issued Mar. 5, 2019); U.S. Patent No. 10,238,067 (issued Mar. 26. 2019); U.S. Patent No. 10,258,005 (issued Apr. 16, 2019); U.S. Patent No. 10,271,510 (issued Apr. 30, 2019) ; U.S. Patent No. 10,420,317 (issued Sept. 24, 2019); U.S. Patent No. 10,462,991 (issued Nov. 5, 2019); U.S. Patent No. 10,463,002 (issued Nov. 5, 2019); U.S. Patent No. 10,463,003 (issued Nov. 5, 2019); U.S. Patent No. 10,470,397 (issued Nov. 12, 2019); U.S. Patent No. 10,470,398 (issued Nov. 12, 2019); U.S. Patent No. 10,477,799 (issued Nov. 19, 2019); and U.S. Patent No. 10,561,114 (issued Feb. 18, 2020).

[53] *Id. at* claim 2.

[54] *Id.*

[55] *Id. at* claims 4 and 5.

of vegetatively propagating the disclosed plant,[56] v) plants that have all the physiological and morphological characteristics of the disclosed plant,[57] vi) methods of breeding,[58] and **vii)** methods of transforming the disclosed plant.[59]

Utility Patents as an Alternative to PVP for Asexually Propagated Varieties

Differences in Scope

Innovators in the vegetatively propagated plant space should seriously consider filing tissue deposit-based utility patent applications as viable alternatives to corresponding plant patents or PVP applications. This article has already described the differences in protection scope provided by utility patents, plant patents, and PVP. Among these, utility patents potentially provide the broadest scope, encompassing protection not only for the protected plant but also for other plants exhibiting the same phenotypes, progeny of the disclosed plant, products of the disclosed plant, and methods of breeding, growing, and genetically modifying the disclosed plant. Moreover, independent creation of a protected variety is generally not considered a defense to the infringement of an otherwise valid utility claim.

In contrast, courts have limited plant patent protection to the disclosed plant itself and to asexual progeny of said plant. PVP certificates provide protection for the disclosed plant and essentially derived varieties of the disclosed plant. However, as discussed in this article, EDV protection for asexually reproduced plants may be limited for plants that do not stably inherit phenotypes through sexual reproduction. PVP is also curtailed by research/breeding exceptions and by the saved seed exemption,[60] all of which limit the owner's control of the protected genetics.

Comparing Costs

One potential concern for applicants may be the differences in overall cost between the various types of protection. As of the writing of this article, the total government fees for a plant patent are $2,040 for a large entity.[61] The total government fees for securing a PVP certificate are $5,150,[62] and the government fees for a utility patent, including the cost of the deposit and maintenance fees, are $18,320.[63] At first glance, it may appear that utility patent applications

[56] *Id. at* claim 7.
[57] *Id. at* claim 3.
[58] *Id. at* claims 9 and 13.
[59] *Id. at* claim 11.
[60] 7 U.S.C. § 2543 (2018).
[61] $200 basic filing + $420 search fee + $620 examination fee + $800 issue fee.
[62] $518 filing fee + $3864 examination fee + $768 Issue fee.
[63] $300 basic filing + $660 search fee + $760 examination fee + $1000 issue fee + $3000 deposit fee + $12,600 maintenance fees.

are nearly 10 times more expensive than an equivalent plant patent. When assessing cost, however, applicants should note that the reported costs of the utility patent include $12,600 in maintenance fees. These maintenance fees are not due at filing but are instead spread out into three payments over the course of the patent's 20-year term. The largest maintenance fee payment of $7,400 is not due until 11.5 years after the patent is granted, when the applicant would presumably already have some market data and would be able to make an informed decision about the value of keeping the patent in force. Thus a large portion of the cost of utility patents can be delayed—or avoided altogether for inventions that may become obsolete (e.g., with the applicant's development of a second-generation improved variety).

The other major factor accounting for the price difference is the estimated $3,000 deposit fee incurred in the prosecution of the utility patent. Although plant patents do not require deposits, the detailed morphological description requirements for each plant can be onerous and expensive to complete for inventors. The data requirements for PVP applications are similarly complex, involving the gathering of data from large populations of plants across multiple generations to demonstrate the plant's distinctness, uniformity, and stability. Utility patents relying on deposits, in contrast, require only that the applicant provide sufficient written description to effectively examine the application and to "aid in the resolution of questions of infringement"[64]—an effectively lower standard of disclosure. Applicants considering a utility filing should therefore weigh the added deposit fees against the internal costs of meeting the more demanding data requirements of plant patents and PVP.

Deposits for Non-U.S. Applicants

Utility deposits may also be easier to complete than PVP deposits for non-U.S. applicants. Deposits for PVP applications of asexually propagated plants are shipped to the National Laboratory for Genetic Resources Preservation Research (NLGRP) in Fort Collins, CO.[65] The location of a single depository located in the United States may present logistical challenges to applicants outside the country who may have to shepherd live tissue across international borders. In contrast, utility deposits under the Budapest Treaty can be completed at any International Depositary Authority (IDA). A total of 47 IDA depositories are spread around the world, though not all accept plant tissue deposits.[66] In the United States, the National Center for Marine Algae and Microbiota (NCMA) accepts cryogenically preserved tissue, such as lyophilized apices samples.[67] In Scotland, the National Collections

[64] *See* Manual of Patent Examining Procedure, MPEP 2163(I) (9th ed. Rev 8, 2018), (citing Final Rule, 54 Fed. Reg. 34,864 at 34,880 (August 22, 1989)).

[65] *National Laboratory for Genetic Resources Preservation Deposit Form For Plant Variety Protection Voucher Sample,* National Laboratory for Genetic Resources Preservation, https://www.ams.usda.gov/sites/default/files/media/NLGRPTissueCultureForm.pdf (last visited April 27, 2020).

[66] *International Depositary Authority (IDA),* WIPO, https://www.wipo.int/budapest/en/idadb/ (last visited April 27, 2020).

[67] Perpetual cultures also available for $25,000; *Patent Deposits,* Bigelow National Center for Marine Algae

of Industrial, Marine and Food Bacteria (NCIMB) depository accepts plant cultures and in vitro plantlets/shoots. In Germany, the Leibniz Institute (DSMZ) is also listed by the World Intellectual Property Organization (WIPO) as accepting of plant cultures. More depositories can be expected to accommodate non-seed plant deposits in the future. Thus completing a utility deposit may be logistically simpler than completing PVP deposits for inventors outside the United States.

Deposits for Cannabis Varieties Not Classified as Hemp

An additional consideration weighing in favor of utility deposits may be the legal status of the plant for which protection is desired. PVP deposits are handled by the NLGRP, a U.S. federal government facility. Inventors of new cannabis varieties that fall outside the definition of hemp[68] may be denied access for their deposits and may thus be excluded from PVP altogether. In contrast, utility deposits are handled by private facilities with more flexible guidelines and located in countries with differing laws regarding cannabis. Thus, utility-based deposits provide inventors of cannabis, poppy, and other similar plants with viable protection alternatives not offered by PVP.

Difficulty in Producing Deposit

Of course, producing appropriate deposits can itself be a challenge. For utility deposits, applicants must develop tissue samples that are capable of fully regenerating into the claimed plant. Although many species already have published methods for producing viable tissue for cryogenic preservation, others may require the applicant to invest time and resources into developing the appropriate protocols for tissue preparation and regeneration. In contrast, PVP applicants may have an easier time completing their deposits, as the NLGRP has indicated its willingness to accept deposits of live plants.[69] Pursuing PVP would thus free applicants from the burden of producing the tissue culture or stem samples needed for traditional cryopreservation.

Deposit Timing

Another factor to consider when comparing PVP and utility protection is the timing and availability of any completed deposits. In the United States, utility patent applicants are able to delay the submission of their enabling deposits

AND MICROBIOTA, https://ncma.bigelow.org/cms/page/view/page_id/16/ (last visited April 27, 2020).

[68] Both seed and tissue deposits of plants qualifying as hemp under the 2018 Farm Bill should be accepted by the PVP office; Daniel Knauss, Marcelo Pomeranz, & Erich Veitenheimer, *USDA Announces Acceptance of PVP Applications for Hemp*, COOLEY ALERT, (April 26, 2019), https://www.cooley.com/news/insight/2019/2019-04-26-usda-announces-acceptance-of-pvp-applications-for-hemp.

[69] *National Laboratory for Genetic Resources Preservation Deposit Form For Plant Variety Protection Voucher Sample*, National Laboratory for Genetic Resources Preservation, https://www.ams.usda.gov/sites/default/files/media/NLGRPTissueCultureForm.pdf (last visited April 27, 2020).

until the payment of the final issue fee.[70] The option to delay deposits provides applicants with additional time to produce the necessary tissue for submission and to learn the commercial value of the disclosed plant before incurring the deposit expense. In contrast, PVP deposits must be made at the time the application is filed.[71] This approach requires applicants to front-load the work of developing and propagating the biological deposit, which increases the cost and effort required to get an initial application on file. The requirement for a deposit at filing may also force applicants to delay their initial filing.

Deposit Availability and Inadvertent Disclosure

A critical distinction between utility and PVP application deposits is the availability of the protected plant during the term of the patent. Any deposits that are disclosed in a utility patent application become available to the public on the day the patent is issued. This raises potential competitive concerns, as entities beyond the territorial scope of the applicant's IP might gain access to the genetics. For example, a plant covered by a U.S. utility patent application could be ordered from the depository facility for shipping outside the United States, where that plant may be integrated into a competitor's product line or breeding pipeline without the patent owner's permission, if that owner had no IP protection in that foreign jurisdiction. While this scenario may not be as problematic for large corporations that may file for IP protection globally, it may be of more concern to inventors who choose to limit their IP filings to the United States. For U.S.-only filers, PVP deposits provide a significant advantage. Unlike the deposits for patents, PVP seed deposits are not made available to the public until after the PVP certificate expires, thus reducing the likelihood of unauthorized use of the applicant's plant.[72]

Additional Differences

This article was intended to highlight new strategies for protecting vegetatively propagated plants via utility patents. The sections above therefore focused on the major differences between utility and PVP IP protections for asexually reproduced plants. Experienced practitioners will no doubt be aware of other important differences between the various forms of protection described above. For example, while U.S. utility patents must be filed within one year of any disclosure of the invention by the applicant anywhere in the world, PVP applications must be filed 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 the United States.[73] PVP certificates have a 20-year

[70] 37 C.F.R. § 1.809(c) (2020).

[71] 7 C.F.R. § 97.6(d) (2020) 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.

[72] PVPO Frequently Asked Questions, U.S. Dep't Agric., https://www.ams.usda.gov/services/plant-variety-protection/pvpo-frequently-asked-questions (last visited September 10, 2019).

[73] 7 U.S.C. § 2483 (2018).

term that begins from the date the certificate is issued,[74] whereas both plant and utility patent applications begin their 20-year terms from their earliest effective filing date.[75] A table summarizing the differences among the three forms of IP protection is included with this article. For additional information about the different forms of IP, consider reviewing Knauss et al., "Protecting Plant Inventions," Landslide Magazine, August 5, 2019.

IP Enforcement

As noted above, enforcement litigation of utility patents is much more predictable for patent owners than for plant patents or PVP certificates. In addition to the broader scope of coverage, U.S. federal courts are much more familiar with the assertion of utility patents in lawsuits brought before them. There is also a robust body of appellate caselaw concerning the interpretation and enforcement of utility patents available to litigants evaluating the strength of their litigation positions. Plant patent and PVP certificate enforcement is much less common, which will require litigants to educate their court on what is likely an entirely unknown statutory framework. This is particularly true for PVP certificates covering the now-protectable asexually-reproduced varieties, which have not yet been the subject of any enforcement litigation.

Closing Thoughts

The availability of tissue deposits at approved depository facilities has placed utility patent protection within reach for inventors of asexually reproduced plants. Utility patent protection presents an attractive alternative to plant patents and to the new expanded PVP to asexually propagated plants. Utility patents provide broader scope of protection than their PVP counterparts and do not suffer from the current uncertainty regarding the extent of EDV protection and enforceability under various scenarios.

[74] 7 U.S.C. § 2483 (2018).
[75] That is, the first U.S. nonprovisional or PCT international filing date for the case; *see* 35 U.S.C. § 154 (2018).

Table 1

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.	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). Scope of protection extends to Essentially Derived Varieties (EDVs).	Research exemption allowing use for breeding to develop a new variety. Farmer's exception allowing saving of seed for replanting. Deposit required.