Abstract

Jo Lynn Jeter is a 2004 graduate of the University of Oklahoma College of Law. She wrote this eBrief while working on the Project on Intellectual Property Rights in Living Matter under the direction of Professor Drew Kershen. Below, Ms. Jeter discusses the three types of patent and patent-like protection available in the United States for living material: utility patents, Plant Variety Protection Act (PVPA) certificates, and plant patents. A utility patent, as would be obtained for an ordinary invention, provides the greatest protection but is typically more difficult and expensive to obtain. The plant patent and PVPA certificate provide attractive alternatives to inventors and breeders. Plant patents are designed to protect asexually-reproduced plants. PVPA certificates are not patents at all, and are administered by the U.S. Department of Agriculture to protect sexually-reproduced plants.

Edited by Matthew B. Sellers

AGRICULTURAL BIOTECHNOLOGY: UNITED STATES STATUTORY LAW

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I. Introduction

Throughout the development of patent law in the United States, one principle has remained constant: discoveries in nature are not patentable, only inventions are patentable.¹ However, the question of whether man-made plants, animals or microorganisms are discoveries in nature or inventions has been the subject of considerable controversy. This eBrief discusses such alternating ideology through statutory development and interpretation.

II. History and Background

The U.S. Constitution authorizes Congress "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their

¹ See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) (holding that the discovery that certain bacteria strains of species can be mixed without harmful effect to the properties of either is not patentable because their qualities were the work of nature). The Court also held that patents cannot issue for the discovery of the phenomena of nature. A product must be more than new and useful to be patentable; it must also satisfy the requirements of invention or discovery. *Id.*; *see* Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). *See generally* Graham v. John Deere Co., 383 U.S. 1 (1966). For further discussion about the requirement that an "invention" be an actual invention rather than a "discovery in nature," see Jo Lynn Jeter, *Agricultural Biotechnology: United States Case Law*, 2 OKLA. J.L. & TECH. 15 (2004)

respective Writings and Discoveries...²² Congress' first legislation implementing the Constitutional provision came during the First Congress, when it enacted the Patent Act of 1790.³ This law formed the basis for patents within the United States, creating general requirements of novelty, utility, non-obviousness, and enablement/description.⁴

Before 1930, the federal government denied patent protection for plants and animals.⁵ Plants, even those created by man, were considered "products of nature" and were therefore not subject to patent protection⁶. Even where a biological invention did not constitute a "product of nature," the claim typically could not sufficiently describe the invention in accordance with the written description requirement.⁷

In 1930, Congress enacted the Plant Patent Act ("PPA"), which only applied to certain asexually reproduced plants. ⁸ This signaled as a significant departure from the longstanding doctrine that plants were not a proper subject matter for patent protection and was the first instance of a country awarding patents for living matter aside from yeast.⁹ The PPA afforded the agricultural industry the opportunity to participate in the benefits of the patent system, which had

⁶ Id.

² U.S. CONST. art. I, § 8, cl. 8.

³ See S. REP. No. 1979-82, at 2396 (1952).

⁴ See 35 U.S.C. § 101 (2000) (novelty and utility requirements: "any new and useful process, machine, manufacture or composition of matter, or . . . improvement thereof"); *id.* § 103 (non-obviousness requirements: "[T]he differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would (not) have been obvious"); *id.* § 112 (enablement/description requirement: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."); *see also Graham*, 383 U.S. at 1.

⁵ See Ex parte Latimer, 1889 Dec. Comm'r Pat. 123 (1889).

⁷ See 35 U.S.C. § 112 (2000) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."). ⁸ *Id.* §§ 161-164.

⁹ In 1873, the Patent Office granted Louis Pasteur a patent on "yeast, free form organic germs of disease, as an article of manufacture."

previously only been enjoyed in the industrial field. By 1970 it became evident to Congress that, due to biological advances, true-to-type reproduction was possible for sexually reproduced plants (plants derived from a seed). Accordingly, Congress passed the Plant Variety Protection Act ("PVPA").¹⁰ The PVPA was enacted to provide patent-like protection to sexually reproduced plants. ¹¹

Finally, in 1980, the U.S. Supreme Court ruled that the Patent Act of 1952 does include some living organisms within the scope of its patentable subject matter,¹² despite decisions of the Patent Board to the contrary.¹³ This decision was made more precise in a 2001 U.S. Supreme Court holding that in enacting the PPA and the PVPA, Congress neither expressly nor implicitly removed plants from generally patentable subject-matter.¹⁴ Similarly, Congress did not repeal general patent requirements by passing the more specific Plant Acts because there is no irreconcilable conflict between the statutes.¹⁵

Thus, one wishing to patent living matter in the United States today may have up to three choices of applicable law, each of which contain different requirements and entitlements. These Federal Statutes include the Plant Patent Act, the Plant Variety Protection Act, and the Patent Act of 1952.

¹⁰ 7 U.S.C. §§ 2321-2582 (2000).

¹¹ The purpose of the act is "[t]o encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest." Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970).

¹² See Diamond v. Chakrabarty, 447 U.S. 303 (1980).

¹³ See In re Merat, 519 F.2d 1390 (Cust. & Pat. App. 1975); In re Bergy, 596 F.2d 952 (Cust. & Pat. App. 1979).

¹⁴ J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc. 534 U.S. 124, 145-46 (2001).

¹⁵ *Id*.

III. United States Statutory Law

A. Plant Patent Act of 1930

The Plant Patent Act of 1930 ("PPA") is a sub-chapter of the general Patent Act and, in

relevant part, provides that:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title. No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible. In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.¹⁶

The conditions for obtaining a patent under the PPA are considerably different than those under general patent law. For example, the PPA requires the plant variety be *distinct*¹⁷, rather than *useful*¹⁸ as required for a general utility patent. Distinct characteristics may include: habit; immunity from disease; soil conditions; color of flower, leaf, fruit or stems; flavor; productivity; storage qualities; perfume; form; ease of asexual reproduction; and defectiveness.¹⁹ It is immaterial whether the characteristics are inferior or superior to those of the existing varieties.²⁰

Furthermore, the written description requirements of general patent law are less stringent in the PPA, requiring only a description "as complete as is reasonably possible."²¹ The U.S. Court of Customs and Patent Appeals has interpreted this provision to mean that there is no

¹⁶ 35 U.S.C. §§ 161-163 (2000).

¹⁷ Id. § 161.

¹⁸ *Id.* § 101.

¹⁹ See S. REP. No. 315-71 (1930); see also Pan-Am. Plant Co. v. Matsui, 433 F. Supp. 693, 696-97 (N.D. Cal. 1977). A plant variety is substantially different, and hence does not infringe an existing plant patent, where the new plant has the ability to asexually reproduce with a far smaller percentage of culls than the existing plant. The lack of defectiveness formed a significantly different characteristic that made it a different variety, despite the appearance that the plants seemed to be of the same variety. *Id*.

²⁰ See S. REP. No. 315-71 (1930).

²¹ 35 U.S.C. § 162 (2000).

enablement requirement in a plant patent application.²² This is due to the impossibility of producing the patented plant from a description, because it must be asexually reproduced.²³ Nevertheless, the applicant ultimately bears the burden of clearly and precisely describing those characteristics which define the new variety.²⁴

Both the PPA and the Patent Act include novelty and non-obviousness requirements. "Novelty" refers to newness in its conception.²⁵ "Non-obviousness" requires that there be actual inventiveness at the time the invention was made.²⁶

The limited scope of the PPA, applying only to asexually reproduced plants, ensures that plant breeders reproduce their plants identically in every respect to the parent plant. Plant patents under the Act cover only a single plant and its asexually reproduced progeny.²⁷ Propagation by asexual reproduction may be obtained through grafting, budding, cuttings, layering, and division, for example, but not by seeds.²⁸

In applying the PPA, as in applying the Patents Act, there is a presumption of patent validity that the challenger has the burden to overcome.²⁹ This presumption must be overcome by sufficient evidence to invalidate an existing patent.³⁰ If the patent is valid, a plant

²² In re Greer, 484 F.2d 488, 490-91 (Cust. & Pat. App. 1973).

²³ See Ex parte Solomons, 201 U.S.P.Q. (BNA) 42 (Bd. Pat. App. & Interf. 1978).

²⁴ In re Greer, 484 F.2d at 491.

²⁵ Yoder Bros., Inc. v. Cal.-Fla. Plant Corp., 537 F.2d 1347, 1377 (5th Cir. 1976).

 $^{^{26}}$ 35 U.S.C. § 103 (2000) ("A patent may not be obtained...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which such subject matter pertains.").

²⁷ Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1566-70 (Fed. Cir. 1995). As a result of the Plant Patent Act's asexual reproduction requirement, only a single plant, i.e., reproduction from one original specimen, is protected by the plant patent. A defense to plant patent infringement is showing that the alleged infringing plant is not an asexual reproduction of the patented plant. Part of this proof could be that defendant independently developed the allegedly infringing plant. Infringement is not shown by proof of a plant having the same essential characteristics as the patented plant. *Id*.

²⁸ In re Arzberger, 112 F.2d 834, 836 (Cust. & Pat. App. 1940).

²⁹ 35 U.S.C. § 282 (2000).

³⁰ *Id*.

patentee has the "right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced."³¹

B. Plant Variety Protection Act

The Plant Variety Protection Act ("PVPA") is administered by the United States Department of Agriculture, rather than the United States Patent Office. The PVPA provides in

relevant part that:

The breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety... shall be entitled to plant variety protection for the variety, subject to the conditions and requirements of this chapter, if the variety is: (1) new, in the sense that... propagated or harvested material of the variety has not been sold or otherwise disposed of to other persons...; (2) distinct, in the sense that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application; (3) uniform, in the sense that any variations are describable, predictable, and commercially acceptable; and (4) stable, in the sense that the variety, when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.³²

The PVPA and the PPA differ significantly in their purposes and the scope and nature of

their protection. The PPA grants a plant patent to one who "invents or discovers and *asexually* reproduces any distinct and new variety of plant."³³ The PVPA, however, entitles one to plant variety protection if he has *sexually* reproduced the variety and otherwise met the requirements of the Act.³⁴ As a result, protection under the PVPA extends to the entire plant variety, while the PPA only protects that specific plant and its progeny.³⁵

³¹ *Id.*. § 163.

³² 7 U.S.C. § 2402 (2000).

³³ 35 U.S.C. § 161 (2000).

³⁴ 7 U.S.C. § 2402 (2000).

³⁵ Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1566-70 (Fed. Cir. 1995); see discussion supra note 21.

To qualify for a PVPA certificate, the variety must be new, distinct, uniform and stable.³⁶ These requirements are significantly less strict than those of the general patent law. *Uniformity* under the PVPA requires that the variety be "describable, predictable and commercially acceptable,"³⁷ and *stability* requires the variety "remain unchanged with regard to the essential and distinctive characteristics of the variety" upon reproduction.³⁸ These requirements reduce the precise written description and enablement requirements.

One wishing to patent a sexually reproduced plant variety must acquire a certificate of protection from the Plant Variety Protection Office.³⁹ This certificate confers on the owner the exclusive right "to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing a hybrid or different variety" to the extent provided by the PVPA.⁴⁰ The certificate is good for twenty years.⁴¹

The PVPA contains three major exemptions from infringement, reducing the protection of its patents as compared to those covered under the Patent Act. First, the PVPA allows for a Public Interest Exemption, providing that "the Secretary may declare a protected variety open to use…in order to insure an adequate supply of fiber, food or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair."⁴² Thus, the exemption authorizes compulsory licensing upon the determination of public need. A second exemption to the PVPA is the Research Exemption, which allows for the use and reproduction of a protected variety for plant breeding or other *bona*

³⁶ 7 U.S.C. § 2402(a)(1)-(4) (2000).

³⁷ *Id.* § 2402(a)(3).

³⁸ *Id.* § 2402(a)(4).

³⁹ *Id.* § 2402.

⁴⁰ *Id.* § 2483(a)(1).

⁴¹ Id. § 2483(b)(1). The 1994 Amendments, Pub. L. No. 103-349, substituted "20" years for "18" years.

⁴² 7 U.S.C. § 2404 (2000).

fide research.⁴³ The third exemption is the Farmer's Exemption. This exemption allows a farmer to use seed produced from a patented plant for production on his or her farm.⁴⁴ The farmer may also sell the seed, so long as it is not for reproductive purposes.⁴⁵ The Farmer's Exemption was significantly diluted when Congress amended the PVPA in 1994. Congress struck the provision which allowed a farmer to sell seed for reproductive purposes to other farmers. Prior to 1994, the Farmer Exemption was given much attention and was interpreted to allow farmers to sell seeds directly to other farmers, so long as they only kept and sold enough to replant their own acreage.⁴⁶

In addition to substantially weakening the farmer's exemption, Congress' 1994 amendments considerably changed other aspects of the PVPA. For example, Congress inserted the provision including tuber-propagated plants, such as potatoes, within the scope of the PVPA.⁴⁷ This provision was the first form of intellectual property protection in the United States for tuber-propagated plants. Congress also adopted a "Rule of Construction" stating that the "sale or disposition of hybrid seed shall be considered to be a sale of harvested material of the varieties from which the hybrid was produced."⁴⁸ Thus, the PVPA was altered to protect first-generation hybrids. The amendments granted PVPA certificate holders protection for all "essentially derived" varieties, in addition to their "initial" varieties.⁴⁹ An "essentially derived variety" is defined as "a variety that is predominantly derived from another variety or from a

⁴³ *Id.* § 2544.

⁴⁴ *Id.* § 2543.

⁴⁵ *Id*.

⁴⁶ See Delta & Pine Land Co. v. Peoples Gin Co., 694 F.2d 1012, 1017 (5th Cir. 1983) (holding the farmer's exemption is for direct sales between farmers, without the active participation of third parties. Third parties cannot serve as a broker (create the sale), but can have an indirect role); Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 794-95 (1995) (holding that under the farmer's exemption, farmers can only keep for sale the amount of seed that they need to plant their own acreage).

⁴⁷ 7 U.S.C. § 2402 (2000).

⁴⁸ *Id.* § 2401(b)(3).

⁴⁹ *Id.* § 2541(c).

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."⁵⁰ Other provisions were inserted that barred the right to protect public or known varieties, varieties for which there was a filing of an application in another country more than one year before the date of filing in the United States, and of varieties for which another person was entitled to an earlier date of determination.⁵¹

Congress described the 1994 amendments to the PVPA as an attempt to make the Act consistent with the International Convention for the Protection of New Varieties of Plants ("UPOV") of March 1991.⁵² The United States became a member of the UPOV in 1981 in order to afford U.S. plant breeders protection in other countries.⁵³ The UPOV "provides for uniform practices in the construction and administration of plant variety protection laws in the various member states."⁵⁴

Once a patent certificate is granted pursuant to the PVPA, the patent is presumed valid. Infringement may occur if, during the years of protection, one without authority performs any of the following acts regarding the protected variety: sells or markets the variety, imports or exports the variety, sexually multiplies the variety for growing purposes, uses the variety in producing a hybrid or different variety therefrom, or dispenses the variety to another without notice that it is

⁵⁰ *Id.* § 2401(a)(3).

⁵¹ *Id.* § 2402(a), (b). "Date of determination" refers to the date in which an applicant who has filed for a PVPA certificate has met all the requirements of the PVPA. Thus, § 2402 (b)(1) states that "if two or more applicants submit applications on the same effective filing date for varieties that cannot be clearly distinguished from one another, but that fulfills all other requirements of subsection (a) of this section, the applicant who first complies with all requirements of this chapter shall be entitled to a certificate of plant variety protection, to the exclusion of any other applicant."

⁵² H.R. 699, 103d Cong. 2423 (1994).

⁵³ *Id.* at 2425.

⁵⁴ Id.

protected.⁵⁵ The foregoing is not an exhaustive list of possible acts of infringement, but it provides a basis for understanding the protection granted under the PVPA.

Generally, one charged with violating another's rights under the PVPA will claim one or more of three common defenses to patent infringement: invalid patent, non-infringement, or authorized infringement.⁵⁶ Should a court find infringement pursuant to the PVPA, the remedies available to the patent owner are more limited than under the general patent law. For example, the Act provides courts the authority to grant an injunction to prevent the violation of any rights under the PVPA, rather than damages.⁵⁷ Moreover, there is a limit to the amount of damages awarded for infringement of a PVPA patent.⁵⁸ For example, the Act supplies the court with guidelines directing the amount of damages that may be awarded with regard to particular situations.⁵⁹ Courts may refuse to award damages when a patent owner cannot establish that the alleged infringer knew, or should have known, that the variety was covered by the PVPA and no relevant exemptions applied.⁶⁰

Protection under a patent certificate extends only to the owner of the patent or to an assignee of the patent who has been assigned the entire bundle of common-law rights.⁶¹ Any transfer of less than all of the common-law rights is a "license" and such an arrangement does not entitle the licensee the right to sue for patent infringement.⁶² The right to sue is based on title

⁵⁵ 7 U.S.C. § 2541(a) (2000).

⁵⁶ See id. § 2541(b)(1) (stating "Subject to paragraph (2), the owner of a protected variety may authorize the use of the variety under this section subject to conditions and limitations specified by the owner").

⁵⁷ *Id.* § 2563.

⁵⁸ Id. § 2567.

⁵⁹ See id. § 2564.

⁶⁰ See id. § 2564(d); see also Delta & Pine Land Co. v. Sinkers Corp., 197 F. Supp. 2d 1184, 1192 (E.D. Mo. 2001) (finding that the alleged infringer must have known, or should have known, that the variety was protected by PVPA).

 ⁶¹ Public Varieties of Miss., Inc. v. Sun Valley Seed Co. Inc., 734 F. Supp. 250, 252 (N.D. Miss. 1990).
⁶² Id.

of the patent certificate. A licensee's only remedy is suit against the patent holder for breach of contract.

C. Patent Act of 1952

The Patent Act of 1952 forms the foundation for all patent protection in the United States. General utility patents have provided protection for inventions outside the agricultural sector for many years while the U.S. Patent and Trademark Office ("USPTO") refused to apply the general Patent Act to living things, concluding they were discoveries in nature rather than inventions.⁶³ Finally, in 1980, the U.S. Supreme Court, in the landmark case of *Diamond v. Chakrabarty*, found that Congress intended the patentable statutory subject matter to include "anything under the sun that is made by man."⁶⁴ Thus, interpretation of the Act finally concluded that general utility patents may serve as intellectual property protection for plant and animal genetics.⁶⁵

The Patent Act of 1952 conveys patent protection to "whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof."⁶⁶ The U.S. Supreme Court, after examining the text and legislative history of the Patent Act, gave the terms "manufacture" and "composition of matter" a broad interpretation to include a live, human-made microorganism.⁶⁷ The Court reiterated that discoveries in nature are not patentable, but stated that a non-naturally occurring manufacture or

⁶³*See In re* Merat, 519 F.2d 1390 (Cust. & Pat. App. 1975) (appellants sought patents for the process of breeding a strain of dwarf hens with normal cocks, and for the product of the resulting dwarf chickens). The examiner rejected the patents on the theory that a method of breeding animals is not a "process" within the meaning of § 101, and a "thing occurring in nature under controlled propagation is not a manufacture." *Id.* at 1393. The board agreed with the examiner and entered new rejections under 35 U.S.C. § 103 (Non-obvious subject matter) and § 112 (specificity in description). The court agreed with the rejection entered by the board under § 112, and therefore did not reach the additional grounds of rejection). *See also supra* note 1.

⁶⁴ Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

⁶⁵ See Ex parte Allen, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Interf. 1987) (relying on the U.S. Supreme Court's decision in *Chakrabarty*, the Board of Patent Appeals held that oysters, although they were animals, qualified as patentable subject matter under § 101 of the Patent Act so long was they were made by man). *See generally Chakrabarty*, 447 U.S. at 303.

⁶⁶ 35 U.S.C. § 101 (2000).

⁶⁷ Chakrabarty, 447 U.S. at 308.

composition of matter that is a product of human ingenuity and has a distinctive name, character, and use is patentable subject matter under § 101 of the Act, even if it is living matter.⁶⁸ In *Chakrabarty*, the Court found that a human-made, genetically engineered bacterium that was capable of breaking down crude oil met the requirements necessary for a utility patent.⁶⁹ This broad interpretation of the Act led to the USPTO issuing utility patents for plants, plant parts and seeds.⁷⁰ The USPTO had issued nearly 2000 utility patents for plants by the time the U.S. Supreme Court issued a clear ruling that plants were patentable subject matter under the general Patent Act.⁷¹

Because living matter was found to be patentable under the Patent Act of 1952, the Patent Act's patentable subject matter overlaps with the subject matter included under the purviews of the PPA and the PVPA. However, the availability of one form of statutory protection does not preclude the availability of protection under another form.⁷² Examining the text of the Acts and the legislative history, neither of the plant-specific Acts expressly excludes any plant subject matter from protection under the general patent law.⁷³ The U.S. Supreme Court addressed the differences in the Acts, but found that the differences did not present irreconcilable conflicts.⁷⁴ Thus, the different acts are to be read together.

⁶⁸ *Id.* at 309-10.

⁶⁹ *Id.* at 303 ("Respondent filed a patent application relating to his invention of a human-made, genetically engineered bacterium capable of breaking down crude oil, a property which is possessed by no naturally occurring bacteria. A patent examiner's rejection of the patent application's claims for the new bacteria was affirmed by the Patent Office Board of Appeals on the ground that living things are not patentable subject matter under § 101. The Court of Customs and Patent Appeals reversed, concluding that the fact that micro-organisms are alive is without legal significance for purposes of the patent law. *Held:* A live, human-made micro-organism is patentable subject matter under § 101. Respondent's micro-organism constitutes a 'manufacture' or 'composition of matter' within that statute.").

⁷⁰ See Ex parte Hibberd, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Infer. 1985).

⁷¹ J.E.M. AG Supply, Inc. v. Pioneer Hi-bred Int'l, Inc., 534 U.S. 124, 127 (2001).

⁷² *Id.* at 132, 145.

⁷³ Id. at 137-38 (referring to the Plant Patent Act); id. at 143-44 (referring to the Plant Variety Protection Act).

⁷⁴ *Id.* at 134-37, 142.

The first Patent Act in 1790 defined patentable subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof."⁷⁵ In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process" to form the Patent Act of 1952.⁷⁶ "Process" was substituted due to its broader scope of interpretation, denoting a process, art, or method. ⁷⁷ The common requirements of novelty, utility, and non-obviousness remained intact.⁷⁸ Similarly, the strict description requirements remained.⁷⁹

Therefore, to obtain utility patent protection, a plant breeder must show that the plant he has developed is new, useful, and non-obvious.⁸⁰ A plant is considered new if it was not known or used by others before its discovery.⁸¹ Moreover, to be new, the plant must be "one that literally had not existed before, rather than one that had existed in nature but was newly found."⁸² To receive a utility patent, the invention must also be useful.⁸³ The "product of a patented process is useful if it may serve some identifiable purpose."⁸⁴ The invention's potential for commercial success is irrelevant; the standard is actual and identifiable usefulness.⁸⁵ Next, a plant must be non-obvious.⁸⁶ The "emphasis on nonobviousness is one of inquiry, not quality."⁸⁷

⁷⁵ Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109, 109-10.

⁷⁶ Ch. 10, § 101, 66 Stat. 792, 797 (1952).

⁷⁷ See S. REP. No. 1979-82, at 2409-10 (1952); see also 35 U.S.C. § 101(b) (2000) ("The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material").

⁷⁸ 35 U.S.C. §§ 101-103 (2000).

⁷⁹ Id. § 112.

⁸⁰ Id. § 101.

⁸¹ See id. § 102(a).

⁸² Yoder Bros., Inc. v. Cal.-Fla. Plant Corp., 537 F.2d 1347, 1378 (5th Cir. 1976).

⁸³ 35 U.S.C. § 101 (2000).

⁸⁴ Imperial Chem. Indus., PLC v. Henkel Corp., 545 F. Supp. 635, 645 (D. Del. 1982).

⁸⁵ *Id.* at 644-45.

⁸⁶ 35 U.S.C. § 101 (2000).

⁸⁷ Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

Obviousness serves as "Congress' articulation of the constitutional standards of invention."⁸⁸ Basically, there must be an actual invention, and non-obviousness requires the invention to entail a degree of skill and ingenuity greater than that possessed by one with an ordinary level of knowledge in the practice or trade.⁸⁹

In addition, the applicant for a utility patent must meet the stringent description specifications of § 112 of the general patent law.⁹⁰ An applicant is required to provide "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains... to make and use the same."⁹¹ Today, advances in biological knowledge and expertise in genetic modifications have allowed plant breeders to satisfy these demanding description requirements. In addition to a written description of the plant, which is publicly accessible.⁹²

Due to the stringent requirements under general patent law, it is much more difficult to obtain a utility patent for a plant than to obtain a Plant Patent or a PVPA certificate. However, if an applicant can overcome these stringent requirements, a utility patent may be more desirable due to its greater scope of protection. For example, unlike the PVPA, the Patent Act does not

⁸⁸ *Yoder*, 537 F.2d at 1378.

⁸⁹ *Id.* at 1379.

^{90 35} U.S.C. § 112 (2000).

⁹¹ Id.

⁹² See 37 C.F.R. § 1.801-1.809 (2001). Section 1.801 states: "[B]iological material shall include material that is capable of self- replication either directly or indirectly." Section 1.802(a) provides: "Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material." Section 1.802(b) provides:

Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.

contain exemptions that limit the scope of protection.⁹³ Also, the PVPA limits protection to a single variety⁹⁴ and the PPA limits protection to a specific plant⁹⁵. The Patent Act has neither of these limitations. Specifically, the PVPA protection falls short of a utility patent because a breeder can use a plant that is protected by a PVP certificate to "develop" a new inbred line, but the breeder cannot use a plant patented under the general Patent Act for such purpose.⁹⁶ With greater protection under the Patent Act, a patentee may better serve his economic and/or commercial interests.

A patent issued under the general Patent Act is good for twenty years and conveys the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process to exclude others from using, offering for sale, or selling throughout the United States, or importing into the United States, products made by that process."⁹⁷

IV. Conclusion

Though it was once held that living matter could not benefit from protection under intellectual property laws in the United States, today there are alternative forms of statutory protection to consider when dealing with living subject matter, including the Plant Patent Act, the Plant Variety Protection Act, and the Patent Act of 1952. While considering the alternative

⁹³ The PVPA contains three exemptions from infringement limiting its scope in protection: 1. Public Interest Exemption, § 2404; 2. Research Exemption, § 2544; and the Farmer's Exemption, § 2543.

⁹⁴ 7 U.S.C. § 2402(a) (2000).

⁹⁵ 35 U.S.C. § 161 (2000). The PPA limits protection to a specific plant because of the asexual reproduction requirement for a plant patent. Without sexual reproduction, all offspring is genetically identical to the original plant. Thus, what is covered by a plant patent is any plant with a specific genetic *identity* covered by the patent, whereas PVPA certificates protect seeds and offspring of certain plants not because of their genetic identity but merely because of their status as offspring of a protected plant variety. *See* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560 (Fed. Cir. 1995), *cert. denied*, 518 U.S. 1018 (1996).

 ⁹⁶ See 7 U.S.C. § 2541(a)(4) (2000) (stating that infringement includes "use of the variety in producing (as distinguished form developing) a hybrid or different variety therefrom").
⁹⁷ 35 U.S.C. § 154 (2000).

forms of patent protection, one must be aware of the differences in the requirements and the scope of protection offered by each Act. Many plant patent applicants may prefer to secure patent protection under the general Patent Act due to its broad scope and greater protection. However, plant varieties that are unable to satisfy the stringent requirements of the Patent Act may qualify for protections afforded by the PPA or PVPA.