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Mother Nature and the Courts: Are Sexually Reproducing Plants and their Progeny Patentable Under the Utility Patent Act of 1952?

by

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COMMENTS

MOTHER NATURE AND THE COURTS: ARE SEXUALLY REPRODUCING PLANTS AND THEIR PROGENY PATENTABLE UNDER THE UTILITY PATENT ACT OF 1952?

INTRODUCTION

Did Congress intend to extend patent protection to plants and their progeny that are capable of sexual reproduction under the Utility Patent and Trademark Act (UPTA) of 1952?[1] The answer may soon be forthcoming because the United States Supreme Court has granted certiorari in *Pioneer Hi-Bred Int'l, Inc. v. J.E.M. AG Supply, Inc.*[2] *Pioneer v. J.E.M.* is destined to finally resolve the issue of whether the Plant Patent Act of 1930 (PPA)[3] and the Plant Variety Protection Act of 1970 (PVPA)[4] "are the exclusive forms of protection for plant life."[5]

Patents issued under 35 U.S.C. to Pioneer Hi-Bred (Pioneer), the world's largest seed corn producer,[6] are the subject of a patent infringement suit against J.E.M. AG Supply Inc., Farm Advantage Inc., and others (J.E.M.).[7] Pioneer, the holder of seventeen plant patents under the general utility patent statutes for sexually reproducing plants, alleges that the defendants infringed on its patents "by making, using, and selling, or offering for sale, Pioneer seed corn" without authority.[8] Pioneer sells these products "under a limited label license that [does] not allow for resale, but solely for use 'to produce grain and/or forage.'"[9] J.E.M. raised the affirmative defense of patent invalidity, maintaining that sexually reproducing plants are not patentable under the general utility

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1 35 U.S.C. §§ 101-112 (1984 & Supp. 2001).

2 200 F.3d 1374 (Fed. Cir. 2000).

3 35 U.S.C. §§ 161-64 (1984 & Supp. 2001).

4 7 U.S.C. §§ 2321-2582 (1999).

5 *Pioneer*, 200 F.3d at 1376.

6 Andrew F. Nilles, *Plant Patent Law: The Federal Circuit Sows the Seed to Allow Agriculture to Grow*, 35 LAND & WATER L.REV. 355, 362 (2000). Pioneer Hi-Bred is an agribiotech company that produces genetically engineered crops and is the world's largest seed corn producer. Pioneer Hi-Bred Int'l, Inc. v. J.E.M. AG Supply, Inc., 49 U.S.P.Q.2d (BNA) 1813, 1814 (N.D. Iowa 1998).

7 *Pioneer*, 49 U.S.P.Q.2d (BNA) at 1813.

8 Nilles, *supra* note 6, at 362.

9 *Id.* at 362-63.

patent laws because they are exclusively covered under the PVPA.[10] The district court, relying on the Supreme Court decision in *Diamond v. Chakrabarty*,[11] found that plants as living organisms were patentable under the general patent and trademark statute.[12] Furthermore, the court relying on the Board of Patent Appeals and Interference's (BPAI) decision in *Ex parte Hibberd*,[13] ruled that Congress did not intend to restrict the scope of subject matter protection under § 101 of the UPTA by enacting the PPA and the PVPA.[14] Thus, the court ruled against J.E.M., finding unpersuasive the assertion that sexually reproducing plants are not patentable under the general utility patent statute, and refused to invalidate Pioneer's patents.[15] Subsequently, J.E.M. filed an interlocutory appeal with the United States Court of Appeals for the Federal Circuit (Federal Circuit), which the court granted.[16] The Federal Circuit adopted the reasoning of the lower court and affirmed the ruling. J.E.M. filed for a writ of certiorari that the Supreme Court granted.[17] In the ensuing period, the Supreme Court has invited the Solicitor General to submit an amicus curiae brief on behalf of the United States in *Pioneer v. J.E.M.*[18]

The biotechnology[19] and seed industries are watching the Court with great interest because this decision could have enormous implications for both industries by potentially changing the landscape of intellectual property protection throughout the world.[20] Although utility patents are not the exclusive forms of protection for transgenically[21] altered plants

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10 *Id.*

11 447 U.S. 303 (1980).

12 *Pioneer*, 49 U.S.P.Q.2d at 1819.

13 227 U.S.P.Q. (BNA) 443 (B.P.A.I. 1985).

14 *Pioneer*, 49 U.S.P.Q.2d at 1819.

15 *Id.*

16 Pioneer Hi-Bred Int'l, Inc. v. J.E.M. AG Supply, Inc., 1998 U.S. App. LEXIS 34137, at *2 (Fed. Cir. Oct. 27, 1998) (unpublished).

17 J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 121 S.Ct. 1077 (2001) (mem.).

18 J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 531 U.S. 807 (2000) (mem.).

19 Biotechnology is defined as "direct manipulation of genetic material in animals, plants, and microorganisms to produce new types of organisms or improve existing life forms." MODERN DICTIONARY FOR THE LEGAL PROFESSION (2d ed. 1996).

20 *See* Nilles, *supra* note 6, at 361-62.

21 Transgenic organisms are organisms that contain DNA from another organism inserted by genetic engineers through biotechnological processes. Carrie F. Walter, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025 (1998).

and seed, they are widely believed to provide the broadest protection.[22] Currently plants and seed (genetically altered and otherwise created varieties) are afforded protection under various types of intellectual property statutes and laws including the PPA, PVPA, state trade secret law, license agreements, contracts, and utility patents.[23] Despite multiple layers of intellectual property protection available for plants and seed, industry prefers the coverage provided under the UPTA because it allows for the greatest amount of protection by excluding others from "making, using and selling" patented plants without exemption.[24] This comment discusses the topic of whether sexually reproducing plants and their progeny (seed) are indeed patentable under the utility patent statutes, and the implications of the Supreme Court's pending decision in *Pioneer v. J.E.M.*[25]

Sexually reproducing organisms are, by nature, genetically dynamic.[26] The very essence of sexual reproduction is the recombination of genetic material between gametes in each generation.[27] Consequently, in order to accommodate the patenting of sexually reproducing plants under 35 U.S.C., the Patent and Trademark Office (PTO) necessarily relaxed the legal requirements of § 112 as well as other sections of the general utility statutes.[28] Relaxing the legal standard to serve special situations could have legal implications when considering the issue of patentability for other inventions, particularly in light of recent controversies over the patentability of genes, gene fragments (ESTs), and higher forms of life. The position taken in this comment is that for several reasons, the PTO has erred by relaxing the legal requirements of the utility patent statutes. First, this comment takes the

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[22] *Ex parte* C, 27 U.S.P.Q.2d 1492 (B.P.A.I. 1992). The "C" designation is used by the BPAI for this particular seed name to shelter the identity, as a Doe designation is used in cases where the identity of the parties is not revealed. *Id.*

[23] *See* David G. Scalise and Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 85 (1995); J. Benjamin Bai, Commentary, *Protecting Plant Varieties under TRIPS and NAFTA: Should Utility Patents Be Available for Plants?*, 32 TEX. INT'L L.J. 139, 140-47 (1997); Debra L. Blair, Note, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 298 (1999); Peter J. Goss, Comment, *Guiding the Hand That Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 CAL. L. REV. 1395, 1397 (1996).

[24] Goss, *supra* note 23, at 1399.

[25] *Pioneer*, 200 F.3d 1374.

[26] H. VAN DEN ENDE, SEXUAL INTERACTIONS IN PLANTS 143-146 (1976).

[27] *Id.*

[28] *Ex parte C*, 27 U.S.P.Q.2d at 1492-1502; *Ex parte Hibberd*, 227 U.S.P.Q. at 444-47.

position that the BPAI misinterpreted the Supreme Court's decision in *Chakrabarty* when deciding in *Ex parte Hibberd* that sexually reproducing plants could be patented under the general utility patent statutes.[29] Second, the BPAI erred in assuming that there was no difference between depositing an exemplar of a bacterium in the American Type Culture Collection (ATCC) that reproduces through asexual reproduction and depositing an exemplar of a seed that reproduces sexually.[30] Third, while it may be that Congress did not repeal or restrict the subject matter of § 101 by enacting the PPA and the PVPA as the Supreme Court determined in *Chakrabarty*, neither did Congress intend to relax the requirements of 35 U.S.C. for sexually reproducing plants and their progeny.[31] Congress has chosen the type of protection it intends to extend to sexually reproducing plants and their progeny, and that is the *patent-like* protection of the PVPA, which the USDA administers.

Part II outlines the historical development of intellectual property protection for plants in the United States. Part III compares and contrasts the currently available forms of intellectual property protection available to the seed and biotechnology industries in relation to the utility patent statutes. In Part IV the development of the legal precedence relied on by the PTO to enable the PTO to issue utility patents to sexually reproducing plants is discussed. Part V deals with the requirements of the UPTA in light of sexually reproducing plants. Part VI distinguishes the BPAI decision in *Ex parte Hibberd* from the Supreme Court's decision in *Diamond v. Chrakrabarty* in light of the Supreme Court's pending decision in *Pioneer v. J.E.M.* Part VII of this comment identifies the main arguments against the patentability of sexually reproducing plants and their progeny. Part VIII examines recent changes made by Congress to the PVPA that diminish concerns previously expressed by the seed industry, and discusses the appropriateness of restricting patent protection for sexually reproducing plants to the PVPA.

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[29] *See Ex parte Hibberd*, 227 U.S.P.Q. at 445.

[30] *See id.* at 447.

[31] *See Chakrabarty*, 447 U.S. at 313-15; *Ex parte Hibberd*, 227 U.S.P.Q. at 444-45.

II. HISTORICAL PERSPECTIVE OF THE SEED INDUSTRY'S INFLUENCE ON THE DEVELOPMENT OF PLANT INTELLECTUAL PROPERTY PROTECTION IN THE UNITED STATES

Congress has the power under Article I, section 8, clause 8 "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[32] However, since the enactment of the first Patent Act in 1790, protecting the efforts of plant breeders and their developed germplasms[33] has been a problem.[34] Early seed companies realized the need to establish a market but because of the ease with which openly pollinated[35] varieties could be propagated, the seed industry had little incentive to invest in extensive research programs.[36] Because seed naturally reproduces generation to generation, the marketed product once sold to farmers was available for replanting subsequent crops or for resale to others from a single seed sale.[37] Traditionally farmers have engaged in the practice of saving seed from each year's harvest for replanting during successive years, a practice that cuts into the seed market.[38] With the advent of hybrid technology,[39] which produces high yield in the first generation cross with subsequent yields declining, the seed industry finally had an incentive to develop new and improved varieties because farmers must return to the seed producer each year for their seed supply.[40]

Hybridization, the production of hybrid seed, is accomplished as follows: parental lines are developed by repeatedly inbreeding through self-pollination within a single line so that a homozygous (genetically uniform) line suitable

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[32] U.S. CONST. art. I, § 8, cl. 8.

[33] Germplasm refers to the genetic material of the plant and the plant breeders and biotechnologist's intellectual property interests because it incorporates their efforts.

[34] Blair, *supra* note 23, at 297-306.

[35] Open pollination is natural cross pollination whereby the pollen from the anther of one plant is transferred by either insects or wind to the stigma or silk of another plant to complete the sexual reproductive cycle. *See* Blair, *supra* note 23, at 304 n.72 (citing JOHN MILTON POEHLMAN, BREEDING FIELD CROPS (3d ed. 1987)).

[36] *Id.* at 302.

[37] *Id.* at 303-04. *See also* JACK RALPH KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 1492-2000, at 37 (1988).

[38] Blair, *supra* note 23, at 300-06.

[39] Hybrid technology is the cross-pollination of two inbred parental lines resulting in a crop with improved vigor in the first generation with subsequent declining yields in later generations. *See id.* at 304-306.

[40] *Id.* at 304-06.

for crossing is developed.[41] When two parental lines are crossed or inter-bred, the resulting hybrid plants have a mix of new genetic material that makes them more vigorous in the first generation after cross with accompanying high yields that drop off in subsequent generations, a phenomenon known as hybrid vigor.[42] Because seed companies often only their hybrid seed on the open market, the parental lines can be protected under trade secret law from competitor seed producers through grower confidentiality agreements, unlabeled fields, and purchase agreements on hybrid seed sales.[43] The farmer rather than being able to replant from the previous year's crop must return each year to the seed company for additional seed purchases in order to replant with the same results.[44]

In 1926, Henry Wallace in Des Moines, Iowa founded the Hi-Bred Corn Co. (now Pioneer-Hi-Bred International, Inc.,) and began marketing the first hybrid seed corn.[45] By 1943, nearly ninety percent of the corn planted in the "corn-belt" of the U.S. was hybrid seed corn.[46] Although there was financial success in the development of these markets due to hybridization technology, there were still problems in the intellectual property arena.[47] For instance, protecting parental inbred lines under trade secret law, a form of state law protection "developed from other areas of the law, such as contracts, torts, and property requires a costly commitment to keeping the genetic makeup of the parental lines confidential as well as being costly to enforce.[48] Unfortunately for the seed companies, hybridization techniques are not applicable to certain types of important agricultural crops that are open or self-pollinating, such as soybean and cotton.[49] Thus, there is little incentive to develop new varieties of these openly pollinated crops.[50]

In 1930, Congress enacted the Plant Patent Act for the protection of asexually reproduced plants, which the PTO administers.[51] However, there was still a need for intellectual

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41 Goss, *supra* note 23, at 1418.
42 *Id. at* 1419; Blair, *supra* note 23, at 305.
43 Goss, *supra* note 23, at 1415-19.
44 *Id.* at 1418.
45 Blair, *supra* note 23, at 305.
46 *Id.*
47 *Id.* at 306-7.
48 *Id. at* 308.
49 *See id.* at 306.
50 *See id.*
51 35 U.S.C. §§ 161-64 (1984 & Supp. 2001).

property protection for sexually reproducing plants, including the self-pollinating varieties and the parental lines for crops such as corn.[52] "In 1961, the Union for the Protection of New Varieties of Plants (UPOV) was created by six European nations to provide an international legal framework for Plant Breeders Rights legislation."[53] Based on the UPOV system, Congress enacted legislation that provided "*patent-like protection*" without the strict requirements of the utility patent statutes: the Plant Variety Protection Act of 1970.[54] The PVPA, which the United States Department of Agriculture (USDA) administers, allows for *patent-like protection* to "originators of novel varieties of sexually reproducible crop plants."[55] Under the PVPA, Congress has given originators of novel varieties the "exclusive right to the production and sale of seed of the protected variety."[56] However, the PVPA contains two caveats: the "farmers' exemption," which reserves to farmers the right to save seed for replanting subsequent crops; and the "research exemption," which allows for the development of new varieties from protected varieties.[57]

With the advent of biotechnology techniques in the 1970s and 80s that allowed plant breeders to introduce improved genetic traits to plant material, there was increased need for intellectual property protection for all types of crops.[58] With the ability to produce transgenically altered plants[59] that are resistant to insect infestations, better equipped to endure herbicide applications, and resist drought and frost damage, the promise of increased returns was great.[60] However,

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[52] *See* Goss, *supra* note 23, at 1407. *See also* S. REP. NO. 1246 at 3 (1970) (stating that "[n]o protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.").

[53] Blair, *supra* note 23, at 307; Kloppenburg, *supra* note 37 at 136-37.

[54] Blair, *supra* note 23, at 307 (emphasis added). *See* 7 U.S.C. 2321-2582 (1994).

[55] Blair, *supra* note 23, at 307(quoting JOHN MILTON POEHLMAN, BREEDING FIELD CROPS 4, 692 (3d ed. 1987)).

[56] *Id.*

[57] Goss, *supra* note 23, at 1408-10.

[58] *Id.* at 1398-99.

[59] There are generally two techniques commonly used to genetically alter or engineer plants. For some crops, like corn, genetic engineers insert genes or snippets of DNA into a single cell using a DNA particle gun. The bullet for the gene gun has a plastic tip containing tiny metal pellets coated with DNA. Another method utilized for crops such as cotton and soybean employs common soil bacteria (*agrobacterium tumefaciens*) to carry the DNA snippet or gene into the target cell. Oczek, *infra* note 66, at 633 n.44 (citing NEIL A. CAMPBELL, BIOLOGY 399, 411 (4th ed. 1996).

[60] *Id.* at 1399. *See also* Joshua M. Stone, Student Article, *Restraints on Competition*

research costs were very high and without the promise of protection for research investments, the seed and biotechnology industries would not undertake such expensive and time-consuming endeavors.[61]

Along with traditional legal protection under contracts and state trade secret law as well as protection under the PPA and the PVPA, the biotechnology firms and seed industry sought more protection under the Utility Patent and Trademark Act of 1952 (the UTPA).[62] The UPTA provides the greatest amount of protection for intellectual property pursuits because there are no exemptions to coverage under the act; however, utility patents are difficult and costly to obtain.[63] Furthermore, there have been persistent questions regarding the patentability of plants and seed, under 35 U.S.C., especially those produced through sexual reproduction, due to the stringent requirements of subject matter, utility, novelty, obviousness, and enablement through the written description.[64] A more thorough understanding of the various forms of intellectual property protection available for the protection of plants and seed is necessary in order to determine if utility patents are imperative to insure the protection of this property interest. Therefore, after a brief introduction to intellectual property protection for seeds and plants in general, this comment will turn to a discussion and comparison of plant protection under state trade secret law, the PPA, the PVPA and the UPTA.

III. PLANT INTELLECTUAL PROPERTY PROTECTION

Seed and biotechnology innovators have expended large sums of time, energy, money, and intellectual power in creating new varieties of genetically engineered seed and plants, thereby creating distinct property interests that are separate and independent from the physical entity created.[65] Consequently, it is the physical embodiment of the intellectual property interest that makes genetically engineered seeds

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Through the Alteration of the Environment at the Genetic Level, 8 N.Y.U. ENVTL. L.J. 704 (2000).

[61] Goss, *supra* note 23, at 1398-99.

[62] *See* Blair, *supra* note 23, at 315-18.

[63] *Id.* at 318.

[64] *See Ex parte* C, 27 U.S.P.Q.2d 1492 (B.P.A.I. 1992); *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (B.P.A.I. 1985).

[65] Jeremy P. Oczek, Note, *In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seed*, 41 B.C. L. REV. 627, 636 (2000) (citations omitted).

valuable and not the ownership of the physical entity.[66] Statutory and common law rights are the only protection available to inventors for the protection of their intellectual property interests embodied in the newly developed seed and plants.[67] Without legal restraints against the free use and disposition of this interest, industry would not have the incentive to invest enormous amounts of resources to develop these new varieties.[68] Therefore, protection of these interests is essential to the development of the biotechnology and seed industry, but the question remains: how much protection is necessary?[69]

A. Trade Secrets

Until the PTO reversed its stance on the issuance of utility patents for sexually reproducing plants, seed companies typically employed trade secrets to protect their parental seed lines.[70] Trade secret protection can be a valuable tool in protecting the interest of seed producers because unlike patent protection, which affords protection to innovation for a fixed period of time, trade secret protection can last indefinitely as long as the innovation remains confidential.[71]

As mentioned above, state trade secret law arose mainly out of the law of torts and property.[72] The essence of trade secret law is to establish and uphold a basic commercial morality by imposing liability for "misappropriation" of another's commercially valuable "trade secret."[73] The original Restatement of Torts of the American Law Institute states that "[a] trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."[74] The Restatement Third states that a "trade secret is any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others."[75] Thus, the key to

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[66] *Id.*
[67] *See id.*
[68] *See id.* at 636-37.
[69] *Id.* at 636.
[70] Blair, *supra* note 23, at 308.
[71] Goss, *supra* note 23, at 1415.
[72] *Id. at* 1414; Blair, *supra* note 23, at 308.
[73] Goss, *supra* note 23, at 1414.
[74] Blair, *supra* note 23, at 308.
[75] RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 39 (1995).

protection of an intellectual property interest under trade secret law centers on keeping the interest confidential, which in turn necessitates that the interest "possess at least a modicum of originality which will separate it from everyday knowledge."[76] However, the degree of originality necessary for trade secret protection need not rise to the level of the requirement of novelty nor non-obviousness under the general patent statutes.[77]

Trade secret protection differs from plant patent protection in a significant way: the owner of a trade secret does not enjoy an absolute property right in the trade secret that would exclude all others from using the secret.[78] Unlike other types of inventions, intellectual property interests embodied in seed are self-replicating. This makes protection under trade secret law difficult because seeds can be acquired legally, genetically analyzed, and replicated indefinitely.[79] Nevertheless, plant breeders have been able to employ trade secret laws to protect their inbred parental lines of hybrid seed considering that it is difficult to determine the genetic makeup of parental line from the seed itself.[80]

One of the most significant cases involving trade secrets in the seed industry[81] is *Pioneer Hi-Bred International v. Holden Foundation Seeds, Inc.*[82] Pioneer accused the defendant of misappropriating inbred parental lines of corn that Pioneer had protected under trade secret law.[83] Holden argued that it should not be liable because Pioneer did not keep the parental lines secret, that Pioneer had failed to prove that Holden possessed the protected lines, and that the lines were unlawfully obtained.[84] Additionally, Holden argued that the PVPA preempted "state trade secret law as applied to sexually reproducing plants."[85] The court assuming without deciding that the parental lines were protectable as a trade secret, found that Holden had misappropriated Pioneer's trade secret.[86] The court also found that protection for sexually reproducing

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[76] Blair, *supra* note 23, at 308.
[77] Goss, *supra* note 23, at 1416-19.
[78] *Id. at* 1416.
[79] *Id. at* 1417.
[80] *Id.*
[81] Blair, *supra* note 23, at 308.
[82] 35 F.3d 1226 (8th Cir. 1994).
[83] Blair, *supra* note 23, at 308.
[84] *Id.* at 309.
[85] *Id.* (quoting *Pioneer Hi-Bred*, 35 F.3d at 1242).
[86] *Pioneer Hi-Bred*, 35 F.3d at 1246.

plants under the PVPA did not preempt coverage of parental lines under state trade secret law because the law generally recognizes that "trade secret and patent protection can 'peacefully coexist.'"[87] The Eighth Circuit Court of Appeals affirmed the judgment of the lower court and the award of damages, thus establishing state trade secret law as a viable intellectual property protection.[88] Nevertheless, the case "consumed the attention of the district court for over a decade, requiring ten weeks of actual trial time, and involved court-ordered complex scientific testing and growouts."[89]

While *Pioneer Hi-Bred v. Holden* shows that sexually reproduced inbred parental lines used to create hybrids can be protected by trade secret, the confidentiality requirement and difficulties in enforcement coupled with the associated costs, make this form of protection less attractive.[90] As alluded to above, seed companies usually employ a package of protection to protect the research and development of their sexually reproducing proprietary lines by combining protection under trade secrets, contracts, plant patents under the PVPA, and utility patents.[91]

B. *Plant Patent Act of 1930*

The need for statutory protection of plant-related inventions as an incentive to promote the progress and development of plant science has long been recognized in this country.[92] Patent legislation was proposed at least as early as 1892,[93] but it was not until the passage of the Townsend-Purnell Plant Patent Act in 1930 (the PPA)[94] that plant-inventions were afforded patent protection.[95] The Townsend-Purnell Act was the first legislation anywhere in the world to grant patent rights to plant breeders, and was supported by such prominent individuals as Thomas Edison who stated that "[n]othing that Congress could do to help farming would be of greater value and permanence than to give to the plant breeder the same status as the mechanical and chemical inventors now

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[87] *Id.* at 1243 (quoting Kevanee Oil Co. v. Bicron Corp., 416 U.S. 470, 486 (1974)).
[88] *Id.*
[89] Blair, *supra* note 23, at 309.
[90] *Id. at* 309 (quoting *Pioneer Hi-Bred*, 35 F.3d at 1229).
[91] *Id. at* 310.
[92] Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1562-63 (Fed. Cir. 1995).
[93] *Id.* at 1562.
[94] 35 U.S.C. § § 161 et seq. (1984 & Supp. 2001).
[95] *Imazio*, 69 F.3d at 1562-63.

have through the law."[96] Through passage of the PPA, Congress intended to place agriculture, as far as was practicable, on the same footing as industry in regards to receiving benefits under the patent system.[97]

Initially there were two reasons for denying patent protection that Congress had to overcome to pass patent protection for living plants.[98] First was the belief that plants were the "products of nature and therefore not subject to patent protection," even those plants bred by man.[99] Secondly, plants were considered not to be "amenable to the written description requirement of . . . 35 U.S.C. § 112" under the utility patent statutes because they would not sufficiently breed true-to-type generation after generation.[100] A plant breeds "true-to-type" if it has sufficient distinguishing characteristics that are unique only to that plant and these characteristics are reproduced consistently in subsequent generations without human intervention.[101] Thus, the question under § 112 was whether a plant could be sufficiently distinguished by written description from any other plant variety after reproducing generation after generation.

In enacting the PPA, Congress recognized "that the work of the plant breeder 'in [the] aid of nature' was [a] patentable invention" under the general patent statutes.[102] Congress' response to the difficulty of meeting the written description requirement applicable to utility patents was to relax the requirement in favor of "a description . . . as complete as is reasonably possible[,]"[103] along with the deposit of an exemplar in an approved facility.

Congress originally enacted the PPA as an amendment to the general patent provisions, and it was not until the promulgation of the UPTA of 1952 that the plant patent provisions were included as a separate chapter of 35 U.S.C.[104] Nevertheless, even with the separation of the plant provisions into their own chapter, the statute explicitly states that "[t]he provisions of this title relating to patents for inventions shall

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96 *Id.* at 1562 (quoting S. REP. NO. 315, at 3 (1930)).
97 *Id.* at 1563.
98 *Id.*
99 *Id.*
100 *Id.*
101 Diamond v. Chakrabarty, 447 U.S. 303, 308-11 (1980).
102 *Id.* at 312.
103 *Id.*
104 *Id.*

apply to patents for plants, except as otherwise provided."[105] Thus, the specifications of a plant patent application must meet the requirements of basic patent law under the utility statutes, which Congress engrafted onto the PPA, except as otherwise provided.[106]

The PPA provides the plant breeder patent protection to a single claimed plant with a unique characteristic, either physiological or anatomical, that can be cloned by grafts, buds, or cuttings, resulting in a new plant with the same characteristic.[107] Protection which excludes all others from making, selling, or reproducing a patented plant continues for twenty years from the date the patent application is filed.[108] Title 35 U.S.C. § 161 provides that "[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, 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."[109] Thus, while Congress appeared to relax the requirements under § 112 by requiring a description that is as complete as possible, the written description requirement is satisfied by example rather than words because each protected plant is a replica of the deposited exemplar. However, sexually reproduced plants and their progeny, plants produced from seed, were not recognized for protection under the PPA.[110] It would not be until the passage of the PVPA in 1970 that Congress would recognize *patent-like protection* for sexually reproducing plants and seeds.[111]

C. *Plant Variety Protection Act of 1970*

The Plant Patent Act, which only confers patent protection to asexually reproduced plants, was little help to the establishment and promotion of the developing seed and agricultural industry, due to the fact that most agricultural crops reproduce sexually and multiply by seed.[112] It is not

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105 35 U.S.C. § 161 (1984 & Supp. 2001).

106 *Chakrabarty*, 447 U.S. at 308-11.

107 Nilles, *supra* note 6, at 361.

108 *Id.*

109 *Imazio*, 69 F.3d at 1564. Asexually reproduced plants are plants reproduced through propagation or grafting so that each individual plant is the exact replica or clone of the plant from which it came. Oczek, *supra* note 65, at 637.

110 Oczek, *supra* note 65, at 637.; *Imazio*, 69 F.3d at 1563-68; Nilles, *supra* note 6, at 360.

111 Nilles, *supra* note 6, at 360.

112 Blair, *supra* note 23, at 311.

economically feasible to propagate agricultural cash crops such as soybean, cotton, wheat, barley, oats and rice through asexual reproduction, so the PPA did not provide the protection necessary to promote the agricultural industry.[113] Because many of these same cash crops are not amenable to hybridization techniques, are self-pollinating, and are grown in the open, breeders cannot employ state trade secret law to protect their intellectual property interest.[114] The need to fill this protection gap in the intellectual property regime was recognized as being essential to the development of the burgeoning seed market.[115] The American Seed Trade Association (ASTA), an organization founded in 1883 to promote the interest of the seed industry before the government, lobbied for an amendment to the PPA for the protection of sexually reproducing crop plants.[116] Although unsuccessful in their attempts to amend the PPA, the ASTA and the UPOV were instrumental in bringing about the passage of the PVPA in 1970.[117]

The Plant Variety Protection Act, administered by the Plant Variety Protection Office (PVPO) through the United States Department of Agriculture (USDA) provides "*patent-like protection* to novel varieties of sexually reproduced plants . . . which parallels the protection afforded asexually reproduced plant varieties . . . under Chapter 15 of the Patent Act."[118] Under the PVPA, a plant breeder is issued a certificate of protection for novel and distinct varieties that breed true-to-type (are uniform and stable) through sexual reproduction.[119] The requirement that novel varieties breed true-to-type under the PVPA is more restrictive than the requirement under the PPA for a variety that is new and distinct.[120] The concept of breeding true-to-type is embedded in the term "variety" under the PVPA as interpreted by the Federal Circuit in *Imazio Nursery Inc. v. Dania Greenhouses* (1995).[121] "Variety" in this

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113 Scalise, *supra* note 23, at 93.

114 Blair, *supra* note 23, at 311; *See also* Scalise, *supra* note 23, at 93.

115 Blair, *supra* note 23, at 303.

116 *Id.* at 307.

117 *Id.* at 311.

118 *Imazio*, 69 F.3d at 1567 (emphasis added).

119 Oczek, *supra* note 65, at 638.

120 *Imazio*, 69 F.3d at 1567; Goss, *supra* note 23, at 1407.

121 *Imazio*, 69 F.3d at 1567. In *Imazio*, the court recognized the importance of the asexual reproduction requirement. The court defined "variety" within the meaning of 35 U.S.C. §161 to mean all asexually reproduced plants from a single patented specimen based on the fact that only a single claim can be made. *Id.* To infringe upon a patented plant under the PPA, it is necessary for the patentee to

context refers to the taxonomic use of the term:

> mean[ing] a plant grouping within a single botanical taxon of the lowest known rank . . . defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged.[122]

Thus, "plants failing to exhibit the same traits when grown out over several generations are not eligible for protection" under the PVPA unless the variation is "predictable and commercially acceptable, and having reasonable stability."[123] Like the PPA, the PVPA contains the liberal written description requirement, which is more relaxed than under the general patent statutes.[124] The PVPA requires that the applicant submit a specification that describes "as complete as is reasonably possible" the plant or variety, including breeding history, along with a deposit of the seed for viability testing.[125]

Certificate holders have "the right, during the term of the plant variety protection [twenty years], 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 (as distinguished from developing) a hybrid or different variety therefrom."[126] The right to exclude others also carries with it the associative right to sue for infringement against anyone violating the rights granted by the PVPA certificate, which is analogous to the rights of a patent holder under the general statutes.[127] The most distinguishing difference between the coverage provided by the PVPA, the PPA and utility patents is the existence under the PVPA of two unique exemptions, one for farmers and the other for researchers.[128]

1. Farmers' Privilege

In light of reduced profits realized by the seed industry, the most significant and controversial exemption is the so-

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prove that the alleged infringer had access to the patented specimen and actually reproduced the specimen through asexual reproduction. *Id.* at 1569.

122 *Id.* at 1567 (quoting 7 U.S.C. § 2401(a)(9) (1994)).

123 Scalise, *supra* note 23, at 93; Goss, *supra* note 23, at 1407.

124 Scalise, *supra* note 23, at 93.

125 *Id.*; Blair, *supra* note 23, at 313.

126 Oczek, *supra* note 65, at 638.

127 *Id.*

128 Goss, *supra* note 23, at 1409.

called farmers' privilege.[129] The scope of the privilege is defined by 7 U.S.C. § 2543, permitting farmers "to sell crops produced from a protected variety for other than reproductive purposes" and "to save seed from their protected crops for future use or for planting on the farm."[130] The first part of this exemption gives farmers the natural and logical right to market their crops and little or no attention has been given to this particular privilege.[131] However, the second part of the exemption identified under § 2543, commonly referred to as the "farmers' privilege" or crop exemption, gives farmers the right to save seed for replanting in subsequent years.[132] The farmers' privilege applies only to those farmers "whose primary occupation is the growing of crops for sale for other than reproductive purposes."[133] However, because the exemption limits the seed producer to a single one-time sale to eligible farmers, industry has generally viewed the exemption as a substantial encroachment upon inventors' rights, creating a substantial disincentive to investment for developing new plant varieties.[134]

The farmers' privilege reflects a statutory recognition of the long practiced tradition of farmers saving the best seed from each year's crop to replant in subsequent years.[135] This practice represents more than mere reluctance on the farmers' part to reinvest in subsequent seed purchases.[136] Historically, American agriculture has developed through a process of adapting both native plant species and plants brought to this country from foreign countries with immigrant farmers to local environments through the farmers' practice of saving the best seed.[137] In the mid-nineteenth century, the development of new plant varieties entered the governmental realm with the establishment of the USDA and research programs in land grant universities.[138] Through the cooperative efforts of the government and land grant universities, new and improved varieties were developed and distributed free to farmers who in turn adapted these new varieties to local growing conditions

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129 Scalise, *supra* note 23, at 94.
130 *Id.*; *See also 7* U.S.C § 2543 (1999).
131 Scalise, *supra* note 23, at 94.
132 *Id. at* 95.
133 *Id.*
134 *Id.*
135 Oczek, *supra* note 65, at 631.
136 *Id. at* 632.
137 *Id. at* 631.
138 *Id. at* 632.

through the practice of saving seed.[139] In the early part of the twentieth century, there was a shift toward privatization of the seed industry, and in 1924, Congress enacted legislation to end the free federal seed-distribution program.[140] This trend towards encouraging privatization through legislative enactment continued with the passage of the PVPA in 1970.[141] However, considering that the "majority of the development of crop and seed throughout the world was accomplished mainly through governmental" and farmers' efforts, the crop exemption reflects a natural compromise between the competing interests of the farmers and industry.[142] It has also been suggested that as an additional justification for the crop exemption, Congress intended to "allay fears that the legislation would burden farmers" by increasing costs and thereby reducing profits that are already marginal at best.[143]

In the last decade or so, the agricultural industry has been revolutionized by the advent of genetic engineering that allows scientists to "snip, insert and recombine genes in order to edit and reprogram the genetic makeup of plants."[144] With the arrival of genetic engineering, however, there has been a concomitant push for additional legislation to protect the intellectual property interest of seed developers because of the increased cost of research and development.[145] The crop exemption has now become a "flashpoint between farmers and the seed industry" because it limits sales to a single or one-time transaction to farmers.[146] In 1994, the Supreme Court and Congress responded to the seed industry's concerns and amended the PVPA by restricting but not eliminating the farmers' exemption.[147] Whether or not these restrictions on the scope of the crop exemption of the PVPA have sufficiently closed the gap to meet the needs of the seed industry will be discussed further in Part VIII.

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139 *Id.*

140 *Id. at* 633.

141 *Id.*

142 *Id. at* 631-32; *See* Neil D. Hamilton, *Why Own the Farm if You Can Own the Farmer (and the Crop)? Contract Production and Intellectual Property Protection of Grain Crops*, 73 NEB. L. REV. 48 (1994).

143 Oczek, *supra* note 65, at 639.

144 *Id. at* 633.

145 *Id. at* 636.

146 Goss, *supra* note 23, at 1410.

147 *Id.*

2. Research Exemption

The second exemption of the PVPA is referred to as the "research or breeders exemption."[148] Under the breeder's or research exemption, "[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under [the PVPA]."[149] This does not mean that others are free to use the protected variety at will. For instance, a breeder cannot use a certificate holder's variety "in producing (as distinguished from developing) a hybrid or different variety therefrom."[150] The terms "producing" and "developing" have not been legally defined, however, "producing" seems to refer to the use of the protected variety without adding an inventive step whereas in order to "develop," one would have to engage in inventiveness.[151] In other words, scientists are able to use the protected varieties as stepping-stones to develop new varieties and advance agricultural biotechnology through research.[152] When Congress amended the PVPA in 1994, the scope of the research or breeder's exemption was narrowed in scope "by declaring that varieties 'essentially derived' from protected varieties are infringing under the PVPA."[153] While there is ample room for litigation, the gist of the "essentially derived" language appears to reflect Congress' intent to allow breeders and researchers access to the protected material for the advancement of the art while protecting the interest of the certificate holder.[154] Discussion concerning the importance of the research exemption and its relationship to the enablement requirements under the utility patent will occur in Part V.

D. License and Contract Agreements

The scope of contract coverage as a means of protecting intellectual property interest is too broad to be discussed fully in this comment. Therefore, only a brief introduction to the subject with a few well-chosen examples will be presented.

Traditionally contracts and license agreements were utilized in agriculture primarily in the production of hybrid

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148 Blair, *supra* note 23, at 313.
149 Goss, *supra* note 23, at 1409.
150 *Id.*
151 *Id.*
152 *Id.*
153 *Id. at* 1410.
154 *Id.*

seed and for many vegetable and horticultural crops.[155] Today, however, contracts and license agreements are being used throughout the entire breadth of agriculture, "a trend which has been labeled as part of the industrialization of agriculture."[156] This trend is part of the overall protection employed by the seed industry to protect its intellectual property interests.[157] Two examples of the types of contracts employed by the seed industry are the "purchase agreement" and the "label notice."[158] "Purchase agreements" and "label notices" notify the purchaser of the businesses' development and research costs embodied in the seed and the supplier's proprietary interest in the use of subsequent production from the seed being purchased.[159]

In *Mallinckrodt v. Medipart Inc.*, the Federal Circuit approved the use of "label notices" on patented devices limiting the purchaser to a single one-time use.[160] The patent at issue in *Mallinckrodt* was a general utility patent under 35 U.S.C. for a medical device.[161] Whether or not label notices are enforceable under state law or preempted by federal legislation under the PVPA and the PPA remains to be answered.[162] In any case, "enforceability of such contract[s] would depend on whether the buyer was aware of the provision and whether the courts would otherwise find [the agreement] legal" and binding.[163] While legal questions remain, at the present time seed companies are able to use "grower agreements" to fill the gaps in protection under the PPA and PVPA. In fact, with the coupling of "grower agreements" with patent protection under the PPA and *patent-like protection* under the PVPA, the additional protection provided by adding utility patents is nominal. Even so, newcomers to the seed industry such as petro-chemical and pharmaceutical conglomerates, grain and food processing companies and genetic engineering firms have rushed to the PTO seeking utility patent protection for their new varieties of plants and seed.

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155 Hamilton, *supra* note 142, at 52.
156 *Id.*
157 Goss, *supra* note 23, at 1419.
158 *Id.* at 1419-21.
159 *Id.*
160 *Id. at* 1420.
161 *Id.*
162 *Id.*
163 Hamilton, *supra* note 142, at 94.

IV. DEVELOPMENT OF UTILITY PATENT PROTECTION OF SEXUAL REPRODUCED PLANTS AND PLANT PROGENY

A. *Diamond v. Chakrabarty*

Since the initial establishment of patent protection in the United States, experts have questioned whether plants and seed could enjoy patent protection comparable to that of man-made inventions.[164] Before the Supreme Court's decision in *Diamond v. Chakrabarty*[165] in 1980 and the BPAI's decision in *Hibberd*[166] in 1985, patent protection for living plants and their progeny was not available under the UPTA because of two general obstacles: the "product of nature" doctrine and the "written description" requirement.[167] The "product of nature" doctrine was the common misconception that Congress did not intend to authorize the patenting of living matter under § 101 of the Act, because all living things were the products of nature and thus not patentable.[168] Section 101 of the UPTA provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[169] In other words this doctrine was centered around the idea that utility patents were not appropriate for things produced by nature, even artificially bred plants, because man cannot be considered to have invented that which is found in nature. Following *Ex parte Latimer* [170] the Supreme Court found

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[164] *See* Blair, *supra* note 23, at 310.

[165] 447 U.S. 303 (1980).

[166] *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (B.P.A.I. 1985).

[167] *Chakrabarty*, 447 U.S. at 308-11.

[168] The "products of nature" doctrine encompasses the concept that things naturally occurring in nature are not patentable because they contain no human inventive step and encompass basic knowledge that should remain in the public domain for the good of all. This includes natural phenomena, laws of nature, physical phenomena, and abstract ideas. *See Id. at* 311 (citing *eg.* Parker v. Flook, 437 U.S. 584 (1978); Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

[169] 35 U.S.C. § 101 (1984 & Supp. 2001).

[170] 1889 Dec. Comm'r Pat. 123. *Latimer* involved a patent claim for a fiber found in the needle of the *pinus australis* that was rejected because a contrary result would permit "patents [to] be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible." *Id.* at 126. Thus, *Latimer* came to stand for the general proposition that plants could not be

in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[171] and *American Fruit Growers v. Brogdex Co.*[172] that plants were not the products of manufacture in the sense of the general patent law.[173] However, the Supreme Court clarified its stance on the "product of nature" doctrine in *Diamond v. Chakrabarty*.[174]

In *Chakrabarty* the Supreme Court addressed whether bacteria transgenically altered to feed on oil-spills were patentable under the UPTA.[175] The Court made it clear that Congress did not intend to restrict the scope of subject matter under § 101 to inanimate inventions, finding instead that Congress intended that "anything under the sun that is made by man" can be patented under the UPTA.[176] Thus, the Court's decision in *Chakrabarty* has been interpreted as putting an end to the "products of nature" doctrine as an obstacle to the patenting of living matter.[177] However, the Court's decision did not ostensibly resolve all the issues regarding the patentability of living plants and seed under § 101 of the UPTA.[178]

B. Ex parte Hibberd

The second obstacle to plant and seed patents under the general utility statutes was the "written description" requirement under § 112. While the Court in *Chakrabarty* acknowledged that plants were generally believed to be "not amenable to the 'written description' requirement" of 35 U.S.C. § 112, it did not see this as an obstacle to the patenting of living matter.[179] The Court in *Chakrabarty* reasoned that Congress must have dealt with the concern over the "written description" requirement because it recognized "the work of the plant

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the subjects of patent protection because plants were the products of nature. *Chakrabarty*, 447 U.S. at 312.

171 333 U.S. 127 (1948). In *Funk*, the patentee sought protection for certain nitrogen fixing root-nodule bacteria that could be used as an innoculum for leguminous plants.The Court concluded that no patent should issue because the patentee had merely discovered "only some of the handiwork of nature." *Id.* at 131.

172 283 U.S. 1 (1931).

173 *Chakrabarty*, 447 U.S. at 311.

174 *See generally id.*

175 *Id. at* 305.

176 *Id. at* 309.

177 *See* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. AG Supply, Inc., 49 U.S.P.Q.2d 1813, 1818 (N.D. Iowa 1998); *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443, 444 (B.P.A.I. 1985).

178 *Id. at* 305-17.

179 *Chakrabarty*, 447 U.S. at 312.

breeder 'in aid of nature' was [a] patentable invention" when passing the PPA.[180] However, the Court did not definitively resolve the issue of whether the "written description" requirement of § 112 could be an obstacle to the patenting of sexually reproducing plants under the general utility statutes.[181] Under the PPA the written description requirement is relaxed in contrast to the UPTA, which requires the deposit of an exemplar in an approved facility. Thus, instead of requiring a detailed written description to "enable one skilled in the art to make and use the invention" as required under the general utility statutes, the PPA allows access to a deposited exemplar that can be replicated by asexual reproduction.

Nevertheless, another decision—this time by the BPAI in *Ex parte Hibberd*—seemed to open the door to the Patent and Trademark Office for accepting plant and seed patents under 35 U.S.C.[182] The issue addressed by the BPAI in *Hibberd* was whether Congress intended to restrict the scope of the Utility Patent Act by providing exclusive protection to plants and seeds under the PVPA and tissue cultures under the PPA.[183] In other words, could plants, seeds, and tissue cultures be patented under both the general utility patent statutes and the PVPA and PPA respectively. The subject matter on appeal in *Hibberd* involved technology designed to increase free tryptophan levels in maize seed, plants, and tissue cultures.[184] The PTO examiner rejected claims drawn to seed and plants as inappropriate subject matter under 35 U.S.C. § 101 because the claims comprise subject matter within the purview of the PVPA.[185] Furthermore, the examiner's position with respect to the claims involving tissue cultures was that these claims were within the purview of the PPA and therefore inappropriate subject matter under § 101.[186] Thus, it was the examiner's position that "to the extent that the claimed subject matter can be protected under the PVPA or the PPA, protection under 35 U.S.C. [§] 101 is not available."[187] Based on the standards of statutory construction, the Board of Appeals failed to sustain the examiner's rejection finding instead that the Supreme

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180 *Id.*
181 *See id.* at 311-12.
182 *Ex parte Hibberd*, 227 U.S.P.Q. at 445.
183 *Id.* at 443-44.
184 *Id.*
185 *Id.* at 444-45.
186 *Id.*
187 *Id.*

Court's decision in *Chakrabarty* "plainly contemplated that the patent laws would be given wide scope."[188]

The board also noted that the Supreme Court, relying on the legislative history of the 1952 Act, found that Congress intended the statutory subject matter to "include anything under the sun that is made by man."[189] The board ultimately concluded that the scope of protection available under the UPTA was not altered or restricted by the passage of the plant-specific acts, but rather these acts were enacted as alternative forms of protection available for plants and seed because of the difficulties in meeting the various requirements of 35 U.S.C. § 101.[190]

While the board's decision in *Hibberd* has been generally interpreted as opening the door of the PTO to allow utility patents for transgenically altered and other plants and seeds, the board's decision did not ultimately resolve the question of whether plants and seeds are patentable subject matter under 35 U.S.C.[191] Plants and seeds must still meet the requirements of 35 U.S.C. for utility, novelty, non-obviousness, and the enablement and the written description requirements of § 112. In fact, the board in *Hibberd* ultimately rejected certain claims based upon a failure to disclose under the first paragraph of 35 U.S.C. 112.[192] As mentioned above, § 112 requires disclosure sufficient to "enable [one] skilled in the art . . . to make and use" the invention set forth.[193] While "the written description requirement" may be satisfied by allowing access to a deposited exemplar suitable for replication through asexual reproduction under the PPA, § 112 cannot be satisfied by depositing an exemplar of a sexually reproducing plant or seed because an exact replicate of the deposited exemplar cannot be reproduced sexually. Nevertheless, since the BPAI decision in *Ex parte Hibberd* in 1985, over 1,000 plant utility patents have been issued under 35 U.S.C.[194]

V. THE UTILITY PATENT ACT OF 1952

Congress enacted the PPA to recognize the efforts of plant breeders and to assist agriculture in achieving economic

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188 *Id.*

189 *Id.*

190 *Id.* at 445.

191 Nilles, *supra* note 6, at 363-64.

192 *Ex parte Hibberd*, 227 U.S.P.Q. at 444.

193 35 U.S.C. § 112 (1984 & Supp. 2001).

194 *Pioneer*, 49 U.S.P.Q.2d at 1815.

equality with industry; however, in view of the unique nature of plants, Congress only allowed coverage for asexually reproduced plants.[195] The often-quoted rationale for Congress' failure to include sexually reproduced plants under the PPA was the "belief that new plant varieties could not be reproduced reliably by seed."[196] In *Chakrabarty* the Supreme Court, relying on the Government's brief, attributes Congress' failure to include sexually reproduced plants under the 1930 Act to the failure of new varieties to reproduce "true-to-type through seedlings."[197] The Court goes on to explain that by the passage of the Plant Variety Protection Act in 1970, it was generally recognized that "true-to-type" reproduction and plant patent protection for sexually reproducing plants was appropriate.[198] However, the PVPA provides only *patent-like protection*; which while similar to the protection provided under the general utility statutes, it differs in that it is administered by the PVPO, a division of the USDA, contains exemptions for researchers and farmers, and provides for the deposit of an exemplar with the USDA with relaxed specifications to allow access to the protected variety. The author takes the position, more fully developed below, that it cannot be inferred from the Court's comments in *Chakrabarty* regarding "true-to-type" reproduction that there is no longer an obstacle to the patenting of sexually reproducing plants under the general utility patent statutes.[199]

The key to unraveling the question of whether sexually reproducing plants are patentable under 35 U.S.C. resides in what Congress meant by the statement that "new plant varieties could not be reproduced reliably by seed."[200] Based on the Court's comments in *Chakrabarty* regarding "true-to-type" reproduction, it appears at first glance that Congress' initial reluctance to patenting sexually reproducible plants was based only upon a concern that sexually reproducing plant varieties would not breed "true-to-type."[201] The position taken

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[195] Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1563 (Fed. Cir. 1995).

[196] Oczek, *supra* note 65, at 637.

[197] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[198] *Id.*

[199] *Id.*

[200] Oczek, *supra* note 65, at 637; *see also Chakrabarty*, 447 U.S. at 313.

[201] *Chakrabarty*, 447 U.S. at 313. A plant breeds true-to-type if it maintains the phenotypic characteristics, such as yield, quality of seed production, seed color, pubescence, height, etc., for which it was selected from one generation to the next as in a uniform variety.

in this comment is that Congress has always recognized more than just an inability of sexually reproducing plants to reproduce "true-to-type" as an obstacle to patent protection under the general utility patent statutes. Section 101 of 35 U.S.C. states "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[202] It is the author's contention that Congress, as the Supreme Court held *Chakrabarty*, did not intend to restrict patentable subject matter under § 101, but rather recognized the difficulties in meeting the other requirements of patentability under 35 U.S.C. for sexually reproducing plants. Thus, consistent with *Chakrabarty*, Congress enacted the PVPA as an alternative form of protection rather than altering the requirements of patentability under the UPTA.

A. *Enablement and the Written Description Requirement Under § 112*

The essence of the American patent system is a simple bargain or social contract between the public and the inventor, the possessor of knowledge.[203] As mentioned above, Congress has the power under Article I, section 8, clause 8 "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[204] Simply speaking, the inventor discloses her knowledge of her invention, which advances the arts and the sciences by providing a stepping stone of knowledge, in exchange for the right to exclude others from employing the invention for a limited period of time.[205] Since the beginning, the American system of patent law has embodied a balance between the property interest of the inventor as a carrot to produce, the need to promote the progress of science, and the recognition that progress comes from imitation, and the refinement of imitation that is essential to a competitive economy.[206] Speaking of the American system, Thomas Jefferson recognized the difficulties in "drawing a line between the things which are worth to the public the

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202 35 U.S.C. § 101 (1984 & Supp. 2001).

203 MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 1 (1998).

204 U.S. CONST. art. I, § 8, cl. 8.

205 ADELMAN, *supra* note 203, at 1.

206 *Id. at* 4.

embarrassment of an exclusive patent, and those which are not."[207]

The enablement and disclosure requirements of the general patent statutes—as do the requirements of novelty, utility, and nonobviousness—reflect these values and the balance that has been struck in the American patent system to foster a free market.[208] Section 112 demands as follows:

> The specifications 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.[209]

The applicant seeking exclusive protection under the utility patent system whose "invention satisfies the requirements of novelty, nonobviousness, and utility, and who is willing to reveal to the public the substance of his discovery and 'the best mode . . . of carrying out his invention,' 35 U.S.C. [§] 112, is granted 'the right to exclude others from making, using, or selling the invention throughout the United States,' for a period of [20] years."[210] In the alternative, the inventor may keep her invention secret and reap the benefits of her labors indefinitely. In consideration of disclosure thru the Patent System thus offers the inventor the carrot of exclusiveness through patent.[211] It is against this backdrop that the requirements of enablement and written description under § 112 of the general utility patent statutes should be weighed when determining whether sexually reproducing plants and animals are patentable under 35 U.S.C. The requirements of utility, novelty, and nonobviousness will be discussed first in order to more fully develop all of the arguments against allowing utility patents for sexually reproducing plants in light of the enablement requirements of § 112.

B. Utility

From reading § 101, it is clear that an invention must be "useful" in order to receive patent protection.[212] The question of "how useful" an invention has to be in order to be patentable

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[207] *Id. at* 5.
[208] *Id. at* 4.
[209] 35 U.S.C. § 112 (1984 & Supp. 2001).
[210] ADELMAN, *supra* note 203, at 7.
[211] *Id.*
[212] *Id. at* 181.

has been well-defined in the case law and presents little or no trouble to the average patentee.[213] In 1817, the Massachusetts circuit court in *Lowell v. Lewis*[214] set out the black letter law that "all that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society."[215] In other words, the PTO is looking not for something that is better, but rather for something that is different from the state of the art. Outside of the chemical-patent field, the "utility" requirement has presented little or no obstacle to patenting[216] and has only rarely, if ever, been raised as an obstacle to the patenting of breeders' and biotechnicians' efforts in the plant arena.[217] Given that "utility" is a threshold requirement and that plants and seed are by their nature useful (whether grown for food or for ornamental purposes), there should be few problems to patenting sexually reproducing plants based on "utility."

C. *Novelty*

Under § 102 of the utility patent statute, a person is entitled to a patent unless "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."[218] Reading § 102 (a) of the statute makes it clear that patents are barred when the invention is not new or "novel."[219] While 102 (a) is written as a statutory bar, the real emphasis is on bestowing protection to the "true inventor" of something new, and of all the general requirements this subsection represents; the core value of our patent system.[220] To be eligible to receive patent protection, a person must be the first to invent something new under the United States patent system.[221] Although simple in concept, the relationship of a claimed invention to the existing art in the public domain is among the most difficult and misunderstood aspects of the substantive U.S. patent law.[222] In order for a

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213 *Id.*

214 15 F.Cas. 1018 (C.C.D. Mass. 1817).

215 ADELMAN, *supra* note 203, at 7.

216 *Id. at* 190.

217 Geertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 J.L. & TECH. 143, 149 (1999).

218 35 U.S.C. § 102 (1984 & Supp. 2001).

219 ADELMAN, *supra* note 203, at 203.

220 *Id.*

221 *Id.*

222 *Id.*

"reference" or "prior art" to invalidate a claimed "each and every element of the claimed invention must be disclosed in the prior art reference" in such a way that would enable others to practice the invention.[223] In other words, if someone of "ordinary skill in the art" would be able to discern the claimed invention from the prior art reference, then the patent is said to be invalid due to "anticipation," because it is not new or novel.[224]

While the extent of litigation under § 102 (a) in the case law is considerable, the requirement of novelty presents the same obstacle to patenting in the case of plants and seed produced by sexually reproduction as it would for inventors in any field.[225] To wit, the question to be answered under 102 (a) is the same for plant breeders and bioengineers as for inventors in any other field: who was the first to invent something new? It is not surprising then that commentators have raised few objections to the patenting of plants based on 102 (a) in this country.[226] Furthermore, with the demise of the "products of nature" doctrine, there are no remaining fundamental conflicts between breeders' and bioengineers' plant products and the patentability requirement of absolute novelty.[227]

D. Obviousness/Non-inventiveness

Under § 103 (a), "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in § 102 of this title, 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 said subject matter pertains."[228] Thus, like novelty under § 102, obviousness under § 103 is a statutory bar to patent protection.[229] The statutory bar for obviousness was probably best described by the court in the early case of *Gadd & Mason v. The Mayor of Manchester*.[230] The court in *Gadd* explained that:

> [i]f, practically speaking, there are no difficulties to be

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223 *Id. at* 205.
224 *Id.*
225 Overwalle, *supra* note 217, at 152.
226 *Id.*
227 *Id.*
228 35 U.S.C. § 103(a) (Supp. 2001).
229 ADELMAN, *supra* note 203, at 408.
230 Quoted in ADELMAN, *supra* note 203, at 407-08

> overcome in adapting an old contrivance to a new purpose, there can be no ingenuity in overcoming them, [and] there will be no invention.... [Furthermore,] [t]he same rule... appl[ies] to cases in which the mode of overcoming the so-called difficulties is so obvious to every one of ordinary intelligence and acquaintance with the subject matter of the patent, as to present no difficulty to any such person. Such cases present no real difficulty to people conversant with the matter in hand, and admit of no sufficient ingenuity to support a patent.[231]

Thus, the statutory bar under § 103 is in principle an expression of the "congressional determination that trivial advances should not be rewarded with patent protection."[232]

Unlike the requirements of utility and novelty, the requirement of nonobviousness under § 103[233] could present a real obstacle to the patenting of breeders' and bioengineers' plant products.[234] "Various objections based on § 103 have been put forth in this and other countries that traditional methods [of plant breeding] were not beyond the grasp of the ordinary artisan" because such breeding did not involve an inventive step.[235] Under the American system, which recognizes the "sweat of the brow"[236] doctrine, the lack of an inventive step has never really been an obstacle since plant breeding is quite laborious even if a "flash-of-genius" is not present.[237] Section 103 (c) indicates that "[p]atentability shall not be negatived by the manner in which the invention was made."[238] In other words, inventions inspired by a "flash of genius" are on the same footing with "those created through the plodding path of exhaustive research and development."[239]

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[231] *Id.*

[232] ADELMAN, *supra* note 203, at 408.

[235] Under section 103(a) "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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 said subject matter pertains." PAUL GOLDSTEIN, et. al., SELECTED STATUTES AND INTERNATIONAL AGREEMENTS ON UNFAIR COMPETITION TRADEMARK, COPYRIGHT AND PATENT (10th ed. 2000).

[234] Overwalle, *supra* note 217, at 152.

[235] *Id.*

[236] The "sweat-of-the-brow" doctrine encompasses the concept that an invention is patentable if it would take painstaking efforts or extensive experimentation above and beyond the existing art to achieve the inventive results. ADELMAN, *supra* note 203, at 447.

[237] *Id.*

[238] 35 U.S.C. § 103(c) (Supp. 2001).

[239] ADELMAN, *supra* note 203, at 447.

Under the U.S. system, the most often levied objection is that traditional plant breeding techniques are obvious to an ordinary artisan skilled in the art of plant breeding.[240] However, this argument should fail under the "sweat-of-the-brow" doctrine as well, considering that traditional breeding techniques can involve a multitude of steps of selecting desired characteristics or traits and breeding repeatedly to develop stable varieties that reproduce "true-to-type."[241] While the process or technique of traditional plant breeding is well known and unpatentable based on § § 102 and 103, plant varieties developed by these methods should not face a bar to patenting under § 103 for obviousness. In fact, Congress recognized the human inventive step in plant breeding as deserving of patent protection when enacting the PPA in 1930.[242] The elements of novelty, utility, and nonobviousness under the utility statute are comparable to the elements of "invents" or "discovers," distinct and new, under the PPA.[243] Therefore, the question of whether the nonobviousness requirement is an obstacle to the patenting of plants, those either sexually or asexually reproduced, is considered settled under the American system.

While nonobviousness is not a problem for traditionally bred plants, the question becomes more complicated when discussing the patenting of a bioengineering process and the resulting genetically altered plant product under § 103.[244] "The search for a coherent nonobviousness doctrine in biotechnology has . . . proven elusive, as demonstrated by the enactment of § 103 (b)."[245] Under 103 (b):

> [A] biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) [of the statute] . . . shall be considered nonobvious if —- (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person . . . [A biotechnological process is defined under the act as] a process of genetically altering or otherwise inducing a single- or multi-celled organism to —- (i) express an

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240 Overwalle, *supra* note 217, at 152.

241 *See supra* note 236 for the definition of the "sweat of the brow" doctrine.

242 Scalise, *supra* note 23, at 92.

243 *Id.*

244 ADELMAN, *supra* note 203, at 494.

245 *Id.*

> exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism. [246]

In other words, an invention meets the requirement of nonobviousness under 103 (b) in the biotechnology realm only if the claimed process and the claimed composition of matter are patented together. Presently, the courts have not legally interpreted § 103 (b) as it pertains to transgenically altered sexually reproducing plants, and it is difficult to discern what interpretation the courts will give this statute in this context. Generally, § 103 (b) has been applied to microbiological processes such as the patenting of genes and their resulting protein products rather than macrobiological processes such as the genetic alteration of plants.[247] In any case, Congress has expressed a clear intent that the nonobviousness requirement will not defeat biotechnological processes even if nonobviousness is defined in a more restrictive manner in terms of transgenic organisms. [248] Therefore, the requirement of nonobviousness under § 103 does not appear to be a bar to the patenting of sexually reproduced organisms under the utility patent statutes.

VI. PRECEDENT DERIVED FROM *CHAKRABARTY*, *EX PARTE HIBBERD*, AND *EX PARTE C*

Following the BPAI decision in *Hibberd*, the issue of whether plants and seeds were patentable under 35 U.S.C. was not addressed by a court until the district court's decision and the Federal Circuit's affirmance in *Pioneer v. J.E.M.*[249] In this case, which has been appealed to the Supreme Court, Pioneer puts forth the argument that its patents are valid under the general utility patent laws because over one thousand plant utility patents have been issued by the PTO in response to the BPAI decision in *Ex parte Hibberd* in 1985.[250] Pioneer contends that after the BPAI decision in *Hibberd* there were no further obstacles to patenting sexually reproducing plants under 35 U.S.C. because science and technology had advanced to the point of allowing "plant inventors to satisfy the legal

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[246] 35 U.S.C. § 103(b) (Supp. 2001).

[247] ADELMAN, *supra* note 205, at 508.

[248] *Id.* at 494-508.

[249] Pioneer Hi-Bred Int'l, Inc. v. J.E.M. AG Supply, Inc., 200 F.3d 1374 (Fed. Cir. 2000).

[250] Nilles, *supra* note 6, at 363 (citing Pioneer Hi-Bred Int'l, Inc. v. J.E.M. AG Supply, Inc., 49 U.S.P.Q.2d (BNA) 1813, 1815 (N.D. Iowa 1998))

requirement for statutory subject matter."[251] However, as noted previously, historically there were two obstacles to extending utility patent protection to sexually reproducing plants and seed: the "products of nature" doctrine and the "written description requirement."[252] Pioneer maintains that *Ex parte Hibberd* stands for the proposition that plants are patentable under the general patent laws and the plant specific acts as well "because Congress has not clearly and expressly excluded sexually reproduced plants from § 101."[253] The crux of Pioneer's argument is that the principles of construction demand that repeal by implication is not favored and therefore sexually reproducing plants are patentable under the PPA, PVPA, and the UPTA. Nevertheless, Pioneer does not address the remaining obstacle of enablement under § 112.[254]

Defendant J.E.M. argues that sexually reproducing plants are not patentable under the UPTA but instead are exclusively covered by the PVPA.[255] J.E.M. relies on a congressional report issued prior to enactment of the PVPA, stating that no protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds.[256] Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans."[257] J.E.M.'s argument has merit but fails to explain why Congress believed that new varieties of sexually reproducing plants were not eligible for protection under the utility patent act.

Both the Supreme Court's decision in *Chakrabarty* and the BPAI's decision in *Ex parte Hibberd* addressed the issue of whether Congress intended to restrict the subject matter of § 101 of the UPTA by passing the PPA and the PVPA.[258] The answer given by the Court in *Chakrabarty* and the board in *Hibberd* was that based on the canons of statutory construction and the congressional record, Congress did not intend to restrict the subject matter of § 101 by passing the PPA and the PVPA. In the aftermath of *Chakrabarty* and *Hibberd*, it can be

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251 *Id.*

252 Nilles, *supra* note 6, at 363.

253 *Id.* (quoting *Pioneer*, 49 U.S.P.Q.2d. (BNA) at 1815).

254 *Id. at* 363-64.

255 *Id.* at 364 (quoting Pioneer Hi-Bred Int'l, Inc., v. J.E.M. AG Supply, Inc., 33 F. Supp. 2d 794, 795 (N.D. Iowa 1999)).

256 *Id.*

257 *Id.* (quoting *Pioneer*, 49 U.S.P.Q.2d (BNA) at 1818, in turn quoting S. REP. NO. 91-1246 (1970)).

258 *See* Nilles, *supra* note 6; *see also Chakrabarty*, 447 U.S. 303.

safely assumed that there is no longer an obstacle to patenting plants under 35 U.S.C. based on the "products of nature" doctrine. But what remains of the "written description requirement" as an obstacle to the patenting of plants under the utility statutes after *Chakrabarty* and *Hibberd*? If Congress did not intend to restrict the subject matter under § 101 by implication, then *a fortiori* Congress did not intend by implication to relax the legal requirements of 35 U.S.C.

In *Hibberd* the board ultimately rejected the patentee's claims on the ground that the written description requirement under paragraph one of § 112 was not sufficient to enable someone skilled in the art to make and use the invention.[259] The board stated that:

> Claims . . . are rejected as unpatentable under the first paragraph of 35 U.S.C. 112. The subject matter covered by these claims is described in terms of an assigned accession number for seeds deposited with In Vitro International, Inc. The disclosure is inadequate to enable one skilled in the art to make and use the invention set forth in [the] claims. Assuming that seeds may be deposited in the same manner as micro-organisms to comply with 35 U.S.C. 112, there is insufficient evidence in the record as to the availability of the deposited seeds. The depository here, In Vitro International, Inc., is not a recognized public depository, as was the case in *In re Argoudelis*, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970). Nor is there evidence here indicating that In Vitro International, Inc., is under a contractual obligation to maintain the seeds deposited in a permanent collection and to supply samples to anyone seeking them once the patent issues.[260]

Thus, the board in *Hibberd* assumes that even if seed can be deposited in the same manner as micro-organisms in a national public depository, the depository must be under an obligation to maintain the seed in a permanent collection and to supply samples to anyone seeking them once the patent issues.[261]

In *Ex parte C*, the PTO confirmed the patentability of plants and seeds under 35 U.S.C. § 101.[262] The issue in *Ex parte C* was whether the specification requirement under § 101 could be relaxed for an applicant who was seeking a utility patent for "a novel variety of soybean plant, seeds produced therefrom, and a method of producing the seeds by self-pollinating the soybean plant."[263] The specification submitted to the patent

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259 *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443, 450 (B.P.A.I. 1985).

260 *Id.*

261 *Id.*

262 *Ex parte* C, 27 U.S.P.Q.2d 1492, 1493 (B.P.A.I. 1992).

263 *Id.*

examiner generally conformed to the requirements for specification under the PVPA providing only the information that is submitted to the Department of Agriculture for a certificate.[264] The specification failed to explain "the nature and gist of the invention or the inventive concept," nor did it contain any specific language that distinguished the "claimed soybean variety from other soybean varieties."[265] The examiner objected to the application because the specification failed "to provide (a) a full written description, and (b) enablement and best mode of practicing the claimed invention," and rejected the claims under the first paragraph of 35 U.S.C. § 112.[266]

The BPAI, relaxing the requirements of enablement, found that the applicant's offer to deposit seed of the soybean variety in the American Type Culture Collection (ATCC) was sufficient for enablement.[267] In reaching its decision, the board compared the *Ex parte C* case to that of *In re Argoudelis*[268] where the PTO accepted the deposit of a microorganism in the ATCC as an alternative procedure for meeting the requirements of 35 U.S.C. § 112.[269] Consequently, the board saw "little difference between the concept of screening a microorganism to develop a desired strain . . . and the concept of screening plants to develop a desired variety."[270] The board also rejected the examiner's argument "that certain language used by [applicant] to describe the plant variety [was] considered as inherently so indefinite that one skilled in the art [would be] unable to identify the plant variety and distinguish it from other[s]."[271]

In reaching its decision to relax the written description requirement and the enablement requirement of § 112, the board in *Ex parte C* mistakenly assumed that microorganisms and plants can be screened and developed in the same manner.[272] In making this assumption, the board failed to

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264 *Id.*

265 *Id.* 37 C.F.R. 1.71(b) (2001) sets out the requirements as stated: "The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth."

266 *Ex parte C*, 27 U.S.P.Q.2d at 1494.

267 *Id. at* 1495.

268 434 F.2d 1390 (C.C.P.A. 1970).

269 *Ex parte C*, 27 U.S.P.Q.2d (BNA) at 1495.

270 *Id. at* 1496.

271 *Id.*

272 *Id.*

consider the difference between sexual reproduction in eukaryotic[273] plants and asexual reproduction in procaryotic[274] bacteria, and the inherent indefiniteness of sexually reproducing organisms.

VII. ARGUMENTS AGAINST ALLOWING UTILITY PATENTS FOR SEXUALLY REPRODUCING PLANT VARIETIES

A. *Understanding the Genetics of Asexual Reproduction*

At the beginning of the twentieth century "genetics embodied . . . the idea that an actual hereditary material existed, that it was of a particulate nature, and that its behavior in transmission from one generation to another could be predicted."[275] Today, genetics and biotechnology embrace the idea that organisms can be transgenically altered at the chromosomal level by inserting a desired gene into the target organism's DNA to create a new organism that exhibits characteristics of other species.[276] At the core of all living organisms is the need to reproduce in order to survive either through a process of asexual or sexual means. [277] Once a transgenically created organism is produced, it may or may not continue to exhibit a particular characteristic depending upon whether or not it reproduces through sexual or asexual means.

The organism in question in *In re Argoudelis* was a bacteria; bacteria reproduce through the process of mitosis, which "produces an even cellular division of essential hereditary components."[278] Through mitosis and cell division (fission), two genetically identical cells are reproduced and genetic

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[273] Eucaryotes ("true nucleus") are the more complex form of cell found in the majority of living species, the cells of multicellular organisms that have a nuclear membrane that separates the genetic material from the cytoplasm. MONROE W. STRICKBERGER, GENETICS 10 (2d ed. 1976).

[274] Procaryotes ("before the nucleus") including bacteria and blue-green algae are characterized by nuclear material that is not separated from the cytoplasm by a discrete membrane. *Id.* Bacteria reproduce through the process of mitosis, which "produces an even cellular division of essential hereditary components." *Id.* at 13. In bacteria, the chromosome and its newly mitotic-formed replica are attached at opposite ends of the bacterial cell membrane. As the cell elongates during cell division, one portion of the cell carries one chromosome and the other end carries its replica. To complete cell division when sufficient separation has occurred between the two chromosomes, the membrane between them invaginates and cleaves producing two cells each with exactly the same hereditary material. *Id.*

[275] *Id.* at 8.

[276] Goss, *supra* note 23, at 1400.

[277] STRICKBERGER, *supra* note 273, at 12-13.

[278] *Id.* at 13.

change occurs only through mutation.[279] Consequently, by depositing a single exemplar of a particular desired strain in the ATCC, anyone skilled in the art may obtain a sample of the culture and replicate it exactly; thus the invention is enabled within the meaning of § 112. However, when a transgenically altered organism reproduces through sexual reproduction, the new transgenically created characteristic may or may not be found in subsequent generations.

B. *Indefiniteness: A Truism for Sexually Reproduced Organisms*

Sexual reproduction in higher plants and organisms is much more complicated than asexual reproduction in bacteria.[280] While a thorough explanation of the process of sexual reproduction is beyond the scope of this comment, a simple explanation of sexual reproduction will show the difficulties in meeting the requirements under 35 U.S.C. § 112. Sexual reproduction is characterized by the fertilization between male and female gametes (i.e. pollen and ova in corn) to form an embryonic cell called the zygote.[281] Each sex cell

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[279] *See id.* at 13. Asexual division of "a single bacterium gives rise to a *clone* of descendants all genetically related to each other through their common ancestor." *Id.* at 33. However, when accidental changes in the genetic constitution (mutation) occurs and that clone "will, of course, differ to that extent from other clones." *Id.* A means of obtaining genetic variation in bacteria has also been recognized in certain clones (auxotrophs and prototrophs) of *Escherichia coli* through a process of swapping genetic material through a physical bridge between two clone types. *Id. at* 34.

[280] In corn, sexual reproduction occurs through a process that has a series of complex stages with the production of haploid spores that multiply mitotically to yield gametophytes (haploid male and female stages) which, in turn, form the gametes. The male gametophyte or pollen grain (haploid microspore) is located in the tassels (stamens) on the top of the plant. The female gametophyte (haploid macrospore) is located in the ears of the plant, the pistil. The haploid pollen nucleus mitotically divides forming a tube nucleus and a generative nucleus, the latter of which subsequently divides once more to form the two male gametic nuclei. In the development of the female gametophyte, only one of the four haploid macrospore nuclei becomes the functional occupant of the embryo sac (the female gametophyte). The nucleus of this cell then divides mitotically forming two daughter nuclei that divide mitotically twice more to form eight haploid nuclei, four at each in of the embryonic sac. A single nucleus from each end group combines at the center to form the diploid endosperm. The three nuclei closest to the point of entry of the pollen tube differentiate into the synergids and a single female gametic nucleus. Upon fertilization the pollen grain makes contact with the silk of the pistil and germinates into a long pollen tube carrying the male sperm to the embryonic sac. One of the male gametes combines with the female gametic nucleus to form the zygote (one haploid nuclei and one female nuclei), while the other male gamete combines with the diploid endosperm nucleus to form the tissue that nourishes the embryo. *Id.* at 41-44.

[281] *Id.* at 15.

produced through meiosis[282] is haploid in nature containing only one half of the chromosomal number of the parent.[283] Upon fertilization the haploid gametes combine to produce the diploid state (full chromosomal number) of the zygote that in turn gives rise to the new plant, each parent contributing one of a homologous pair of chromosomes to an offspring.[284] Thus, the essence of sexual reproduction is the recombination of genetic material between parental lines in each successive generation, with each parental unit contributing fifty percent of the genetic material to the offspring.

Currently, biotechnology has not yet reached and may not ever reach the stage where scientists can predict the actual genetic makeup of any given offspring resulting from any given sexual union.[285] Thus, even if an applicant for a utility patent could describe the entire mapped plant genome of a deposited exemplar, upon successive cycles of sexual reproduction, the progeny would differ at the genetic level from the deposited exemplar. *In re Argoudelis* may be distinguished from *Ex parte C* based on the difference between the type of reproduction, either asexual or sexual, exhibited by the deposited exemplar.[286] In the case of sexually reproducing plants, a single seed cannot enable someone skilled in the art to reproduce the exact organism deposited beyond a single generation. Furthermore, based on the specification provided in *Ex parte C*, which merely identify the parental lines that were crossed in order to produce the claimed new seed variety, not

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[282] "Meiosis is simply the process by which the chromosomes are separated during the formation of sex cells and their numbers reduced from the diploid to the haploid condition." *Id.* at 16.

[283] *Id. at* 16-17.

[284] Sexual reproduction or fertilization occurs as follows:

> Fertilization then marks the event in which two haploid nuclei join to reform a diploid cell. . . . In diploid cells prior to meiosis each individual chromosome (e.g. A) usually has a pairing mate, or homologue (e.g. A'), so that a parental karyotype of four chromosomes (diploid number) would consist of two homologous pairs, eg., AA' and BB'. Meiosis in such an organism would then produce haploid gametes each one containing two individual chromosomes, one from each pair (A or A', together with B or B', e.g., AB, A'B, AB', or A'B'). Upon fertilization by another gamete, a diploid zygote is formed with two homologous chromosome pairs which, in many higher organisms, now divides mitotically to produce a diploid adult. . . . Meiosis ensures the presence of one A (or A') and one B (or B') chromosome . . . of each homologous pair into separate gametes.

Id. at 17.

[285] *Id. at* 17-33.

[286] *See Ex parte* C, 27 U.S.P.Q.2d 1492 (B.P.A.I. 1992); *In re* Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970).

even the inventor could specifically identify the genetic makeup of the exemplar.[287]

In *In re Merat,* the Court of Customs and Patent Appeals affirmed a final rejection of claims relating to a "Method of Improving Strains of Chickens" on the basis of definiteness under the second paragraph of § 112.[288] "Claims [one through four] [were] rejected under 35 U.S.C. 112, second paragraph, as not distinctly claiming that which the [applicant] regard[ed] as their invention."[289] The court defined the inquiry under the second paragraph of 112 as determining "whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity."[290] "It is here where the definiteness of the language employed must be analyzed. . . ."[291] In *In re Merat,* the specification explained the breeding of dwarf hens (double recessive for dwarfism) with normal cocks (either double dominant normal or dominant normal with a recessive gene for dwarfism) to produce normal sized cooking chickens as an improved method of breeding chickens for meat production.[292] The court, however, recognized that through sexual reproduction a cross between a phenotypically normal cock (Nr Nr or Nr nr) and a dwarf hen (nr nr) results in different phenotypic males (either 100% Nr nr males or 50% Nr nr and 50% Nr Nr males) .[293] The court therefore, rejected the claims because the language was not "precise enough to indicate which kind of cock to use to produce the result required by the claims, [causing it to] fail to comply with [§] 112, second paragraph."[294] The court recognized that the possible spectrum of possible products could not be reconciled with the claim language, and the claims were therefore indefinite.

C. *Distinguishing Chakrabarty from Ex parte Hibberd and Ex parte C*

Recalling that *Chakrabarty* dealt with the question of whether a patent should issue under 35 U.S.C. § 101 for a genetically engineered bacterium, *Ex parte Hibberd* and *Ex parte*

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287 *See In re Argoudelis,* 434 F.2d at 1392..

288 *In re* Merat, 519 F.2d 1390, 1391 (C.C.P.A.1975).

289 *Id.* at 1393.

290 *Id.* at 1394 (quoting *In re* Moore, 439 F. 2d 1232, 1235 (1971)).

291 *Id.*

292 *Id.* at 1394-95.

293 *Id.* at 1395-96.

294 *Id.* at 1396.

C may be distinguished on the basis of the type of reproduction exhibited by the organism the applicant was seeking to patent.[295] *Chakrabarty* stands for the proposition that microorganisms as "living things" are "products-of-nature," and therefore are within the subject matter of 35 U.S.C. § 101.[296] However, the Court in *Chakrabarty* never reached the question of whether or not sexually reproducing organisms can meet the enablement and written description requirements of § 112.[297] The Court in *Chakrabarty* emphasized that Congress has two options: it may amend § 101 to exclude certain subject matter[298] or it "may choose to craft a statute specifically designed for such" subject matter.[299] Congress chose the latter option when enacting the PVPA in 1970 to cover sexually reproducing plants.[300] According to the Senate Report accompanying the passage of the PVPA, the reason for the statute was that "[n]o protection [was] available to those varieties of plants which reproduce sexually, that is, generally by seeds."[301] Furthermore, it is significant that Congress did not enact the PVPA for sexually reproducing plants under the general utility patent statutes as it did with the PPA for asexually reproduced plants in 1930.[302] The clear and logical distinction between the PPA and the PVPA is the mode of reproduction, either asexual or sexual. Therefore, Congress recognized the efforts of plant breeders in the production of new varieties of sexually reproducing plants as patentable subject matter under § 101, but at the same time recognized that these new varieties were not amenable to the strict enablement and written description requirements of 35 U.S.C. § 112.

D. Enablement

Enablement is more than a technical requirement; it represents the inventor's side of the bargain in the social contract.[303] The inventor must disclose his invention in such a manner that those skilled in the art will be able to reproduce

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295 Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980)

296 *Id.* at 318.

297 *See id.*.

298 *See* 42 U.S.C. § 2181(a) (1994) (excluding from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon."); *Chakrabarty*, 447 U.S. at 318.

299 *See Chakrabarty*, 447 U.S. at 318.

300 *See* 7 U.S.C. §§ 2321-2582 (1999).

301 S. REP. NO. 91-1246 at 3 (1970).

302 *See* 35 U.S.C. §§ 161-64 (1984 & Supp. 2001); 7 U.S.C. §§ 2321-2582 (1999).

303 *See* ADELMAN, *supra* note 203, at 1-7; 35 U.S.C. § 112 (1984 & Supp. 2001).

the protected invention in exchange for the exclusive monopoly rights of the inventor.[304] Thus, without sufficient enablement the social bargain fails, and the inventor gets a windfall in monopoly profits.

The PVPA contains a liberal written description requirement much like that of the PPA requiring that the applicant specify that the claim is "as complete as is reasonably possible," yet Congress did not enact the PVPA under the utility statutes as it did with the PPA.[305] The Plant Variety Office of the Department of Agriculture administers the PVPA, while the PTO administers the PPA.[306] One possible explanation for the difference is that Congress recognized that placing an exemplar in any public use depository like the ATCC could enable asexually reproduced organisms because they replicate exactly. Due to the capricious nature of sexually-breeding uniform plant varieties, however, Congress may have specifically selected the Department of Agriculture for its expertise in dealing with crop plants as the public depository for sexually reproducing plants. The PVPA's research exemption enables those skilled in the art of plant breeding to have access to the protected varieties for research purposes so that they may develop new varieties, recalling that developing is differentiated from producing a new variety.

E. *Agricultural Crops are Different than Bacteria*

Another obvious argument can be made to distinguish the bacteria in *Chakrabarty* and *In re Argoudelis* from the sexually reproducing crop plants of *Ex parte Hibberd, Ex parte C,* and Pioneer's patents in *J.E.M.* Crop plants grown for grain, forage, and fiber like corn, soybean, and cotton are mass-produced in open fields and not under controlled laboratory conditions like bacteria. These openly-grown crops will always be susceptible to pollination by plants grown in nearby fields. Therefore, the genetic pool will always be susceptible to becoming mixed in any given circumstance. Accidental crossover of genetic material between patent-protected and non-protected plants could easily occur; thus, difficulties exist in proving actual infringement if only a single gene distinguishes one variety from another. Moreover, without the proper written description and enablement requirements that generally flesh-

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304 *Id.*

305 Scalise, *supra* note 23, at 93.

306 Imazio Nursery, Inc. v. Dainia Greenhouses, 69 F.3d 1560, 1567 (Fed. Cir. 1995).

out claims under the utility patent statutes, the "doctrine of equivalents" would broaden the scope of the patent protection to unreasonable bounds.[307] Under the PVPA, Congress has specifically defined the metes and bounds of protection offered to certificate holders establishing infringement against someone only under certain circumstances.[308] Therefore, it can be argued that Congress has expressed its preference for the type of protection and coverage it intends to extend to sexually reproducing plants by enacting the PVPA. The board in *Ex parte* C erred in relaxing the requirements of § 112 to the PVPA level, while simultaneously providing the same amount of

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[307] *See Ex parte C*, 27 U.S.P.Q.2d at 1492. (General specification offered with patent application). Given that these plants will be grown openly and genetic mixing is likely to occur, the "doctrine of equivalents" could over extend the coverage to all types of soybeans.In the alternative the patent could provide no coverage if infringement cannot be proved because the patent is invalid as indefinite and overly broad. 35 U.S.C. § 112 (1984 & Supp. 2001).

[308] (a) Acts constituting infringement

Except as otherwise provided in this subchapter 7 U.S.C. 2531-2582, it shall be an infringement of the rights of the owner of a protected variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a protected plant variety with the notice under section 2567 of this title:

(1) sell or market the protected variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;

(2) import the variety into, or export it from, the United States;

(3) sexually multiply, or propagate by a tuber or a part of a tuber, the variety as a step in marketing (for growing purposes) the variety;

(4) use the variety in producing (as distinguished from developing) a hybrid or different variety therefrom;

(5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to progate the variety;

(6) dispense the variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received;

(7) condition the variety for the purpose of propagation, except to the extent that the conditioning is related to the activities permitted under Section 2543 of this title;

(8) stock the variety for any of the purposes referred to in paragraphs (1) through 7);

perform any of the foregoing acts even in instances in which the variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or instigate or actively induce performance of any of the foregoing acts.

7 U.S.C. 2541 (1994).

patent protection as any other utility patent.[309]

VIII. PLANT PROTECTION UNDER THE PLANT VARIETY PROTECTION ACT: EXCLUSIVE MODE OF INTELLECTUAL PROPERTY PROTECTION FOR SEXUALLY REPRODUCING PLANT VARIETIES

As discussed above, the research exemption to the PVPA reflects the balance in the social contract between the plant breeder or biotechnologist and the public by providing the best mode of enablement for sexually reproducing plant varieties.[310] The PVPA, however, contains two exemptions: the farmers' or crop exemption and the research exemption.[311] The crop exemption has been the most contentious and is the primary reason that the seed and biotechnology industries have sought utility patent protection.[312] In *Asgrow Seed Co. v. Winterboer* [313] the Supreme Court defined and narrowed the limits of the crop exemption.[314] The crop exemption under the PVPA allows a farmer who produces for grain or forage to save and replant a portion of a protected variety from each year's crop to replant the next year's crop.[315] The issue in *Asgrow* was whether the crop exemption allowed a farmer to sell more seed than was needed to replant his subsequent crop under the exemption to other farmers for reproductive purposes, a practice known as brown-bagging.[316] "The [Winterboers] raised two of Asgrow's PVPA-protected soybean varieties," and sold forty-nine percent of each year's crop as their "versions" of these varieties in brown bags.[317] The Supreme Court held that "a farmer who meets the requirements set forth in the provision to [7 U.S.C. §] 2543 may sell for reproductive purposes only such seed as he has saved for the purposes of replanting his own acreage."[318] The Court also determined that an exempted farmer was someone who primarily farmed crops for reasons other than reproductive purposes, and farming constituted "the preponderance of the farmer's business, not just the

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309 *See Ex parte C*, 27 U.S.P.Q.2d at 1492.
310 *See* Goss, *supra* note 23, at 1409-10.
311 *See supra* Part III, sections C(1) and C(2).
312 Goss, *supra* note 23, at 1410-11.
313 513 U.S. 179 (1995).
314 *Id.* at 192.
315 Blair, *supra* note 23, at 313.
316 *Id.*
317 Goss, *supra* note 23, at 1412.
318 Blair, *supra* note 23, at 313 (citing Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 192 (1995)).

preponderance of his business in the protected seed."[319]

In 1994 Congress removed the sale provision from the crop exemption altogether, thus limiting a farmer's right to save seed for replanting purposes only and limiting sales to seed sold "for other than reproductive purposes."[320] While limitations on the farmers' exemption have basically closed the gap in protection under the PVPA, the seed and biotechnology industries have still sought protection under the UPTA because of the prevailing view that patent protection affords industry a better opportunity to recoup total research and development costs.[321] Protection under the UPTA, however, may not afford the patent holder any greater protection than a certificate holder enjoys under the PVPA, and arguably even less protection may be afforded to patent holders because of the "first sale" doctrine.[322] Early on, the courts recognized the need for a mechanism to balance the competing interests of society to achieve optimal levels of creativity with minimal interference with usage. The "first sale" doctrine has been long recognized as a judicial limitation on a patentee's absolute right to control his patented invention.[323] The "first sale" doctrine stands for the proposition that once a person purchases a patented machine from the patentee or his assignee, the purchaser is free to use the machine irrespective of the rights of the patentee or assignee.[324] "The right to manufacture, the right to sell, and the right to use are each substantive rights" that may be granted separately or not conferred at all, but once granted by receiving consideration for its use the patentee parts with the right to restrict that use.[325] Of course, seeds as patented inventions present a unique situation because seed are self-replicating and are intended to be developed and sold for exactly this purpose. No court presently has dealt with the applicability of the "first sale" doctrine to seed and plant patents under the utility patent act, but due to the unique nature of the subject matter it does not seem likely that the courts will apply the doctrine. The application of the "first sale" doctrine to utility patents for seed and sexually reproducing plants is another example of the overall inapplicability of the

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319 *Id.*

320 Goss, *supra* note 23, at 1413.

321 *Id.* at 1414.

322 Adams v. Burke, 84 U.S. (17 Wall.) 455-56 (1873).

323 *Id.* at 455-56.

324 *Id.*

325 *Id. at* 456.

utility patent act to sexually reproducing and self-replicating organisms. Rather than stretching the utility statutes and common law to fit unique and special circumstance, the better approach would be to enact special legislation specially designed to cover the unique subject matter, which is exactly what Congress did by enacting the PVPA.

VIII. CONCLUSION

In *Chakrabarty*, the Court emphasized that Congress has the power to amend § 101 to exclude from patent protection certain subject matter, or Congress may choose to craft a statute specifically designed for certain subject matter such as living things. Congress has done exactly that by enacting the PVPA for sexually reproducing plants. In doing so, Congress has expressed its preference for the type and scope of protection it wishes to afford sexually reproducing plants, either those produced through traditional breeding programs or biogenetically engineered plants. By enacting the PVPA under a separate statute to be administered by the USDA, Congress has weighed the various policy considerations in light of the goals of patent protection and provided *patent-like protection* to sexually reproducing plants with a system of enablement that respects the balance in the social contract between inventor and the public.

Legislative intent is evidenced by the fact that in passing the PVPA as a separate statute, Congress recognized a distinct difference between sexual and asexual reproduction in living organisms. In other words, even though Congress recognized that the work of the plant breeder "in aid of nature" was deserving of patent protection, it did not provide for protection of sexually reproducing plants until 1970.[326] In passing the PVPA as a separate statute, Congress must have recognized that sexually reproduced organisms are inherently indefinite and not amenable to the enablement and written description requirements of the utility patent act.

While the PPA has a relaxed written description requirement, Congress still saw fit to enact the PPA under the general utility patent statutes because each and every asexually reproduced plant is exactly the same as the patent protected one. This, however, is not the case for sexually reproducing plants. In fact, Congress, while relaxing the written description

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[326] Diamond v. Chakrabarty, 447 U.S. 303, 312 (1980) (citing S. REP. NO. 315, 7-9 (1930); H.R. REP. NO. 1129, 7-9 (1930)).

in favor of a system of depositing an exemplar for sexually reproducing plants, still did not enact the PVPA under the general patent statutes. Recognizing the efforts of plant breeders as deserving of patent protection but at the same time recognizing the unpatentability of sexually reproducing organisms, Congress did the next best thing by affording *patent-like protection* to sexually reproducing plants under a separate statute administered by the USDA.

It is not within the province of the courts to redefine the limits of patentability once Congress has spoken on the subject. *Chakrabarty* stands for the principle that Congress did not intend to limit the scope of patentable subject matter under § 101 of 35 U.S.C. by the passage of the PPA and the PVPA. But *Chakrabarty* also stands for the principle that Congress—not the courts—defines the limits of patentability under the general patent statutes. In both *Ex parte Hibberd* and *Ex parte C*, the BPAI relaxed the requirements of § 112 to accommodate the special needs of affording patent protection to sexually reproducing plants and their progeny based on its reading of *Chakrabarty*. However, nothing in *Chakrabarty* can be read to suggest that Congress intended to change the requirements under the general utility patent statutes by passing the PPA and the PVPA. If anything, *Chakrabarty* makes clear that the process of balancing competing values and interests is the business of the legislature and elected representatives in our democratic system.[327] In light of these values and interests, Congress enacted the PVPA with the farmers' privilege and research exemption in place to be administered by the USDA rather than under the general utility statutes. To receive patent protection under the general utility patent statute, the applicant must meet all the requirements including those of § 112 for enablement and written description, and these requirements should not be relaxed in favor of certain subject matter. The PVPA provides the sole form of *patent-like protection* for sexually reproducing plants; whether Congress will enact statutes to provide *patent-like protection* for other sexually reproducing organisms remains to be seen.

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[327] *Chakrabarty*, 447 U.S. at 317.