WILL PLANTS FINALLY GROW INTO FULL PATENT PROTECTION ON AN INTERNATIONAL LEVEL? A LOOK AT THE HISTORY OF U.S. AND INTERNATIONAL PATENT LAW REGARDING PATENT PROTECTION FOR PLANTS AND THE LIKELY CHANGES AFTER THE U.S. SUPREME COURT'S DECISION IN J.E.M. AG SUPPLY V. PIONEER HI-BRED.

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I. INTRODUCTION

The international patent scene has become a hotbed of controversy following the decisions of U.S. courts to recognize living things as patentable subject matter.¹ Patent lawyers representing the interest of the U.S. biotechnology industry are in the forefront of the debate, pressing for other countries to adopt more extensive patent laws recognizing living materials as patentable subject matter, just as U.S. courts and the United States Patent & Trademark Office have.²

^{1.} See Neil D. Hamilton, Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources, 28 Tulsa L.J. 587, 646 (1993).

^{2.} See id. at 646-47.

In the United States a variety of intellectual property protections are available.³ Although all types of intellectual property rights provide an inventor or creator with a limited time monopoly on the making, selling, and copying of a product, patent rights awarded under a utility patent⁴ are considered to offer the greatest amount of protection against other persons trying to create or sell the product as their own.⁵ Regarding plants, however, there has been an ongoing question as to whether plants are entitled to this utility patent protection or whether plants are precluded from such protection due to two other statutes specifically addressing alternative forms of patent-like protection for plants. In the recent Supreme Court case *J.E.M. Ag Supply v. Pioneer Hi-Bred*,⁶ the Court ruled that plants are in fact eligible for utility patent protections.⁷

In an increasingly globalized society, however, it is not only U.S. law that affects the profitability and marketability of agricultural seed and technology products, but international law and country specific law as well. Currently there is no such thing as an "international patent" for any type of invention.⁸ Therefore, "[t]he type of intellectual property to be protected and the legal and administrative system of the country where the right is being sought affect the extent of rights, such as the scope of the protection and the geographical limits to and duration of the rights" available to patentholders.⁹ This means that even though a patent right is awarded to an invention in the United States, another country is not bound to honor that patent.¹⁰ In order to obtain patent protection in other countries, an inventor must apply for patent rights in all countries where patent rights are likely to be needed.¹¹ Patent rights can also prevent others from importing inventions which have already been patented in another country, pro-

^{3.} See Paul Goldstein, Copyright, Patent, Trademark and Related State Doctrines 3-5 (5th ed. 2002) (describing the different types of federal protection for intellectual property).

^{4.} See Patent Act, 35 U.S.C. § 101 (2000).

^{5.} See Philip G. Pardey et al, Int'l Food Policy Research Institute: A Primer on Intellectual Property Rights and Agricultural Biotechnology, 2000-01 Annual Report (2002), at http://www.ifpri.org/pubs/books/ar2000/ar2000_essay02primer.htm.

^{6.} J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).

^{7.} *Id.* at 145.

^{8.} PARDEY, *supra* note 5, *at*

http://www.ifpri.org/pubs/books/ar2000/ar2000_essay02primer.htm.

^{9.} Id

^{10.} See id

^{11.} See generally id.

vided the importing country has chosen to recognize the patent rights of other countries.¹²

Because there is no such thing as an international patent, international treaties and various organizations attempt to regulate and oversee intellectual property rights on an international scale by trying to provide a uniform framework, setting out the minimum standards and requirements which would ideally be adopted and observed by all participating countries.¹³ The United States and Europe have been the leaders of the World Trade Organization ("WTO") member countries in recognizing and implementing express statutory laws that provide some patent protection specifically for plants.¹⁴ Even among those countries that recognize some patent protection for plants, however, there is still a great divide, regarding whether or not plant patent protection should also extend to genetically modified plant varieties.¹⁵ The general disposition that plants do not qualify for full patent protection is based upon a philosophical stance that "[a]nyone is free to make, use, or sell whatever technology or knowledge is available for crops in countries where that technology is not subject to intellectual property protection, irrespective of whether the crop is grown for subsistence or commercial use or whether the technology is protected elsewhere."¹⁶

As a result of the lack of uniformity in patent protections available from country to country, agribusinesses are challenged when trying to assess their rights and potential market share on an international level.¹⁷ This can lead to substantial differences in the prices paid by farmers for the same product from country to country. This pricing difference is illustrated dramatically in the situation regarding Roundup Ready soybeans.¹⁸ In 1998, U.S. growers paid twenty to twenty-three dollars per fifty pound bag of Roundup Ready soybeans, compared to Argentine farmers, who paid only twelve to fifteen dollars per fifty pound bag.¹⁹ A 2000 General Accounting Office report cited two primary reasons for this great price discrepancy: stronger patent protection in the United States, and black market sales of Roundup Ready soybeans in Argentina.²⁰ Such pricing

^{12.} *Id*.

^{13.} *See id.*

^{14.} See id.

^{15.} See id.

^{16.} *Id*.

^{17.} See id.

^{18.} See U.S. GEN. ACCOUNTING OFFICE, GAO/RCED/NSIAD-00-55, BIOTECHNOLOGY: INFORMATION ON PRICES OF GENETICALLY MODIFIED SEEDS IN THE UNITED STATES AND ARGENTINA 4 (2000) available at http://www.gao.gov/new.items/r400055.pdf.

^{19.} See id.

^{20.} See id. at 5.

discrepancies for major agribusiness products may significantly affect future international trade agreements and intellectual property protections.

Currently, patenting life forms looms as one of the most highly controversial issues on an international level, not only for plant patents, but for other traditional products as well.²¹ Although there are obvious economic aspects of the debate, there are cultural and ethical aspects as well.²² Many developing countries resist recognition of full patent protection for living organisms based upon ethical and religious beliefs that life forms should not be treated as inventions.²³ Traditionally life forms and related technologies have been viewed as non-patentable by these countries.²⁴ Also, in cultures where agricultural knowledge, skills, and plant varieties have been developed and passed on from generation to generation, there is resistance to granting patent protection for a known plant variety that has been altered only by biotechnology.²⁵ Yet, as shown in the preceding example with Roundup Ready soybeans, this places farmers in countries where such patents are honored in a disadvantaged situation for purchases of seed and international marketing of their crops at competitive prices. As a result, "[t]he World Trade Organization is set to re-evaluate the obligation of member states to protect plant materials legally."26

This article is intended to offer background and to highlight issues of this emerging international controversy. Part two of this article reviews the history and development of U.S. patent law, as applied to plants, up to the recent Supreme Court decision *J.E.M. Ag Supply v. Pioneer Hi-Bred*. Part three examines the development of international patent law and organizations with regard to patent protection for plants. The final section of the article discusses potential impacts of negotiations on international plant patent protection at the next WTO

^{21.} See Jeroen van Wijk, *Plant Patenting Provision Reviewed in WTO*, 34 BIOTECHNOLOGY & DEV. MONITOR 6 (1998), *available at* http://www.biotech-monitor.nl/3403.htm (last visited Feb. 26, 2003).

^{22.} See id.

^{23.} See id.

^{24.} See id.

^{25.} See Sean D. Murphy, Biotechnology and International Law, 42 HARV. INT'L L.J. 47, 65 (2001) (stating "Life forms were considered special and different and not reducible to property rights that might be possessed by some and denied to others. To the extent certain property rights are accorded to life forms, many developing states perceived an imbalance in Western intellectual property regimes, which deny intellectual property rights for medicinal or agricultural knowledge, skills, and material which have been handed down over generations. Arguably the new biotechnology 'invention' is just a further step (albeit a radical one) in our comprehension of a genetic evolution spanning millennia.").

^{26.} Jeroen van Wijk, *supra* note 21, at 6.

meeting in the wake of the Supreme Court's decision in *J.E.M. Ag Supply v. Pioneer Hi-Bred* and full patent protection for plants.

II. U.S. PATENT LAW HISTORY REGARDING PLANT PATENTS

It has been argued that "the range and breadth of [Intellectual Property Rights] claims authorized by a society—through its legal mechanisms—are the most significant determinants enabling the growth and privatization of technology and scientific advance." In the development of Intellectual Property Rights ("IPR") claims for plants in the United States, the first step was the enactment of statutes offering protection to plants. The second step was whether the Patent Office and the courts would interpret the statutes so as to find that the inventions did in fact fall within the protections offered through the statutes.

A. Statutory Law

In the United States, the Plant Protection Act,³⁰ the Plant Variety Protection Act,³¹ and the Utility Patent Act³² provide potential protection for the inventors of new plants. Although utility patent protection is the oldest of the three, plants were not actually recognized as patentable subject matter until the enactment of the Plant Protection Act.

1. Utility Patent

The authorization for Congress to create a patent system and the formation of the United States Patent and Trademark Office ("USPTO") comes directly from the United States Constitution under Article I.³³ The standards for obtaining a utility patent issued by the USPTO can be found at sections 101 through 122.³⁴ In order to receive full utility patent protection, the invention must be new, novel,

^{27.} Neil D. Hamilton, Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms, 6 DRAKE J. AGRIC. L. 81, 109-10 (2001).

^{28.} See generally Hamilton, supra note 1, at 594-99.

^{29.} See generally id. (describing the role of courts in interpreting existing patent law to seeds and the various differences under each statute).

^{30.} See 35 U.S.C. §§ 161-164 (2000).

^{31.} See Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (2000).

^{32.} See 35 U.S.C. §§ 101-105 (2000).

^{33.} See id. § 1; see also U.S. CONST. art. I, § 8, cl. 8.

^{34.} See 35 U.S.C. §§ 101-122 (2000).

non-obvious, and the written description of the variety or invention must be sufficiently detailed and specific so as to meet the written description requirements of 35 U.S.C. § 112.³⁵

2. Plant Protection Act

The Townsend-Purnell Plant Patent Act of 1930 ("PPA")³⁶ was the first of its kind not only in the United States, but anywhere in the world.³⁷ This statutory law offered specific patent protection to plant breeders of varieties that could be reproduced asexually.³⁸ The congressional intent behind the PPA was to provide agriculture the same incentives and protection for developing new varieties and innovations in crop production that were currently being used to encourage mechanical and scientific developments in other industries.³⁹ Under the provisions of the PPA, if a plant breeder can show that a plant with new and unique characteristics has been created and that this plant can be reproduced through budding, grafting, or cutting techniques resulting in a new plant with the exact same new and unique characteristic, that plant breeder will be entitled to PPA protection for the plant.⁴⁰ This protection lasts for a period of twenty years and prevents others from making, selling, or reproducing the patented variety.⁴¹

One important feature of the PPA is that it helped plant breeders overcome the barrier of the written description requirements for obtaining a utility patent. Developments in traditional plant breeding were hard to record on paper with sufficient detail to satisfy the written requirements of § 112, yet generally these developments could easily be seen with the naked eye. For example, "[w]hen a new plant differed from the old only in color, scent or texture, it was almost impossible to satisfy the written description requirement. Consequently, plant breeders were denied substantive protection for their discoveries, derailing innovation in this field." To correct this problem and to recognize plant breed-

^{35.} See id.

^{36.} See id. §§ 161-164.

^{37.} See Elisa Rives, Comment, Mother Nature and the Courts: Are Sexually Reproducing Plants and Their Progeny Patentable Under the Utility Patent Act of 1952?, 32 CUMB. L. REV. 187, 197 (2001).

^{38.} See 35 U.S.C. § 161 (2000).

^{39.} *See* Rives, *supra* note 37, at 197-98.

^{40.} See id.

^{41.} See id. at 199.

^{42.} See id. at 198

^{43.} David G. Scalise & Daniel Nugent, International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture, 27

ers rights to patent protection, the PPA was enacted.⁴⁴ The PPA relaxes the written description requirement by accepting a deposit of an exact specimen of the plant as an alternative to providing a detailed written description in order to receive patent-like protection.⁴⁵

The PPA legislation was supported by well respected inventors like 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 have through the patent law."⁴⁶

The PPA also spurred an increase in research on asexual plant reproduction and varieties because of the guarantee to plant breeders of exclusivity to the production and sale over patented varieties.⁴⁷ However, despite the Congressional intent behind the enactment of the PPA, the protection actually provided by the PPA turned out to be quite limited.⁴⁸ Because it only applied to asexually reproducing varieties, the statute offered little or no protection for many agricultural crops which reproduce primarily through sexual reproduction and dispersal of seed progeny.⁴⁹ Due to the fact that the vast majority of plants used in agricultural production produce sexually, the PPA provided little incentive for researchers of agricultural crops and other sexually reproducing varieties to create new varieties.⁵⁰ The researchers realized that any developments of new varieties of sexually reproducing plants would be unprotected and that they would never be able to recoup the time, money and resources required to create and perfect a new variety.⁵¹ "The need to fulfill this protection gap in the intellectual property regime was recognized as being essential to the development of the burgeoning seed market."52

CASE W. RES. J. INT'L L. 83, 91 (1995).

- 44. Id
- 45. See Rives, supra note 37, at 199.
- 46. S. REP. No. 71-315, at 3 (1930).
- 47. Scalise & Nugent, *supra* note 43, at 93 ("The PPA was a qualified boon to the science of plant breeding, as evidenced by the 2,700 plant patents issued between its enactment, in 1930, and 1970").
 - 48. See generally id. at 92-93.
 - 49. Rives, *supra* note 37, at 199.
 - 50. See id.
 - 51. *See id.*
 - 52. *Id.* at 200.

3. Plant Variety Protection Act

In 1970, a new form of statutory patent protection for plants emerged when Congress enacted the Plant Variety Protection Act ("PVPA").⁵³ Despite the domestically recognized need for greater patent protection of plants, the PVPA was actually enacted in response to the Western European nations responsible for forming the Paris Union, also known as the Union for the Protection of New Plant Varieties ("UPOV").⁵⁴ In 1961, six European countries came together to form the UPOV, which was founded in an attempt to provide uniform protection for plant breeders of new varieties.⁵⁵ The United States did not join the UPOV until 1981, but had enacted the PVPA eleven years earlier in order to be consistent with the UPOV, and to facilitate patent protection to plant breeders working on both a domestic and an international level.⁵⁶

The PVPA is administered by the United States Secretary of Agriculture, and provides patent-like protection to plant breeders who apply for patent protection in the United States.⁵⁷ The PVPA can be found at 7 U.S.C. §§ 2321-2582 and is separate from the patent protections of the PPA.⁵⁸ PVPA protection consists of a certificate that is issued to plant breeders who have created novel and distinct varieties.⁵⁹ The variety may be replicated through sexual reproduction, but the variety must breed true-to-type over several generations.⁶⁰ This means that the variety must generate the same novel and distinct characteristics when reproduced over several generations;⁶¹ otherwise, PVPA protection is not warranted.⁶² The only variations allowed from generation to generation are those that are "predictable and commercially acceptable, and hav[e] reasonable stability."⁶³ This is different from the more lenient requirement under the PPA, which

^{53.} See Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (2000).

^{54.} See Rives, supra note 37, at 193.

^{55.} *Id*.

^{56.} See Debra L. Blair, Note, Intellectual Property Protection and Its Impact on the U.S. Seed Industry, 4 DRAKE J. AGRIC. L. 297, 312 (1999).

^{57. 7} U.S.C. §§ 2323, 2402 (2000); see Rives, supra note 37, at 193.

^{58.} *See* Rives, *supra* note 37, at 193 n.54.

^{59.} See 7 U.S.C. § 2483 (2000).

^{60.} See Plant Variety Protection Act, 7 U.S.C. § 2402 (2000); see also Imazio Nursery Inc. v. Dania Greenhouses, 69 F.3d 1560, 1564-68 (Fed. Cir. 1995) (discussing the term "variety" and the concept of breeding true-to-type); Rives, supra note 37, at 200.

^{61.} *See* Rives, *supra* note 37, at 201.

^{62.} See id.

^{63.} *Id*.

only requires a variety to be new and distinct.⁶⁴ With regard to the written description requirements, however, the PVPA follows the PPA by relaxing the written description provision by allowing a deposit of seed as an alternative to providing a detailed written description.⁶⁵ Under the PVPA, plant breeders were initially entitled to protection for seventeen years, but since the 1994 amendments, that period of protection has been increased to twenty years.⁶⁶ This protection excludes all others from selling, offering for sale, reproducing, importing, or exporting the variety for the next twenty years, unless the certificate holder grants permission otherwise.⁶⁷

Two important exemptions to the PVPA certificate holder's ability to exclude others from using the patented plant variety are (a) the Farmer's Exemption and (b) the research exemption.⁶⁸

a. Farmer's Exemption

Under the PVPA, an exemption has been carved out for farmers, which allows them to save and sell a limited amount of seeds from year to year without violating the rights of the plant breeders who have obtained a PVPA certificate for a certain variety.⁶⁹ This exemption is based upon the long-standing tradition of farmers who save seeds from their best crop in order to replant those seeds for a good crop in future years.⁷⁰ Under this exemption, farmers may only save seed when their primary occupation is growing crops to be sold for purposes other than seed quality.⁷¹ This exemption would not apply for a farmer whose primary occupation was growing crops specifically for seed quality.⁷² Seed companies, however, complain of lost profits due to this provision because it exempts most farmers who would otherwise have to repurchase seed every planting season.⁷³

^{64.} See Plant Protection Act, 35 U.S.C. § 161 (2000).

^{65.} See Plant Variety Protection Act, 7 U.S.C. § 2422(2) (2000).

^{66.} See id. § 2483(a)-(b).

^{67.} See Rives, supra note 37, at 201.

^{68.} *Id*.

^{69.} See Plant Variety Protection Act, 7 U.S.C. § 2543 (2000).

^{70.} See Rives, supra note 37, at 202.

^{71.} See id.

^{72.} See id

^{73.} *Id.* at 201-02 (stating "[B]ecause 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.").

Prior to 1994, the exemption allowed farmers to save seed from year to year and also to sell seed to others. In 1994, however, the PVPA was amended to bring it into conformity with other international conventions. For example, under the 1994 amendments, PVPA certificate protection over a specific variety was enhanced by extending patent protection to a period of twenty years, and a period of twenty-five years for tree and vine varieties. The amendments also drastically narrowed the farmer exemption so that after April 4, 1994, no sale of protected seed would be allowed without the prior permission of the certificate holder. As a result farmers were only allowed to save seed for their own crops under this newly limited exemption.

b. Research Exemption

The research exemption under the PVPA provides that the use of a protected variety for the purposes of bona fide research study and reproduction will not be a violation of the certificate holder's protection. Under this exemption, scientists are able to use protected varieties like "stepping-stones to develop new varieties and advance agricultural biotechnology through research." This research exemption was also narrowed under the 1994 amendments, by declaring that varieties which are "essentially derived" from protected varieties would be considered an infringement. This new language greatly restricts the amount of research allowed on new varieties because research and newly created varieties which are "essentially derived" from a protected variety, will likely be found to violate the rights of a PVPA certificate holder. This in turn, reduces the amount of research conducted involving these protected varieties because scientists do not want to run afoul of a PVPA certificate holder's rights, and tie up their research resources in costly and time-consuming litigation.

^{74.} Plant Variety Protection Act, 7 U.S.C. § 2543 (2000).

^{75.} *Id.*; Charles C.P. Rories, *Does the U.S.P.T.O. Have Authority to Grant Patents for Novel Varieties of Sexually Reproducing Plants?*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 737, 742 (2001).

^{76.} Plant Variety Protection Act, 7 U.S.C. § 2483 (2000).

^{77.} See Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, § 10, 108 Stat. 3136, 3142 (1994); see also Rories, supra note 75, at 742-43.

^{78. 7} U.S.C. § 2544 (2000).

^{79.} See Rives, supra note 37, at 204.

^{80.} See Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, § 9, 108 Stat. 3136, 3141 (1994).

^{81.} Rives, *supra* note 37, at 204.

4. Utility Patent

As discussed earlier, in order for an invention to receive Utility Patent protection, the invention must be new, novel, non-obvious, and it must be described with such detail and specificity so as to meet the written description requirement of 35 U.S.C. § 112.

Advances in genetic engineering for both seeds and plants now allow scientists to accurately identify varieties which might otherwise be undistinguishable to the naked eye. ⁸² Genetic engineering also allows scientists to accurately identify and distinguish between varieties based upon a seed's genetic composition. ⁸³ This type of technology has finally allowed scientists and inventors to be able to satisfy the demanding written description provision of § 112 when applying for utility patent protection.

Plant utility patents offer the greatest protection when compared to plant patents or PVPA certificates. Plant utility patents allow the inventor-breeder to claim not just one claim on the plant as a whole, as is the case with Plant Patents and PVPA, but the inventor-breeder can also claim the individual components of the variety. In addition to the components of a variety such as the DNA sequence, gene, tissue culture, seed, or specific plant part, the inventor-breeder can claim methods to use the variety to make other varieties or hybrids and those resulting varieties or hybrids. Patenting multiple components or uses of an inventive plant allows for the licensing of those individual component which is an important factor in genetic engineering research.⁸⁴

In addition to providing the opportunity to patent multiple components and parts of a genetically altered plant, obtaining utility patent protection also offers greater enforcement of patent rights because there are no exemptions, such as those found under the PVPA. In addition, the body of case law regarding utility patent protection and enforcement is much greater and tends to favor protecting a patent holder's rights whenever possible.

^{82.} See Blair, supra note 56, at 315.

^{83.} See id.

^{84.} *Id.* at 318.

^{85.} See id.

^{86.} See id. at 313.

^{87.} *See, e.g., In re* Indep. Serv. Org. Antitrust Litig., 989 F. Supp. 1131, 1138 (D. Kan. 1997).

B. Statutory Interpretations

Since the enactment of the patent statutes, the courts have played a key role in monitoring and regulating the specific types of products which are ultimately issued patent protection by the UPSTO. Specifically, four major cases have focused on statutory interpretations for patent protection available for plant material.

1. Diamond v. Chakrabarty

Prior to *Diamond v. Chakrabarty* in 1980, the United States Supreme Court had never ruled on whether a living organism was patentable under a Utility Patent. Plants were recognized as being entitled to limited patent-like protections under the PPA and the PVPA, but had always been denied full utility patent protection.⁸⁸

In a five to four decision, the Court held that a "human-made, genetically engineered bacterium capable of breaking down multiple components of crude oil" was proper subject matter for utility patent protection. 89 Chakrabarty was a microbiologist who had developed the microorganism at issue and filed a patent application for it.90 Chakrabarty initially brought suit against Diamond, the Commissioner of Patents and Trademarks, when he was refused utility patent protection for his microorganism.⁹¹ The application involved three types of claims: (1) a process claim for the method of producing the bacteria; (2) a claim for the inoculum comprised of carrier material and the new bacteria; and (3) a claim to the bacteria themselves. 92 The initial decision by the patent examiner allowed the first two claims, but rejected the third claim on the basis that "(1) [the] micro-organisms are 'products of nature,' and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101."93 Chakrabarty appealed the decision to the Patent Office Board of Appeals, which affirmed the examiner's finding that "§ 101 was not intended to cover living things such as these laboratory created micro-organisms."94 The case next went before the Court of Customs and Patent Appeals, which reversed the decision, noting that the fact

^{88.} See Diamond v. Chakrabarty, 447 U.S. 303 (1980).

^{89.} *Id.* at 305.

^{90.} See id.

^{91.} See id. at 306.

^{92.} See id. at 305-06.

^{93.} Id. at 306.

^{94.} *Id*.

that this patent application involved a living microorganism was "without legal significance." On appeal before the Supreme Court, the issue was a question of statutory interpretation of 35 U.S.C. § 101 and whether or not Chakrabarty's "microorganism constitute[d] a 'manufacture' or 'composition of matter' within the meaning of the statute." If so, then the microorganism would in fact be available for utility patent protection.

The Court began its statutory analysis by first looking to the language of the statute. Using the ordinary, dictionary meaning of the words "manufacture" and "composition of matter," the Court determined that "Congress plainly contemplated that the patent laws would be given wide scope. The Court found that the legislative history behind § 101 supported the finding that patent laws should be broadly construed, and that "Congress intended statutory subject matter to 'include anything under the sun that is made by man." Using a broad interpretation of § 101, the Court concluded that Chakrabarty's oil-eating microorganism clearly fell within the realm of patentable subject matter because the microorganisms fit within the definition of "manufacture."

The Court next addressed two arguments put forth by Diamond that Chakrabarty's microorganism should not be considered patentable subject matter under § 101. Diamond first argued that Congress never intended for living things such as microorganisms to be entitled to § 101 patent protection because it had already enacted two separate statutes addressing patent-like protection for plants. Diamond reasoned that if Congress had intended for § 101 patent protection to extend to living things, then there would have been no reason for Congress to enact the PPA and the PVPA separately from the utility patent statute. December 102 The Court, however, rejected this argument on the basis that in the absence of evidence that Congress had specifically focused on the issue at hand, in this case the patentability of microorganisms, the Court would not find congressional intent that would alter or contradict the plain meaning of the words in § 101.

^{95.} *Id.* (citing *In re* Bergy, 563 F.2d 1031, 1038 (C.C.P.A. 1977)).

^{96.} *Id.* at 307.

^{97.} See id. at 308.

^{98.} *Id*.

^{99.} *Id.* at 309 (noting that "[t]he Act embodied Jefferson's philosophy that 'ingenuity should receive liberal encouragement.'").

^{100.} See id. (stating "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity 'having a distinctive name, character and use.'").

^{101.} See id. at 310-11.

^{102.} See id.

^{103.} See id. at 311-14.

Diamond's second argument was that microorganisms were not patentable subject matter without express direction from Congress that they should be included within the meaning of § 101.¹⁰⁴ The reasoning behind this argument was that because genetic alterations were unforeseen at the time § 101 was enacted, there was no congressional intent that a genetically altered microorganism would be proper subject matter for patent protection under § 101.¹⁰⁵ The Court notes that "[i]t is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is 'the province and duty of the judicial department to say what the law is.'"¹⁰⁶ The Court also reasoned that "Congress employed broad general language in drafting section 101 precisely because such inventions are often unforeseeable," and held that Diamond's second argument was also without merit.¹⁰⁷

The Court also refused to consider concerns from various amicus curiae briefs warning of the potential dangers and unknown consequences surrounding the relatively new field of genetic engineering and research. In choosing to disregard this "gruesome parade of horribles," the Court reasoned that "[w]hether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all." The Court essentially ruled that these issues should be addressed by the legislative branch and not by the Court. The Court was directly inviting Congress to take some kind of action with regard to this subject if it did not like the Court's interpretation of § 101 to include microorganisms and other living things as patentable subject matter.

Although the *Chakrabarty* decision flung the door open for the various types of subject matter that might be able to receive full utility patent protection in the future, there were still many unanswered questions, including whether or not the Patent Office and courts would recognize full patent protection beyond soil bacterium to include more complex living organisms, both plant and animal.¹¹¹

^{104.} *Id.* at 314.

^{105.} See id.

^{106.} *Id.* at 315 (quoting Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803)).

^{107.} Id. at 316.

^{108.} See id.

^{109.} *Id.* at 316-17.

^{110.} See id. at 317.

^{111.} See Scalise & Nugent, supra note 43, at 97-98.

2. Ex parte Hibbard

Following the *Chakrabarty* decision, the issue of whether a sexually reproduced plant that has been altered genetically can be patented under the utility patent of 35 U.S.C. § 101 came before the USPTO in 1985.¹¹² Although *Ex parte Hibbard*¹¹³ is not a court decision, it is an important stepping stone in the development and interpretation of the extent that patent protection was available to plants.

In the initial denial, the patent examiner of the USPTO ruled the plant to be improper patentable subject matter.¹¹⁴ The patent examiner found that patent protection for sexually reproduced plants was limited only to the patent protections available under the PPA and the PVPA.¹¹⁵ The patent examiner believed that the PPA and the PVPA were the only patent protections available for plants.¹¹⁶ Upon review of the examiner's decision, however, the USPTO Board of Appeals and Interferences found the rejection of the patent to be incorrect because neither the PPA nor the PVPA expressly excludes any plant from being proper subject matter for a utility patent under 35 U.S.C. § 101.¹¹⁷

The issue on appeal was whether Congress intended utility patent protection to extend to plants in addition to the protections of the PVPA and the PPA. Using the rules of statutory construction, the Board of Appeals overturned the examiner's utility patent rejection and held that the maize seeds at issue were, in fact, eligible for utility patent protection based on the Supreme Court's holding in *Diamond v. Chakrabarty* that "patent laws [should] be given wide scope." 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." 120

^{112.} See Ex parte Hibbard, 227 U.S.P.Q. 443 (1985) (stating that subject matter relates to maize plant technologies which have increased free tryptophan levels); Rories, *supra* note 75, at 745.

^{113.} Ex parte Hibbard, 227 U.S.P.Q. 443 (1985).

^{114.} *Id.* at 444 n.1.

^{115.} See id. at 444.

^{116.} See id.

^{117.} *Id.* at 444-45.

^{118.} *See id.* at 443.

^{119.} See id. at 444 (quoting Diamond v. Chakrabarty, 447 U.S. 308 (1980)).

^{120.} Rives, *supra* note 37, at 209 (emphasis added).

Although the holding in *Hibbard* heightened the stakes for inventors and breeders of transgenically modified plants by stating that such products were eligible for utility patent protection, the question of whether plants and seeds would ever actually receive patent protection as proper subject matter under § 101 was not answered by *Hibbard*.¹²¹ In essence, although *Hibbard* held that protection is available to plants under the utility patent, it did not automatically mean that they will receive that protection, due to the written description requirements of § 112, which plant breeders had yet to overcome at that time.¹²² Despite this restriction, since the *Chakrabarty* decision in 1980 and the *Hibbard* decision in 1985, more than one thousand utility patents have been issued for plant subject matter.¹²³

3. Asgrow Seed Co. v. Winterboer

After *Ex parte Hibbard* in 1985, the potential for greater intellectual property protections burgeoned for seed companies and biotechnology corporations. However, no one had tested the holding in *Hibbard* in a court of law to determine if full utility patent protection would be recognized for all plant and seed products.¹²⁴ The PVPA, on the other hand, was familiar territory for seed companies and plant breeders, and there was a strong belief throughout the industry that improvements to the PVPA might be able to fulfill the need for greater patent protection, rather than blazing a new path and incurring unknown expenses in an attempt to establish precedence for achieving full utility patent protection for their plant products. In this vein, *Asgrow Seed Co. v. Winterboer*¹²⁵ emerged as an important case in the history and development of patent protection for plants because it greatly reduced the extent of the farmer's saved seed exemption under the PVPA.¹²⁶

The issue before the Court in *Asgrow* involved the PVPA farmer's exemption, specifically focusing on the right of farmer's to save and sell seeds that were protected by the PVPA.¹²⁷ The defendant, Winterboer, was accused of violating the PVPA rights of Asgrow Seed Co. when he allegedly grew, marketed,

^{121.} See id.

^{122.} See id.

^{123.} See id.

^{124.} See id.

^{125. 513} U.S. 179 (1995).

^{126.} See Rives, supra note 37, at 228.

^{127.} See Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 181 (1995).

persons.¹²⁸ Under the PVPA, "sexually multiply[ing] the novel variety as a step in marketing (for growing purposes) the variety" is a violation.¹²⁹ Winterboer, however, claimed that there was no PVPA violation because his sale of seeds was within the limits of the statutory exemption for the farmer's right to save seed.¹³⁰ He argued that there was no limit on the amount of seed he could sell under the exemption as long as the both buyers and sellers were farmers and the crops were being grown for purposes other than producing a new seed crop.¹³¹ Asgrow, on the other hand, argued that the exemption limited sales of seed between farmers to only that amount which the growing farmer would have needed in order to replant his own fields.¹³² For example, under Asgrow's interpretation, if a farmer only had one hundred acres of crops, he would only be allowed to save enough seed to replant that one hundred acres. In this situation, Winterboer's seed sales had surpassed the amount needed to replant his own fields, and under Asgrow's interpretation of the exemption, he was in violation of the PVPA.¹³³ The district court agreed with Asgrow.¹³⁴

Upon appeal to the Federal Circuit Court of Appeals, however, the decision was reversed. The Federal Circuit interpreted the exemption to limit the sale of seed between farmers to half of the crop produced under a PVPA variety. ¹³⁵ Ultimately the issue came before the Supreme Court to determine the meaning and limits, if any, to the farmer's saved seed exemption. ¹³⁶ The Supreme Court held that the farmer's exemption only allowed farmers to save enough seed to replant their own crops, and that farmers would only be able to resell their seed to other farmers. ¹³⁷

Following the decision, Congress responded by enacting amendments to the PVPA mimicking the *Asgrow* decision so as to eliminate all sales of seed by farmers to other persons who were not farmers. The seed companies, however, wanted even more protection than *Asgrow* or the amended PVPA had to offer; the seed companies were striving for full patent protection, which would eliminate and the protection of t

^{128.} See id. at 182-83.

^{129.} *Id.* at 183 n.1 (1995) (citing 7 U.S.C. § 2541(3)).

^{130.} *Id.* at 183-84.

^{131.} *Id.* at 185.

^{132.} See id.

^{133.} See id.

^{134.} See Asgrow Seed Co. v. Winterboer, 795 F. Supp. 915, 918-19 (N.D. Iowa 1991).

^{135.} See Asgrow Seed Co. v. Winterboer, 982 F.2d 486, 490-92 (Fed. Cir. 1992).

^{136.} See Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 181 (1995).

^{137.} See id. at 192.

^{138.} *See* Rives, *supra* note 37, at 229.

nate all exemptions from the sale and purchase of their protected varieties.¹³⁹ Seed companies were discouraged by the exemptions under the PVPA because after investing millions of dollars in research and development to bring new varieties to market, farmers were able to save seed from year to year and to sell that same seed to others, preventing the seed companies from having the opportunity to recoup their investment costs in the development of the new varieties.¹⁴⁰ With only the legal protections of the PVPA available, even as amended, the seed companies foresaw that they would be forced to reduce their research costs or pursue the avenue of full patent protection for their varieties in order to be successful.¹⁴¹ The latter option seems to have been the case.

The most viable option was to seek full patent protection for their genetically altered varieties under the Utility Patent Protection. This option was possible only after the Court's decision in *Diamond v. Chakrabarty*, which opened the floodgates fifteen years earlier, allowing patents for all types of living things, including plants. Ex parte Hibbard reaffirmed that decision by providing that plants were, in fact, eligible for utility patent protection in addition to PPA and PVPA protection. ¹⁴³

The *Chakrabarty* decision and its legacy substantially supplanted both plant protection acts because of the flawed foundation upon which the acts were constructed: that the scientific world could somehow be divided into two classes (the microbiological world of simple matter such as bacteria and parasites, and a macrobiological world of complex living organisms such as plants and animals). This simplistic and antiquated view of the biological world was shattered by the science of biotechnology. 144

Even after the *Hibbard* decision, however, there were still some unsettled issues surrounding patent protection for plants, especially in light of the quick national and international adoption of biotechnology varieties.¹⁴⁵ With the rapid

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^{139.} See id. (discussing that the seed companies wanted to amend the PVPA to prevent or curtail the farmers exemption because it was too large; the seed companies felt that they were not receiving enough protection, and they were suffering economic losses because of the farmers exemption under the PVPA).

^{140.} *See id.* at 202-03 (discussing the scope of the farmer's privilege under the PVPA and its impact on seed companies as a disincentive to invest in developing new plant varieties).

^{141.} See id. at 200 (describing the need to fill in patent law for seed development).

^{142.} Diamond v. Chakrabarty, 447 U.S. 303, 313-14, 318 (1980).

^{143.} Ex parte Hibbard, 227 U.S.P.Q. 443, 444 (1985).

^{144.} Scalise & Nugent, *supra* note 43, at 100.

^{145.} *See* Rives, *supra* note 37, at 209 (discussing the unanswered issues of *Ex parte Hibbard*).

development and adoption of biotechnology, large agribusinesses are doing everything they can to protect and promote their products.

[B]iotechnology companies will look for ways to project their legal interests farther out the production flow of a product in order to capture the value that their actions contribute to it. Biotechnology companies will not be content to sell improved seeds and receive gains from higher seed prices. Instead, they will look for ways to control the production of value-added crops so a portion of the enhanced value resulting from their genetic improvements inures to them. ¹⁴⁶

Although it had been decided that plants were eligible for utility patent protection, there was still an unresolved question of whether Congress intended for plants to receive full patent protection under the utility patent provisions of 35 U.S.C. § 101 in light of the fact that Congress had already enacted two prior statutes specifically addressing plant patent protection. The stage for resolving this question was set when the United States Supreme Court granted certiorari to hear *J.E.M. Ag Supply v. Pioneer Hi-Bred.*¹⁴⁷

4. J.E.M. Ag Supply v. Pioneer Hi-Bred

This case began when Pioneer Hi-Bred alleged patent infringement against J.E.M. Ag Supply ("J.E.M."). ¹⁴⁸ J.E.M. was a small dealership in agriculture supplies that was found to be reselling bags of Pioneer's patented hybrid seed. ¹⁴⁹ J.E.M. denied patent infringement and counterclaimed that Pioneer's patent was invalid because corn plants are not patentable subject matter under 35 U.S.C. § 101. ¹⁵⁰ J.E.M. argued that the statutory provisions under the PPA and the PVPA are the exclusive patent protections available for plants. ¹⁵¹ The case went before the district court, which granted summary judgment for Pioneer on the grounds that plants were clearly within the realm of subject matter under 35 U.S.C. § 101. ¹⁵² Judgment was affirmed by the Federal Circuit. ¹⁵³

152. *Id*.

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^{146.} Hamilton, *supra* note 1, at 645.

^{147. 534} U.S. 124 (2001).

^{148.} J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 128-29 (2001).

^{149.} See id. at 128.

^{150.} *Id.* at 129.

^{151.} Id

^{153.} *Id.* at 129-30.

J.E.M. filed a petition for certiorari with the Supreme Court, and the Supreme Court requested an opinion from the Justice Department on the matter.¹⁵⁴ Despite the recommendation of the Justice Department that certiorari be denied, the Supreme Court granted certiorari. The sole issue before the Supreme Court was whether utility patents might properly be issued for plants under 35 U.S.C. § 101.¹⁵⁵

Looking at the issues as they were presented by the parties, the Court focused its discussion on whether the PPA or the PVPA excluded plants from utility patent protection. Rather than challenging whether the plants at issue met the requirements for utility patent protection, J.E.M. instead argued that the plants in general were not proper subject matter for utility patents because the PPA and the PVPA are the exclusive statutory means for obtaining patent protection for plant varieties. ¹⁵⁶

Looking at the PPA question, J.E.M. advanced three arguments supporting PPA preclusion to utility patent protection for plants: (1) utility patent protection for plants was not available to plants prior to 1930; (2) PPA's limited protection of asexually reproducing plants makes no sense if Congress intended for sexually reproducing plants to qualify for utility patent protection; and (3) Congress would not have moved plant patent protection out of the utility patent provision if it had intended for § 101 protection to remain available to plants.¹⁵⁷

a. Utility Patent Protection Did Not Cover Plants Prior to 1930

The first argument made by J.E.M. was that utility patent protection did not cover plants prior to 1930.¹⁵⁸ The Court, however, dismissed this argument, noting that as a result of advances in plant breeding and the state of patent law since 1930, plants are now able to meet the stringent requirements of § 101.¹⁵⁹ According to the Court, Congress enacted the PPA to recognize and protect the developments of plant breeders who could not meet the requirements of § 101 in the 1930s. In the Court's eyes, however, that did not preclude plants from *ever*

^{154.} Brief for the United States as Amicus Curiae at 1, J.E.M. Ag Supply, Inc, v. Pioneer Hi-Bred Int'l, Inc. 534 U.S. 124, (2001) (No. 99-1996), *available at* http://www.usdoj.gov/osg/briefs/2000/2pet/6invit/1999-1996.pet.ami.inv.pdf (last visited Mar. 10, 2003).

^{155.} J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001).

^{156.} *Id.* at 131-32.

^{157.} *Id.* at 134-37.

^{158.} *Id.* at 132.

^{159.} *Id.* at 134.

being able to complete the utility patent requirements at some point in the future. The Court stated that "[w]hatever Congress may have believed about the state of patent law and the science of plant breeding in 1930, plants have always had the *potential* to fall within the general subject matter of § 101, which is a dynamic provision designed to encompass new and unforeseen inventions." Referring back to its earlier holding in *Chakrabarty*, the Court concluded by stating that the denial of utility patent protection to plants simply because it was not feasible in 1930, would contradict the "forward looking perspective of the utility patent statute." 162

b. Congress Did Not Intend Utility Patent Protection to Cover Sexually Reproducing Plants Because of the PPA's Limited Protection of Asexually Reproducing Plants

J.E.M.'s second argument was that the PPA's limited protection of asexually reproducing plants makes no sense if Congress intended sexually reproducing plants to qualify for utility patent protection. Plant specimens produced through budding and grafting are considered to have been asexually reproduced because the genetic makeup is identical to that of the parent plant or tissue donator, from which the new plant has grown. In simple terms, the new plant is a clone of the original plant. By limiting patent protection to asexually reproducing plants only, Congress was able to greatly control and restrict the type of plants which were receiving patent protection. Because only certain varieties of asexual plants reproduce on their own, and because many others can be asexually reproduced with the assistance of mankind, J.E.M. argued that Congress had a reason for wanting to restrict and control the types of plants that received patent protection; otherwise, Congress would have likely enacted a statute that did not differentiate between plants based upon their reproduction methods, and would have allowed for patent protection to all plants.

The Court addressed this argument by pointing again to the limited understanding of plant breeding and the state of patent law in the 1930s when the

^{160.} *Id.*

^{161.} *Id.* at 135 (emphasis in original).

^{162.} *Id*.

^{163.} See id.

^{164.} See id. at 133.

^{165.} See id.

^{166.} See id. at 135.

PPA was enacted.¹⁶⁷ At that time, Congress believed that the primary way to breed plants true-to-type (preserving the desirable, patentable traits from specimen to specimen) was through asexual reproduction; sexual reproduction was thought to be too unpredictable and unreliable.¹⁶⁸ Thus, the Court reasoned that Congress' focus on asexual reproduction was understandable given the surrounding circumstances regarding the science of plant breeding in the 1930s, but that limited understanding did not, thereby, show an intent by Congress that patent protection for plants should be limited only to asexual reproduction.¹⁶⁹

The Court also noted that another reason for the enactment of the PPA was to address specific concerns within the plant nursery industry, aside from the seed industry. In the 1930s, patent protection for seeds was not an issue because there were few markets for seeds. In Seed packets were freely distributed to farmers through public institutions until 1924. As a result, rather than worrying about variety protection, seed companies were more concerned with trying to commercialize and create markets for seed production. In Seed production.

In the commercialized nursery industry, however, plants were regularly copied and sold through asexual reproduction methods, which led plant breeders to demand patent protection for asexually reproducing plants.¹⁷⁴ The Court concluded that this need for patent protection for asexually reproducing plants and the resulting enactment of the PPA in 1930, however, did not preclude utility patent protection for sexually reproducing plants in the future.¹⁷⁵

c. Congress Would Not Have Moved Plant Protection Out of the Utility Patent Provision if It Had Intended § 101 Protection to Remain Available to Plants

Finally, J.E.M. argued that if Congress had intended the utility protection to remain available to plants it would not have moved plant patent protection out of the utility patent provision in 1952.¹⁷⁶ J.E.M. was attempting to show the

^{167.} See id.

^{168.} See id. at 135-36.

^{169.} See id.

^{170.} *Id.* at 136-37.

^{171.} *Id.* at 136.

^{172.} *Id*.

^{173.} *Id*.

^{174.} See id. at 136-37.

^{175.} See id. at 135.

^{176.} *Id.* at 137 (noting that Congress moved PPA protection to 35 U.S.C. §§ 161-64, whereas all utility patent provisions can be found at 35 U.S.C. §§ 101-57).

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Court that Congress intended for PPA protection to stand alone as patent protection and not as an alternative to utility patent protection.¹⁷⁷ J.E.M. argued that Congress did this by moving the PPA protection away from the utility patent statutory provisions.¹⁷⁸ The Court rejected this argument as well, however, because J.E.M. offered nothing more in its argument than a negative inference about Congress' intentions.¹⁷⁹

Following its PPA arguments, J.E.M. also advanced two arguments supporting PVPA preclusion to utility patent protection for plants: (1) that the enactment of the PVPA and the PVPA legislative history evidences Congress' intent to preclude plants from the broader patent protection available under § 101^{180} and (2) that the PVPA alters, by implication, the scope of plants as proper subject matter under § $101.^{181}$

i. Congressional Intent to Preclude Utility Patent Protection for Plants

J.E.M.'s first PVPA argument was that the enactment of the PVPA and the legislative history of the Act evidences Congress' intent to preclude plants from the broader patent protection available under section 101. ¹⁸² J.E.M. relied upon portions of the legislative history, where some members of Congress expressed a belief that patent protection was not available for sexually reproduced plants. ¹⁸³ The Court, however, held that this "limited view of plant breeding taken by some Members of Congress . . . stems from a lack of awareness concerning scientific possibilities" ¹⁸⁴ and stated that nowhere in the PVPA is there language stating that the PVPA would be the exclusive patent protection available to plants. ¹⁸⁵ The Court also reaffirmed its decision that plants fall within the scope of § 101 by noting that since the 1950s, patent protection has been granted for various processes of creating hybrid plants, including patent protection covering the hybrid plant itself as a product of the patented process. ¹⁸⁶ Apparently the Court reasoned that if the process of creating a hybrid plant, as well as the prod-

^{177.} *Id.* at 137-38.

^{178.} See id.

^{179.} See id. at 138.

^{180.} *Id*.

^{181.} *Id.* at 141.

^{182.} *Id.s* at 138.

^{183.} See id. at 141.

^{184.} *Id*.

^{185.} *Id*.

^{186.} Id.

uct of the hybridization or breeding process could be patented, then the variety itself should also be entitled to full utility patent protection, no matter how the variety was created.

ii. The PVPA Alters the Scope of Patent Protection Available for Plants

The next contention made by J.E.M. was that the PVPA alters, by implication, the scope of plants as proper subject matter under § 101.¹⁸⁷ In past decisions the Court held that in the rare case of a statute repealed by implication, a finding of irreconcilable conflict between the earlier and later statute is required.¹⁸⁸

In this case the Court acknowledged that the there are differences in the standards set by each statute to acquire patent protection, as well as differences in the level of protection offered by a utility patent and a plant variety certificate issued under the PVPA.¹⁸⁹ The Court, however, did not view these differences as being irreconcilable conflicts, finding instead that "there is a parallel relationship between the obligations and the level of protection under each statute" and that there is no "positive repugnancy" between the two statutes that would prevent the statutes from "mutually co-exist[ing]." The Court also noted, that absent a contrary and express intention by Congress, courts have a duty to find the statutes capable of coexistence. Because each of the statutes at issue in this case has different requirements and offers different protections, the Court held that the statutes were compatible with the finding that plants are patentable subject matter under § 101. In light of the absence of irreconcilable conflict, the Court refused to repeal the statute by implication.

iii. The Court's Comparison of Utility Patent Requirements to PVPA Requirements.

The Court also noted that the requirements for obtaining utility patent protection for a plant under § 101 are much more stringent than the requirements

^{187.} *Id*.

^{188.} *See id.* at 141-42 (citing Morton v. Mancari, 417 U.S. 535, 550 (1974) and Matsushita Elec. Indus. Co., v. Epstein, 516 U.S. 367, 381 (1996), which both discuss the overwhelming amount of evidence required to establish repeal by implication).

^{189.} See id. at 142.

^{190.} *Id.* at 142-43.

^{191.} See id. at 143-44.

^{192.} See id. at 144.

to obtain patent-like protection under the PVPA.¹⁹³ Under § 101, a plant must be new, useful, and nonobvious to be granted a utility patent.¹⁹⁴ In addition, a highly detailed written description must also be included to enable others to "make and use" the plant after the minimum sixteen year patent term expires.¹⁹⁵ Part of this description requirement also demands a publicly accessible deposit of the biological material receiving patent protection.¹⁹⁶ On the other hand, under the PVPA, plants receive less intellectual property protection than a utility patent by a showing that the variety is new, distinct, uniform, and stable;¹⁹⁷ no showing of usefulness or nonobviousness is required.¹⁹⁸ The written description requirement for the PVPA is relaxed compared to § 112, and although a deposit of seed into a public depository is required, there is no indication in the statute that the deposit must be accessible to the public during the term of patent protection.¹⁹⁹

In addition, the PVPA contains two significant exemptions: allowing farmers to save seed and also allowing the use of seed or plants for research purposes.²⁰⁰ Thus, plants receive greater patent protection under the utility patent because there are no similar exemptions.²⁰¹ Anyone violating the utility patent holder's property right faces liability for patent infringement.²⁰² The Court explained that because the requirements for a utility patent are more stringent than the requirements for a certificate under the PVPA, it follows that utility patent holders are entitled to greater patent protection.²⁰³

Finally, J.E.M. argued that "dual protection" could not exist where statutes overlap.²⁰⁴ The Court dismissed this argument, however, finding not only that the overlap of the statutes is only partial, but also that in previous intellectual property cases, dual protection has been allowable through both trade secret and patent protection.²⁰⁵

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See id. at 142 (citing 35 U.S.C. §§ 101-103).
     194.
     195.
              See id. (citing 35 U.S.C. § 112).
     196.
              Id. at 143.
              7 U.S.C. § 2402(a) (2000).
     197.
              J.E.M. Ag Supply, Inc., 534 U.S. at 142.
     198.
     199.
              See id. at 142-43 (citing 7 U.S.C. §§ 2422(2), 2422(4) (2000); 7 C.F.R. § 97.6
(2001)).
     200.
              Id. at 140.
     201.
     202.
              See id. at 138 (citing 7 U.S.C. §§ 2402(a), 2541(a) (2000)).
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See id.

193.

^{203.} *See id.* at 124, 142-43. 204. *See id.* at 144.

^{205.} See id.

The Court also noted the fact that for the past sixteen years neither Congress nor agencies dealing with patents have ever questioned the issuance of utility patents for plants as being inconsistent with the PPA and PVPA statutes. Congress even appears to have recognized the availability of utility patent protection for plants by enacting the 1999 amendment to 35 U.S.C.§ 119, covering the right of priority for patent rights. Under the amendments, Congress acknowledged that plant breeders filing an application for plant breeders rights in a WTO member country would be viewed as subject to the same conditions and requirements as patent applications for purposes of determining the right of priority. The Court said that this amendment acknowledged the fact that Congress viewed plants as being subject to patent protection since it had specifically addressed the rights of priority for plant breeders when it enacted the amendment to § 119.

d. Concurrence by Justice Scalia

In Justice Scalia's concurrence, attention was focused on the issues addressed previously in *Chakrabarty*, where the Court questioned whether living things were included within the term "composition of matter." He pointed out that the only way the PPA language could have clarified this ambiguity is if it had distinguished plants as being in their own category, while still being included within the category of other living things. He noted, however, that stare decisis prevents the Court from analyzing the question of whether "composition of matter" includes living things. Justice Scalia also believed that the majority Court correctly applied the canon against repeal by implication.

e. Dissent by Justices Breyer and Stevens

The dissent viewed the issue before the Court to be "whether the words 'manufacture' or 'composition of matter' contained in the utility patent statute . . . cover plants that also fall within the scope of two more specific statutes, the Plant Patent Act of 1930 (PPA) and the Plant Variety Protection Act

^{206.} See id. at 145.

^{207.} See id.

^{208.} See id.

^{209.} See id.

^{210.} *Id.* at 146-47 (Scalia, J. concurring).

^{211.} Id

^{212.} *Id*.

^{213.} *Id*.

(PVPA)...."²¹⁴ The dissent believed that Congress intended only to afford plants the protections offered by the two more specific statutes referring specifically to plants, rather than being granted full utility patent protection.²¹⁵

i. Was Chakrabarty the Controlling Case in this Instance?

The dissent began its analysis by pointing out that the specific issue of plant patent protection was not the question considered in *Chakrabarty*. The dissent distinguished the current case from *Chakrabarty* by pointing out that *Chakrabarty* dealt with whether the terms "manufacture, or composition of matter," from the utility patent statute encompassed such living things as bacteria. That being said, the dissent noted that *Chakrabarty* neither decided nor answered the current question of plant patent protection; therefore, *Chakrabarty* was not controlling in the case before the Court. Neither the PPA nor the PVPA were at issue in *Chakrabarty*. 18

ii. The Enactment of the PPA Showed Congress' Intent to Preclude Plants from Utility Patent Protection.

The dissent turned next to the PPA and the congressional intent behind the enactment of the PPA regarding patent protection available to plants.²¹⁹ Looking at the language of the PPA, the dissent found that the seeds at issue were intended to be covered by the PPA, and are hence excluded from the broader utility patent protection.²²⁰ The fact that a plant under the PPA must have been produced on more than one occasion through asexual reproduction, that is reproduced using a graft, does not mean that plants covered under the PPA are in a separate category from plants that reproduce sexually, thereby producing seed.²²¹ The dissent found that the asexual reproduction requirement for PPA protection was included to ensure that the plant variety could be reproduced in such a way that would guarantee that the protected genetic characteristics stayed true to form showing that a new variety had in fact been created.²²² Otherwise, there was no guarantee that the patented characteristic might not be a result of environmental

^{214.} *Id.* at 147 (Breyer, Stevens, JJ., dissenting).

^{215.} *Id*.

^{216.} See id. at 148.

^{217.} See id. at 147.

^{218.} See id. at 148.

^{219.} *See id.* at 149.

^{220.} See id.

^{221.} See id. at 150.

^{222.} See id.

factors rather than a new variety based on changes in genetic makeup.²²³ Although sexually reproducing varieties that can also be produced asexually fall within the type of plants within the meaning of the PPA, patent protection offered under the PPA was limited specifically to varieties which could *only* produce through asexual reproduction.²²⁴ Under the PPA plant breeders only receive the exclusive right to reproduce their plants asexually; they do not receive the exclusive right to produce that same *variety* through sexual reproduction.²²⁵ The dissent raised the distinction between the scope of the PPA and its limitation of patent protection to *only* those plants produced asexually to refute the majority holding that Congress' understanding of plant breeding was so limited that it never contemplated whether or not sexually reproduced plants could be entitled to patent protection.²²⁶

Based on this interpretation of the PPA, the dissent found the PPA and the Utility Patent Statute to be incompatible.²²⁷ The dissent also noted that the amendments to the PPA in 1952 did nothing to change this interpretation of the original enactment of the PPA.²²⁸

iii. PVPA Provides Exclusive Patent Protection for Sexually Reproducing Plants

The dissent continued its analysis by turning to the PVPA. ²²⁹ Looking at the legislative history, the dissent noted that although a special Presidential Commission recommended the removal of all provisions of the patent statute dealing with plant protection, Congress enacted the PVPA, while continuing to maintain the PPA as well. ²³⁰ Under the PVPA, plants reproduced by seed were entitled to patent-like protection for twenty years. ²³¹ Specifically, under the PVPA plant breeders were entitled "to sell, offer to sell, reproduce, import, or export the [patented] variety, including the seed." ²³² The dissent focused on the exemptions provided by the PVPA and explained that the majority view totally destroys the research exemption. ²³³

^{223.} See id.

^{224.} *Id*.

^{225.} *Id.* at 151.

^{226.} *Id*.

^{227.} See id. at 152.

^{228.} See id. at 153.

^{229.} See id.

^{230.} See id.

^{231.} See id.

^{232.} *Id.* at 154.

^{233.} See id. at 155.

The dissent also dismissed Pioneer's argument that the differences in criteria between obtaining a utility patent and a patent certificate under the PVPA justify the difference in the level of protection offered to the plant variety.²³⁴ It found "no relationship between the criteria differences and the exemptions," and questioned "why Congress would want to destroy the exemptions in the PVPA that Congress created."²³⁵

The dissent also rejected the canon disfavoring repeal by implication, noting that reliance on this canon was "misplaced" in this case because the PPA explicitly amended the utility patent statute by only offering patent protection to plants which had been reproduced asexually. Traditionally, the canon of "implied repeal" occurs in circumstances involving a later statute that implicitly modifies an earlier statute. The dissent finished by stressing that unlike playing a game of "Rubik's Cube," which is based on pure logic, interpreting legislative intent requires "an analysis of language, structure, history, and purpose" to discern the human intent behind the enactment of the statute. The dissent concludes that such an analysis of legislative intent in this case would have led to a majority conclusion that the utility patent statute was never intended to apply to plants.

f. The Court's Holding

In a 5-2 decision, the Supreme Court ultimately found that plants are proper subject matter under 35 U.S.C. § 101 and should receive full utility patent protection; thus plants are not limited solely to the patent-like protection offered by the PPA and PVPA.²⁴⁰ The Court based its decision upon the broad interpretation of the proper subject matter for utility patents should include anything manmade under the sun.²⁴¹ The Court held that although the PPA of 1930 and PVPA of 1970 offer patent protection specifically for plants, nothing in the language of these two statutes indicated that those should be the only types of patent protection available to plants in the future.²⁴²

^{234.} See id. at 154-55.

^{235.} See id. at 155.

^{236.} See id. at 155-56.

^{237.} See id. at 155.

^{238.} *Id.* at 156.

^{239.} *Id*.

^{240.} See id. at 145.

^{241.} See id. at 130.

^{242.} See id. at 132, 138.

III. HISTORY OF INTERNATIONAL PATENT LAW & ORGANIZATIONS DEALING WITH PATENTS FOR PLANTS

Many of the organizations existing today with regard to international patent law and plant patent protection were formed a number of years ago, and these groups and organizations have acted in a variety of ways to influence the development of patent rights not only in the United States, but to the various other member countries as well.

A. Union for the Protection of New Plant Varieties

The Union for the Protection of New Plant Varieties ("UPOV") was created in 1961 by six European nations.²⁴³ It was created to provide an international convention to address and propose legislation dealing with plant breeders rights; a system of uniformity from country to country regarding the general rights of plant breeders.²⁴⁴ Currently, there are fifty-two member states in the UPOV, but limited participation has been viewed as a drawback to the effectiveness of this group.²⁴⁵

To qualify for UPOV protection a plant breeder must show that the new variety is "(i) distinct from existing, commonly known varieties, (ii) sufficiently uniform, (iii) stable, and (iv) new in the sense that [it] must not have been commercialized prior to certain dates established by reference to the date of the application for protection."²⁴⁶ When a state becomes a member of UPOV, it acknowledges and accepts common worldwide principals and practices regarding plant breeding.²⁴⁷ Plant breeders within these member states are assured that their varieties will be protected by the same standards used in other member states.²⁴⁸ Note, however, that under the UPOV, varieties used for research purposes do not

^{243.} *See* Rives, *supra* note 37, at 193.

^{244.} See Scalise & Nugent, supra note 43, at 108 (stating "The purpose of the UPOV Convention is to ensure that the member States of the Union acknowledge the achievements of breeders of new plant varieties, by making available to them an exclusive property right, on the basis of a set of uniform and clearly defined principals.") THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS: WHAT IT IS, WHAT IT DOES (Dec. 2002) [hereinafter THE INTERNATIONAL UNION], available at http://www.upov.int/en/about/pdf/pub437.pdf.

^{245.} See The International Union, supra note 243; see also Scalise & Nugent, supra note 43, at 108-09.

^{246.} THE INTERNATIONAL UNION, *supra* note 243.

^{247.} See id.

^{248.} See id.

require authorization from the plant breeder.²⁴⁹ Despite this research exemption, the UPOV uniform system provides an incentive for plant breeders to invest in and explore foreign plant and seed ventures because all sales of seeds and plant materials will be protected.²⁵⁰

A drawback of the UPOV, however, is that its effectiveness in protecting large investments surrounding improvements in plant varieties and characteristics, including biotechnology, is limited by the number of countries participating as UPOV members.²⁵¹ For example, if you had a new biotechnology variety in a staple crop such as wheat and you were trying to market it worldwide, a uniform system of plant variety protection would only be available in the countries that are member nations of the UPOV. Given the fact that a great majority of the countries in the world today are not members of the UPOV²⁵² and do not have any form of plant variety protection in their own domestic laws,²⁵³ it is easy to see how agribusinesses have become frustrated in their attempts to produce and market improved varieties which are often in high demand worldwide, but at the same time trying to protect their investment costs and resources as well.

A second drawback is that under the UPOV, a member nation may have a domestic law that provides a farmer's exemption regarding the use of protected varieties and seeds.²⁵⁴ As a result, UPOV member nations may be required to abide by such domestic laws, even if the plant variety was registered in a nation that did not provide a farmer's exemption.²⁵⁵

In addition, amendments to the UPOV convention in 1991 also provided that plant breeders' rights and patent rights should be viewed separately. Under the amendments, member nations are not required to grant reciprocal plant breeding rights to those plant varieties and other living organisms which have received patent protection in another country. This is different from other inventions which can receive utility patent protection, based upon the concept of reciprocity between all member countries.

^{249.} See id.

^{250.} See id.

^{251.} See Scalise & Nugent, supra note 43, at 108.

^{252.} Id.

^{253.} *Id*.

^{254.} *Id.* at 109.

^{255.} *Id*.

^{256.} Id.

^{257.} Id.

^{258.} See, e.g.35 U.S.C. § 104 (2000) (stating "where an invention was made by a person while domiciled in the United States or a NAFTA country, the person shall be entitled to the same rights of priority in the United States with respect to such invention").

Reciprocity between the member countries is an agreement to honor the patents issued by other member countries, without requiring a separate and distinct patent application in every member country. But this concept of reciprocity between member countries does not extend to patented plant varieties or patents on other living organisms. Therefore, even if a plant variety from the United States had received patent protection under the UPOV, other member nations would not be required to automatically provide reciprocal plant breeder's rights to such a variety. Electrical plant breeder's rights to such a variety.

Another example of this type of situation where UPOV member countries are not required to reciprocate plant patent protection exists in Argentina.²⁶² Argentina is a UPOV member country that plants and grows Roundup Ready Soybeans which are protected by a plant patent here in the United States.²⁶³ Under the amendments to the UPOV, however, Argentina is not required to honor the U.S. patent on the soybeans because they are plant material which is exempt from the reciprocity requirement.²⁶⁴

B. WIPO—World Intellectual Property Organization

A second international committee that deals with plant patent protection is the World Intellectual Property Organization ("WIPO"). The WIPO serves as the administrative body charged with administration of the Paris Union on the Protection of Industrial Property. The Paris Union is comprised of member countries who share three common objectives: (1) gaining national treatment whereby every member country agrees to provide the same treatment to foreign patent applicants that is provided to domestic patent applicants; (2) establishing a "Right of Foreign Priority," whereby each member state agrees to observe the original filing date in another country as the date of priority in any patent disputes; and (3) establishing provisions and procedure for dealing with unfair competition, so that each member state must enact legislation providing for unfair

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^{259.} Elly Ladas, *WIPO Patent Agenda Request for Comments* (Mar. 5, 2002), *at* http://patentagenda.wipo.int/rfc/rfc1/0046.html (discussing WIPO patent agenda).

^{260.} See Scalise & Nugent, supra note 43, at 109.

^{261.} See id.

^{262.} See U.S. GEN. ACCOUNTING OFFICE, supra note 18, at 3.

^{263.} See id. at 4, 6.

^{264.} See Scalise & Nugent, supra note 43, at 109.

^{265.} See id. at 105-08 (describing the functions of WIPO).

^{266.} Id. at 106.

competition penalties in international trade.²⁶⁷ In other words, "[t]he provisions of the Paris Union benefit foreign inventors by ensuring equal access to the intellectual property laws of member nations and by securing an internationally recognized priority date from the first patent application regardless of where the application was filed."²⁶⁸

The predecessor of WIPO was the United International Bureau for the Protection of Intellectual Property ("BIRPI"), which began in 1893.²⁶⁹ In 1970, BIRPI became known as WIPO.²⁷⁰ By 1974 "WIPO, [had become] a specialized agency of the United Nations system of organizations, with a mandate to administer intellectual property matters recognized by the member states of the UN."²⁷¹ In 1996, WIPO entered into a cooperation agreement with the WTO for the management of intellectual property rights in globalized trade.²⁷² "A fundamental and enduring part of WIPO's activities in promoting the protection of intellectual property is the progressive development and application of international norms and standards."²⁷³

Currently there are 179 member states belonging to the WIPO,²⁷⁴ and as the administrative body of the Paris Union, the WIPO also has a vision of creating a uniform system providing minimum patent protection with the use of one application.²⁷⁵ Ideally, the WIPO would serve as a forum for discussion and debate over potential developments and suggestions regarding international intellectual property laws, however, that goal has not yet been achieved.²⁷⁶

It seems that developed nations would favor WIPO and its actions, however, WIPO is a subsidiary organization of the U.N., meaning that a majority of its members are developing nations.²⁷⁷ Given this fact, developed nations such as the United States are generally wary of the activities taken or suggested by WIPO

^{267.} *Id*.

^{268.} Id.

^{269.} WORLD INTELLECTUAL PROPERTY ORGANIZATION, GENERAL INFORMATION: THE BEGINNING, *available at* http://www.wipo.org/about-wipo/en/gib.htm#P29_4637 (last visited Apr. 7, 2003).

^{270.} *Id*.

^{271.} *Id*.

^{272.} Id.

^{273.} World Intellectual Property Organization, General Information: Development of International Intellectual Property Law, *available at* http://www.wipo.org/about-wipo/en/gib.htm#61_9104 (last visited Apr. 7, 2003).

^{274.} WORLD INTELLECTUAL PROPERTY ORGANIZATION, *supra* note 268, *available at* http://www.wipo.org/about-wipo/en/gib.htm#P29 4637.

^{275.} Scalise & Nugent, *supra* note 43, at 106-07.

^{276.} Id. at 106.

^{277.} *Id.* at 107.

because they worry that the needs and demands of the developing nations will override those concerns of the already developed nations.²⁷⁸ As a result, developed nations agree with private industry's favoritism of GATT as compared to WIPO.²⁷⁹ This is because GATT is a more favorable forum for developed nations due to the fact that it gives developed countries a stronger influence in policy making due to the greater economic power that they can bring to the table.²⁸⁰ Therefore, GATT has "emerged as the principal vehicle for implementing liberalized international trade policy."²⁸¹

In light of the foundation of the WIPO formation and its sensitivity to developing nations' concerns, WIPO has repeatedly denied the inclusion of plants as proper subject matter for patent protection.²⁸² According to WIPO, patent protection for plants should be limited to the terms of the UPOV.²⁸³ WIPO does not seem to want to lead in the solution to the patent issues surrounding plant and animal creations. Rather, WIPO seems content to act as a consultant in achieving international harmonization between countries on the issue of patents for plants and other living things.²⁸⁴

C. The Role of the United States in Creating TRIPs

As a general observation, developed countries are greatly in favor of uniformity of intellectual property standards that offer strong protections for inventor rights.²⁸⁵

Uniform intellectual property standards are essential to the protection of consumers in the developed nations who use and support the cost of the limited monopoly offered under the patent system. ²⁸⁶ Without uniform intellectual property standards, consumers in developed nations are supporting a system which gives inventors (often corporations) a limited monopoly over the product. This time limited monopoly allows the inventors to charge a premium for the new

^{278.} *Id*.

^{279.} *Id*.

^{280.} *Id*.

^{281.} *Id.* at 114.

^{282.} *Id.* at 107.

^{283.} Id.

^{284.} *Id.* at 107-08.

^{285.} See Lee Petherbridge, Comment, Intelligent TRIPs Implementation: A Strategy for Countries on the Cusp of Development, 22 U. Pa. J. INT'L ECON. L. 1029, 1029-30 (2001). 286. See id.

product, while preventing others from mimicking or producing a replica of the product and selling it to the consumer for a lower price.

The United States has been and continues to be a particularly strong advocate for the adoption of worldwide affirmative standards of intellectual property rights.²⁸⁷ The United States began a strong push for reciprocal recognition of patent protection in other countries for U.S. inventions when it passed § 301 of the Omnibus Trade and Competitive Act of 1988.²⁸⁸ Since then, the United States has been joined by Japan, the European Commission, and other developed nations who are also searching for a solution to the dilemma surrounding international patent controversies.²⁸⁹ "The [Omnibus Trade and Competitive] Act requires that U.S. Trade Representatives annually review the intellectual property regimes of the United States' trading partners and place countries whose regimes are below acceptable standards on a priority watch list."290 Once a country has been placed on the watch list, the next step is usually a period of discussions between the United States and the listed country to try and resolve the situation.²⁹¹ If a suitable resolution is not agreed upon regarding the IPRs available in the listed country, the United States will usually enact unilateral sanctions against the listed country.²⁹² "This strategy has been particularly effective when used against countries that rely heavily on exports to the United States."293

Despite the success of § 301, there has been a push by United States businesses and the Government to create new international property law. This demand is probably a result of the inefficiencies associated with the "bilateral methods of encouraging change in the intellectual property policies of U.S. trading partners" Many developing nations, however, who were also members of WIPO and made up the majority in WIPO, refused to promulgate new standards for international intellectual property through WIPO. As a result, the

^{287.} See id. at 1030 (stating that the United States has "strongly encouraged the rest of the world to adopt substantive affirmative standards of intellectual property protection); see Scalise & Nugent, supra note 43, at 114 (stating that the United States has a "push for a universally accepted system of intellectual property protections"). The United States loses approximately \$60 billion a year due to patent infringement by developing nations. Id.

^{288.} Petherbridge, *supra* note 284, at 1030; *see also* 19 U.S.C. §§ 2411-2420 (1999).

^{289.} Scalise & Nugent, supra note 43, at 114.

^{290.} Petherbridge, *supra* note 284, at 1030.

^{291.} *Id*.

^{292.} Id.

^{293.} Id.

^{294.} *Id.* at 1030-31.

^{295.} *Id.* at 1030.

^{296.} Id. at 1031.

United States sought to pursue changes in the area of intellectual property rights through GATT at the Uruguay Round meeting in 1986.²⁹⁷ The key aspect of negotiating intellectual property rights under GATT was that intellectual property rights were now linked directly to trade.²⁹⁸ This gave the United States the greatest amount of leverage and economic pressure to push for strong intellectual property standards, and in 1994, resulted in the passage of the Trade-Related Aspects of Intellectual Property Agreement ("TRIPs").²⁹⁹ TRIPs is a part of GATT, which specifically addresses intellectual property issues.³⁰⁰

D. TRIPs/WTO – GATT-TRIPs Agreement

TRIPs has been hailed by some as "the most significant trade development in the international protection of intellectual property."³⁰¹ Under the TRIPs Agreement, patents are protected for a period of twenty years beginning on the date that the patent was filed. ³⁰² Member states may not pick and choose what industries or fields are available for patent protection; under TRIPs, all fields of science and industry are able to seek patent protection.³⁰³

One of the important improvements made by the GATT-TRIPs agreement has been the alterations to a more practical enforcement procedure. Under the new enforcement procedures a member nation files a complaint before the World Trade Organization panel alleging an injury caused by another nation's trade practices. A country that fails to comply with a panel order faces the prospect of legitimate trade retaliation by the victim country to compensate for the economic injury caused by the offense. Under the TRIPs Agreement there is an obligation to have enforcement rights, which carry over obligations in relation to patents.

^{297.} *Id*

^{298.} *Id.* at 1031-32.

^{299.} *Id*.

^{300.} *Id*

^{301.} PAUL GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES: 1009 (rev. 4th ed. 1999).

^{302.} Id.

^{303.} *Id*.

^{304.} *Id.* at 1009-10.

^{305.} *Id.* at 1010.

^{306.} Id.

^{307.} Cash Crops? Agricultural Biotechnology and Intellectual Property Rights in the Developing World, available at http://www.foodfirst.org/progs/global/ge/gmf-debate.html (last visited Mar. 31, 2003) [hereinafter Cash Crops?] (quoting Jeffrey Kushan from debate transcripts).

Under the TRIPs Agreement, although all fields of science and industry are able to seek patent protection, member states do not have to give patent protection to plant and animal inventions. Section 27.3b of the TRIPs Agreement says that although member states may elect not to grant patent protection to plants, they must provide patent protection to living things which are not plants or animals, such as microorganisms. With regard to plants, member states not providing patent protection to plants must instead offer protection for plant varieties "by an effective *sui generis* system or by any combination thereof." Due to this TRIPs provision, many member states are only providing genetically modified plants and seeds with plant variety protection rather than patent protection.

Because this provision does not specifically address genetically modified plants and seeds, however, it can be argued that these genetically modified plants are in fact entitled to patent protection indirectly given the fact that TRIPs would require member states to provide patent protection to *any* microorganisms and genes used as part of the genetically modified plant, as long as it had been engineered and invented by man and had an industrial application. Under this argument it would appear that once a manmade and engineered gene had been created and patented, TRIPs protection could apply, unless there was some other applicable exclusion. The exclusion preventing patents for life forms would not apply because under TRIPs only plants and animals are excluded from protection; the individual genes comprising genetically engineered plants, would not arguably qualify as a plant or an animal, and therefore should be available for patent protection under TRIPs. Thus, while the TRIPS Agreement may not force states to implement strong intellectual property protection for genetically

310. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 307, at Annex 1C, Part II, § 5, art. 27.3.

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^{308.} Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Part II, § 5, art. 27.3b (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (stating that "Members may also exclude from patentability: . . . plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.").

^{309.} See id.

^{311.} See Murphy, supra note 25, at 68.

^{312.} See id. at 68-69 (stating, "States wishing to deny such protection might argue that genes are not even microorganisms, in the sense of being unicellular organisms capable of propagation. Alternatively, such states might seek to argue that patent protection may be denied to protect ordre public or morality. Yet it is unclear whether such a denial can be justified under the TRIPS Agreement with respect to, say the gene used to create a vitamin-enriched rice, where there is no scientific basis for regarding the gene or the rice as harmful to human health or the environment.").

^{313.} See id.

modified organisms, it may force states to achieve the same result indirectly by protecting patented genes."³¹⁴

IV. WHAT IS LIKELY TO BE THE NEXT STEP IN THE DEVELOPMENT OF PATENT PROTECTION FOR PLANTS?

Although the United States seems to have reached a resolution regarding the type of patent protection available to plants following the *J.E.M. Ag Supply* decision, it is unknown how plant patent protection is likely to be viewed on an international level.

A. WTO Issues Regarding Agricultural Biotechnology

The potential benefits of agricultural biotechnology adoption worldwide could be significant. Through the adoption of genetically altered varieties, one potential benefit might be that the dependence and use of chemical fertilizers and pesticides could be lessened,³¹⁵ while other genetic alterations might lead to improved varieties that would use less water,³¹⁶ or varieties that would supply needed vitamins and minerals to help overcome health problems associated with poor nutrition.³¹⁷ These types of seed developments could in turn also lead to a reduction in the amount of machinery and fuel required for agricultural production practices.³¹⁸ Ultimately, adoption of genetically modified crops should result in lowered production costs, while still meeting ever increasing food demands.³¹⁹

Despite the great promise of biotechnology and its benefits to developing nations, there is a valid concern that the expensive licensing fees associated with the use of these improved products and varieties will prove to be an insurmountable barrier, even if user countries are willing to pay the high fees and overlook the ethical dilemma surrounding the adoption of genetically modified crops. Given the fact that many corporations have invested millions of dollars in research and development of these new agricultural biotechnology products, and compounded by the fact that the corporations only have a limited period to recoup their investment costs through the monopoly provided by the patent system,

^{314.} *Id.* at 69.

^{315.} *Id.* at 55.

^{316.} *Id.* at 56.

^{317.} *Id*.

^{318.} *Id.* at 55.

^{319.} *Id*.

^{320.} *Id.* at 62.

there will be little incentive for the corporations to research and develop those crop varieties that are most likely to be of importance to developing nations.³²¹ From an economic standpoint, agricultural biotechnology companies are going to focus on those products which are produced in countries which are going to be able to pay for the use of its products.³²²

It is important to realize that TRIPs has not by itself created uniformity between countries regarding their intellectual property systems.³²³ With regard to plants, TRIPs allows for the patenting of plants³²⁴ or for plant variety protection under a system such as UPOV,³²⁵ but that in itself does not create much uniformity given the huge difference in the amount of protection offered by these two different protections. Also, just because patent protection is available for a plant does not necessarily mean that a country will not set a higher standard than the United States so that patents for plants in the United States still would not be recognized in other countries because the product or plant does not meet the patent criteria of that particular country. So in reality, there really is not that much uniformity required by the TRIPs agreement regarding plant patent protection.

Another important fact to realize is that the United States has a well established and mature intellectual property system.³²⁶

Virtually nowhere else in the world—particularly in the developing world—do you find this refinement in the legal environment for protection of intellectual property. In fact, in virtually all developing countries, you cannot get patents on things which are not covered under the U. S. patent system, and in many countries in the developing world, you cannot get patents period, because they don't have the wherewithal...there are just not many patents at all out there. 327

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^{321.} *Id.* at 66.

^{322.} See id. at 67 (However, one should also note the situation currently occurring in Argentina and Brazil. Monsanto is selling its Roundup Ready soybeans despite the fact that patent protection for the seeds is not available in either country. Could this decision to sell down there be motivated by the high demand for the product? Does the pure sales volume to these two countries create enough of an incentive and profit margin for Monsanto to sell down there even though the farmers are not paying a premium for the product?

^{323.} See Cash Crops?, supra note 306.

^{324.} Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 307, at Annex 1C, Part II, § 5, art. 27.3b (1994).

^{325.} *See* Rives, *supra* note 37, at 193.

^{326.} See Cash Crops?, supra note 306 (paraphrasing Jeff Kushan from the debate transcripts).

^{327.} *Id*.

Currently there are fifty-two countries operating under the UPOV plant variety protection system.³²⁸ That means that there are still many countries who do not recognize plant breeders' rights, let alone patent protection for plants.³²⁹

B. Will Full Patent Protection for Plants Such as Roundup Ready Soybeans
Be Recognized by Other Countries? Understanding the
Significance of the Jurisgenerative Nature of International Law

Understanding the various bodies and forums of international organizations is important to successfully negotiate the limits and opportunities available on an international scale. But the true key to international business involving patented products is a thorough understanding of the significance and meaning of the domestic laws within a member country.

International law in this area is not generated solely or even primarily through treaties; rather, it emerges from a more complex system of law creation, clarification, interpretation, and implementation that can be viewed as involving three fundamental processes. First, international law is clearly driven in many respects by the self-interest of states. Second, international law develops through the social interaction of state and non-state actors. Finally, international law is often only defined, refined, and made effective after being grounded in national law and society. 330

Basically, the United States has taken the lead in this process as far as creating utility patent rights for plants.

Beyond the adoption of various Intellectual Property Rights ("IPR") agreements on an international level, the practicality and implementation with respect to the domestic laws of individual nations is a hurdle facing biotechnology companies seeking to enforce plant breeder rights and patent protection for living products. ³³¹ "In this regard, the focus is not just on what the law says is subject to IPR claims, but also on how the courts, patent officials, or foreign governments may apply those provisions to individual claims of protection." Consider the case pending in Brazil regarding the issue of whether it will be legal to grow Roundup Ready Soybeans in Brazil after testing has been completed by state agencies regarding the safety and likely environmental effects of growing

329. See id.

^{328.} *Id*.

^{330.} Murphy, *supra* note 25, at 97.

^{331.} See Hamilton, supra note 1, at 646.

^{332.} *Id*

genetically altered plants.³³³ Also, consider the problems that Argentina is having regarding the enforcement of its plant breeders' rights and the requirement that sales of soybean seed protected by these rights be certified.³³⁴ The demand for Roundup Ready soybean seeds has created a profitable and highly lucrative black market.³³⁵ The growers want and need the product so badly that they are willing to risk being caught and found in violation of the plant breeders rights.³³⁶ And given the harsh reality of Argentina's economic situation to support the manpower and technology to properly enforce the rights of plant breeders, the growers estimate that risk of getting caught and being punished is minimal.³³⁷

It is one matter to say a new variety of plant or a genetically altered material is patentable. But, it is another mater for the 'creator' to be able to obtain a patent and defend it against the traditional challenges, such as non-obviousness and prior art, which may be brought by other companies with competing claims or to prevent infringement by other companies in developing nations.³³⁸

Despite questions regarding its own precarious state of patent protection for plants, the United States has been pushing hard for worldwide adoption of full intellectual property standards, especially with regard to patent protection for plants.³³⁹ Since the *J.E.M. Ag Supply* decision by the Supreme Court, any doubts surrounding whether or not plants are in fact entitled to full United States patent protection should be resolved. The pressure for other countries to adopt United States standards for intellectual property protections for plants will likely be even stronger. "The industry view is that the U.S. [is now] in the best position to both advance and standardize an international system of PIPR."³⁴⁰ With the recent *J.E.M. Ag Supply* decision, however, any uncertainty regarding full patent protection for plants seems to have been cleared up: Plants are entitled to full patent protection, and they are not limited solely to protection under PPA or the PVPA.³⁴¹ As a result, the *J.E.M. Ag Supply* decision has placed the United States in a stronger position to push for international adoption of similar IPR standards.

^{333.} *See* Hamilton, *supra* note 27, at 101-102.

^{334.} See generally U.S. GEN. ACCOUNTING OFFICE, supra note 18.

^{335.} *See id.* at 14-16.

^{336.} See id. at 4.

^{337.} See id. at 5 (stating factors in GAO Study on United States-Argentina market).

^{338.} Hamilton, *supra* note 1, at 652.

^{339.} See id.

^{340.} *Id*.

^{341.} See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 144 (2001).

V. CONCLUSION

Currently, with respect to genetically modified ("GM") varieties of crops, the issues receiving the greatest amount of attention are the labeling of GM products and whether countries are going to be able to protect their natural and agricultural diversity. In many instances companies now give away these technologies and varieties in an attempt to promote biotech foods. By offering the seeds to farmers so that they can grow the crops and see the benefits, large agri-businesses hope to promote the use of their GM products. Consumers will also be able to see some of the benefits as new products come down the line, such as Golden Rice.

Eventually, however, U.S. companies will need to recoup their research and development costs, and they will only be able to do so if other countries recognize full patent protection for plants. At present, these companies claim that they can only partially recoup their costs by licensing the technology and the genes used in these genetically altered plants and seeds.³⁴³ They may license the technology to scientists, but these fees pale in comparison to the profit that could be realized on sales of individual bags of seed. Unless all nations begin to recognize full patent protection for GM plants uniformly, however, only United States farmers will bear the high costs of research and development, even though GM crops are grown around the world. And this greater cost to United States farmers makes them less competitive. For example, both Argentina and Brazil grow Roundup Ready soybeans, as do United States farmers, but they do not pay the same technology fees that United States farmers are required to pay, even though the same seed is used.³⁴⁴ This difference in seed cost, coupled with other costs of production required for growing soybeans, gives Argentina and Brazil a large competitive advantage due to a greater profit margin.³⁴⁵ As a result, within the next few years, it is likely that the United States could be replaced as the number one world exporter of soybeans by Argentina and Brazil. 346

The next legal step for biotechnology companies is to press other countries to recognize this as well and allow full patent protection for plants. Given the fact that Congress has not amended the patent statutes since the Supreme

^{342.} Hamilton, *supra* note 1, at 623.

^{343.} See Rories, supra note 75, at 755.

^{344.} See U.S. GEN. ACCOUNTING OFFICE, supra note 18, at 13-14.

^{345.} *See id.* at 11; RANDALL D. SCHNEPF ET AL., USDA., AGRICULTURE IN BRAZIL AND ARGENTINA: DEVELOPMENT AND PROSPECTS FOR MAJOR FIELD CROPS 20, 22 (2001), available at http://www.ers.usda.gov/Publications/wrs013/wrs013.pdf (last visited Apr. 2, 2003).

^{346.} See SCHNEPF ET AL., supra note 344, at 70.

Court's decision to allow living organisms full patent protection, and the Court's reliance upon that holding in *J.E.M. Ag Supply*, it does not seem likely that Congress will now elect to change patent applicability to plants.

As a result, biotechnology lobbyists and advocates will likely use the *J.E.M. Ag Supply* decision to push for greater adoption of full patent protection by other nations, pointing out that plants have been receiving full patent protection in the United States for the past twenty years, and that the rest of the world should view western patent law as a model.

The legal and agricultural communities, as well as the public, must be educated to realize that this is not simply an issue of corporate profits. As shown with the example of Roundup Ready soybeans grown in Argentina and Brazil, the future of American agriculture may be jeopardized if American farmers alone bear the costs of the research and development for development of new GM varieties. Extending patent protection for plants to the international level through the WTO negotiations and TRIPs amendments could be an important next step.