NATIONAL AGLAW CENTER RESEARCH ARTICLE, J.E.M. AG SUPPLY, INC. V. PIONEER HI-BRED INTERNATIONAL, INC.: ITS MEANING AND SIGNIFICANCE FOR THE AGRICULTURAL COMMUNITY

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I. INTRODUCTION

On December 10, 2001, the United States Supreme Court in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* (hereinafter "*J.E.M.*"),[1] held that utility patents may be issued for plants under 35 U.S.C. § 101 (hereinafter "Utility Patent Act")[2] despite distinct protections available under the Plant Variety Protection Act (hereinafter "PVPA")[3] and the Plant Patent Act (hereinafter "PPA").[4] *J.E.M.* was the first United States Supreme Court decision in two decades to rule on the eligibility for patenting under the Utility Patent Act.[5] The Supreme Court's decision has important implications for the agricultural community.[6]

This article addresses the meaning and significance of *J.E.M.* to the agricultural sector. It outlines the factual, procedural and legal background of the dispute in *J.E.M.* and explains the rationale and scope of the Supreme Court's decision. It addresses the implications of the decision for the agricultural community, including agricultural biotechnology companies, seed companies, and agricultural producers. It also explores the unique issues for utility patent applications under the Utility Patent Act.

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1. 534 U.S. 124 (2001).
2. *See* 35 U.S.C. § 101 (1994).
3. *See* 7 U.S.C. §§ 2321–2583 (1994).
4. *See* 35 U.S.C. §§ 161-164 (1994).
5. Gerald J. Mossinghoff, *High Court Upholds Patents on Genetically–Enhanced Seeds*, LEGAL BACKGROUNDER, Jan. 25, 2002, at 1, *available at* LEXIS, Legal News Publications.
6. *See* Andrew F. Nilles, *Plant Patent Law: The Federal Circuit Sows the Seed to Allow Agriculture to Grow*, 35 LAND & WATER L. REV. 355, 362 (2000).

II. THE ISSUE

The broad issue in *J.E.M.* was whether sexually reproducing plants, specifically hybrid and inbred corn plants, are excluded from the scope of the Utility Patent Act.[7] The development of this issue is framed here in four parts: first, a summary of the background facts creating the controversy; second, a brief primer on the science of plant reproduction; third, a description of the relevant patent statutory provisions and two pivotal pre-*J.E.M.* cases interpreting these provisions; and fourth, an outline of the lower court proceedings that defined the issue for the Supreme Court.

A. Background

1. Parties.

The parties in *J.E.M.* were the plaintiff, Pioneer Hi-Bred International (hereinafter "Pioneer"), and defendants, J.E.M. AgSupply, Inc., dba, Farm Advantage, and distributors and customers of Farm Advantage (defendants are collectively referred to in this article as "Farm Advantage").[1] Henry A. Wallace, who later served as Secretary of Agriculture and Vice-President of the United States, founded Pioneer in 1926.[8] As the world's largest seed producer, Pioneer is an agritech company producing genetically engineered crops.[9]

Farm Advantage is a family-owned agricultural supply business located in Belmond, Iowa.[10] The distributors of Farm Advantage are independent contractors distributing supplies on behalf of Farm Advantage.[11]

2. Facts

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7. J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, 534 U.S. 124, 130 (2001).
8. Brief for Respondent at 14, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
9. *See* Brief of Amici Curiae Washington Legal Foundation and Allied Educational Foundation at 3, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
10. Brief for Petitioner at 2, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
11. *See id.*

In the early 1990s, Pioneer applied for patents on certain new varieties of corn.[12] The United States Patent and Trademark Office (hereinafter "PTO") issued the patents to Pioneer under the Utility Patent Act between January 21, 1992, and November 18, 1997.[13] These patents covered the manufacture, use, sale, and offer for sale of Pioneer's inbred and hybrid corn products.[14]

In the 1998 growing season, Farm Advantage purchased 600 bags of hybrid corn seed produced by Pioneer.[15] The tags affixed to the Pioneer corn seed bags stated the following:

> The purchase of these seeds includes a limited license under patent(s) [numbers omitted] (pending patent applications) to produce a single corn crop in the United States (or other applicable country). This license does not extend to the use of seed from such crop or the progeny thereof for propagation or seed multiplication. Furthermore, the use of such seed or the progeny thereof for propagation or seed multiplication or for production or development of a hybrid or different variety of seed is strictly prohibited.[16]

On its face, this limited license imposes two restrictions: first, farmers are limited to planting the seed for only a single corn crop; and second, purchasers of the seed, such as Farm Advantage, are prohibited from making, using, or selling the seed.[17] Notwithstanding this restrictive language, Farm Advantage sold the seeds to certain of its farm customers, who then planted the seeds in their fields.[18]

3. Lawsuit

As a result of Farm Advantage's sales, Pioneer brought a patent infringement claim against Farm Advantage in federal district court.[19] Pioneer asserted that the hybrid seed corn sold by Farm Advantage was the subject of one or more of seventeen utility patents issued to Pioneer.[20]

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12. *See* id. at 2–3.
13. *See* Brief for Petitioner at 3, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
14. J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, 534 U.S. 124, 127 (2001).
15. Brief for Petitioner at 3, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
16. *Id.* at 5–6.
17. Farm Advantage and its distributors were not licensed as sales representatives of Pioneer. *See J.E.M. Ag Supply, Inc.*, 534 U.S. at 128.
18. Brief for Petitioner at 3, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
19. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 128.
20. Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 49 U.S.P.Q. 2d 1813, 1814 (N.D. Iowa 1998).

Farm Advantage filed a counter-claim of patent invalidity on the grounds that sexually reproducing plants (i.e., seed grown plants) are not included within the scope of the subject-matter provision of the utility patent statute, the Utility Patent Act.[21] Farm Advantage asserted that Congress had superseded the original utility patent statute when it created the PPA and PVPA and that seeds and seed grown plants are protected exclusively by federal law under the provisions of the PVPA.[22] Farm Advantage argued that since the PVPA is the sole means of protection Congress intended to provide for sexually reproducing plants,[23] Pioneer's seventeen utility patents were invalid.[24]

In response, Pioneer argued that its utility patents were valid because sexually reproducing plants are within the scope of the Utility Patent Act.[25] Pioneer asserted that neither the PPA nor the PVPA superceded the Utility Patent Act[26] and that the PVPA is not the sole means of protection for sexually reproducing plants.[27]

Until this case, no federal court had directly addressed whether sexually reproduced plants achieved by plant breeding can be patented under the Utility Patent Act.[28] Thus, the parties' allegations set the stage for a definitive ruling on this issue.

B. Plant Reproduction

Plant reproduction is commonly divided into two methods: sexual and asexual.[29] Each method is distinct and raises separate legal issues. Practical considerations determine which method is used for commercial purposes.[30]

1. Sexual Reproduction

Sexual reproduction involves fertilization, the union of male (pollen) and female (ovule) cells (gamates), to produce a fertilized seed that can grow into

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21. *Id.* at 1815.
22. *Id.* at 1817.
23. *Id.* at 1815.
24. *Id.*
25. *Id.*
26. *Id.*
27. *Id.*
28. *See* Brief of Amici Curiae Monsanto Company in Support of the Respondent at 8, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
29. Brief for Respondent at 1, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
30. *Id.*

a plant.[31] Self-fertilization occurs if the male and female gametes come from a single individual, with pollen fertilizing the ovules inside the flowers on the same individual. Cross-fertilization occurs if the gametes are from different individuals, even if genetically similar. A "hybrid" results from the cross-fertilization of plants that are of different varieties, i.e., plant lines that are genetically distinct.[32]

The goal of sexual reproduction is to produce homozygous plants that have uniform genetic makeup in a desired characteristic.[33] Reaching this goal is a "generational" process. The plant grown from hybrid seed will produce seeds of nonuniform characteristics, so that hybrids are not genetically stable after the first generation. Seed from one year's hybrid crop cannot be used to re-grow the same hybrid crop. To produce "inbred" lines, a plant breeder repeats controlled fertilization over many generations, with appropriate selection of offspring containing the desired characteristics, thereby weeding out undesirable traits.[34]

2. Asexual Reproduction

"Asexual reproduction is reproduction without fertilization, i.e., without the union of male and female cells."[35] Asexual reproduction occurs by grafting, cutting, rooting, or budding and produces an offspring with a genetic combination identical to that of the single parent.[36] Asexual reproduction may occur naturally where plants (e.g., some grasses, dandelions) send out runners along the ground or put out underground stems that in turn produce new plants.[37] Asexual reproduction may also occur as part of human plant breeding, where plants are artificially reproduced without fertilization by established human-engineered methods, e.g., grafting one piece of the plant onto a root piece, resulting in growth of a new plant.[38] Where asexual reproduction occurs either naturally or artificially, an asexually reproduced plant is genetically identical to its parent.[39]

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31. *Id.*
32. *Id. at 2.*
33. *Id.*.
34. *Id.*
35. *Id.*
36. *Id. at* 3.
37. *See* PETER H. RAVEN, ET AL., BIOLOGY OF PLANTS (6th ed. 1999).
38. *See* S. REP. No. 71– 315, at 4–5 (1930); H.R. REP. No. 71–1129, at 4–6 (1930); HERBERT HAYES & RALPH GARBER, BREEDING CROP PLANTS (McGraw-Hill 2d ed. 1927).
39. *See* T. EVERETT, THE NEW YORK BOTANICAL GARDEN ILLUSTRATED ENCYCLOPEDIA OF HORTICULTURE 2801 (1981) ("Plants resulting from vegetative propagation are essentially extensions of the old ones, having a separate physical existence, but identical genetically.").

C. Statutory Protection for Plant Patents

In addressing the issue of whether sexually reproducing plants are excluded from the Utility Patent Act, the Supreme Court in *J.E.M.*. examined the relevant provisions of the Utility Patent Act, the PPA, and the PVPA.[40] Each of these statutes is distinct in its development, requirements, and coverage.[41]

1. The Utility Patent Act

The first patent law was authored by Thomas Jefferson,[42] enacted in 1793,[43] and is now codified at 35 U.S.C. § 101. The language of the original act remains substantively unchanged.[44] As amended, 35 U.S.C. § 101 provides that "whoever invents or discovers any new and useful process, machine, manufacture, or composition or matter, or any new and useful improvements thereof, may obtain a patent therefore, subject to the conditions and requirements of [Title 35]."[45]

Patents issued under § 101 are known as "utility patents" because of its requirement that a patentable invention be "useful."[46] Utility patents are

40. *See J.E.M. Ag Supply, Inc.*, 534 U.S. at 132–145.

41. The Constitution of the United States gives Congress the power to enact laws relating to patents in Article I, § 8, which reads "The Congress shall have the power . . .. to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. CONST. art. I, § 8.

42. Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

43. *See* Act of Feb. 21, 1793, § 1, 1 Stat. 319.

44. As summarized by the United States Supreme Court in *Chakrabarty*: "The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].' . . . . Subsequent patent statutes in 1836, 1870, and 1874 employed the same broad language. In 1952, when the patent laws were recodified, Congress replaced the word 'art' with 'process,' but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Chakrabarty*, 447 U.S. at 308–09 (quoting S. REP.. No. 1979, 82D CONG., 2D SESS., 5 (1952); H.R. REP. NO. 1923, 82D CONG., 2D SESS., 6 (1952).

45. 35 U.S.C. § 101 (1994).

46. *See generally* TrafFix Devices, Inc. v. Marketing Displays, Inc., 532 U.S. 23, 29–36 (2001); *see also* Brenner v. Manson, 383 U.S. 519, 528–36 (1966).

distinct from "design patents," which are issued under 35 U.S.C. § 171 for "new, original and ornamental design[s]" for articles of manufacture.[47]

Utility patent protection is generally available for a term of twenty years from the date of filing a patent application.[48] During this period, the owner of the patent has the right to exclude all others from making, using, or selling any product or process containing or using the patented technology.[49]

The requirements for § 101 reflect the balance of promoting the property interest of the inventor, the need to promote the progress of science, and the recognition that progress comes from imitation and its refinement.[50] The need to restrict unfettered patent rights led to three enabling requirements that must be satisfied to qualify as a utility patent: utility, novelty, and unobviousness over the prior art.[51]

In addition to these requirements, a written description is required by § 112. This section requires a patent application to describe the "invention" with sufficient particularity to enable someone skilled in the relevant technological field to make and use the claimed invention without undue experimentation.[52]

More specifically, § 112 states as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[53]

Before 1930, the requirements for a utility patent were viewed as barriers to patenting plants under the Utility Patent Act.[54] This view arose from the widely accepted "products-of-nature" doctrine, which stands for the proposition that patents only can be issued for inventions stemming from human ingenuity, not for something occurring naturally.[55] Thus, little attention

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47. 35 U.S.C. § 171 (1994).
48. *See id.* § 154 (a)(2).
49. *See id.* § 271(a).
50. *See* MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW (1998).
51. 35 U.S.C. § 101 (1994).
52. *See id.* § 112.
53. *Id.*
54. *See generally* Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of its Creation*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 621, 634 n.65 (2000).
55. Diamond v. Charkrabarty, 447 U.S. 303, 311 (1980).

was paid to applying the patent system to plant-related innovations until later in the 20th century.[56]

2. The Plant Protection Act (PPA)

In 1930, new developments in plant reproduction and commercial plant enterprise led to the passage of the PPA.[57] The pertinent language of the PPA is found in § 161 of Title 35, which provides:

> Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.[58]

Congress' intent in creating the PPA was to protect the output of plant breeding efforts[59] and to place agriculture on the same footing as industry with respect to receiving benefits under the patent system.[60] Thomas Edison applauded the PPA, and, in support of it testified before Congress that "nothing 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 law."[61] In passing the PPA, Congress rejected the "products of nature" doctrine.

The PPA extended patent protection to asexually reproduced plants by giving plant patent holders "the right to exclude others from asexually reproducing the plant . . . or selling or using the plant so reproduced."[62] An invention under the Utility Patent Act must be "new and useful" to obtain utility patent protection, while a plant variety need only be "distinct and new" to be protected by the PPA.[63] Moreover, § 161 plant patent applications are expressly exempt from the description requirements of 35 U.S.C. § 112 so long as "the description is as complete as is reasonably possible."[64]

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56. *See generally* Nathan A. Busch, *Jack and the Beanstalk: Property Rights in Genetically Modified Plants*, 3 MINN. INTELL. PROP. REV. No. 2 2002, at 1–35.
57. *See* Fowler, *supra* note 54, at 625–40.
58. 35 U.S.C. § 161 (1994).
59. *See generally* Ann K. Wooster, Annotation, *Construction and Application of Plant Patent Act*, 135 A.L.R. FED. 273 (1996).
60. *See* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1563 (Fed. Cir. 1995).
61. *Id.* at 1562 (quoting S. REP. No. 315, at 3 (1930)).
62. 35 U.S.C. § 163 (1994).
63. *Id.* at § 161.
64. *Id.* at § 162.

The PPA patent protection does not apply, however, to sexually reproduced plants.[65] Both houses of Congress explicitly rejected making sexually reproducing plants patentable subject matter under § 101 of the Patent Act.[66] This restriction reflected the scientific understanding of the times: in 1930 no consensus existed as to whether sexually propagated plants could in fact be distinguished from naturally occurring plants.[67]

3. The Plant Variety Protection Act (PVPA)

Conventional beliefs about plant biology continued to shift and scientific understanding continued to advance. Doubts about the "ability to distinguish new sexually propagated plant varieties from their naturally occurring predecessors had abated."[68] Given this new environment, Congress in 1970 extended non-patent protection to seed-propagated plants by enacting the PVPA.[69]

Another motivating factor for enacting the PVPA was that the governments of several European countries had already "made available in their respective countries a form of plant variety protection to developers of sexually reproduced plants."[70] These European countries were signatories to the 1961 Act of the International Convention for the Protection of New Varieties of Plants (hereinafter "UPOV Convention") that established a system of plant variety protection characterized by the United States Department of Agriculture (hereinafter "USDA") as "similar" to the PVPA.[71]

The PVPA confers patent-like protection for certain sexually reproduced plants by providing plant variety protection for "[t]he breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who

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65. *Imazio Nursery, Inc.*, 69 F.3d. at 1566.

66. A Senate Report noted that: "Whether the new variety is a sport, mutant or hybrid, the patent right granted is a right to propagate a new variety by asexual reproduction. It does not include the right to propagate by seeds.. This limitation in the right granted recognizes a practical situation and greatly narrows the scope of the bill. S. REP. NO. 71–315, at 4 (1930). The House concurred, stating: "To these ends the bill provides that any person who invents or discovers a new and distinct variety of plant shall be given by patent an exclusive right to propagate that plant by asexual reproduction; that is, by grafting, budding, cuttings, layering, division, and the like, but not by seeds." H.R. REP. NO. 71–1129, at 1 (1930).

67. *See* Fowler, *supra* note 54, at 641.

68. Brief of Amici Curiae Biotechnology Industry Organization at 8, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

69. *See* 7 U.S.C. §§ 2321–2583.

70. *Plant Variety Protection Act: Hearing Before the Subcomm. On Agricultural Research and General Legislation of the Comm. on Agriculture and Forestry*, 91st Cong., 2d Sess., at 68 (1970).

71. *See id.* at 52.

has so reproduced the variety . . . ."[72] The PVPA is administered by the Plant Variety Protection Office of the USDA.[73] The PVPA allows a plant breeder to protect seed crops with a certificate of plant variety protection (hereinafter "PVCP") from the Secretary of Agriculture, granting the breeder the right "to exclude others from selling the variety, or offering it for sale, or reproducing it" for twenty years from the date the certificate is issued.[74]

The basic requirement for obtaining a PVCP is that the new variety must be new, distinct, uniform, and stable.[75] To receive protection under the PVPA, therefore, a new plant variety that is reproduced from seed must be clearly distinct from other known varieties.[76] The new plant variety must be uniform, such that variations in the sexually reproduced plants "are describable, predictable, and commercially acceptable."[77] The new plant variety must also be stable so that the essential and distinctive characteristics of the variety are present in sexually reproduced offspring.[78] An application for a PVCP must generally provide a description that is "adequate or as complete as is reasonably possible."[79] It need not provide the degree and detail of disclosure necessary to enable a third party to recreate the new plant variety, as is required of utility patent specifications under 35 U.S.C. § 112.[80] These types of plant inventions can be fully and precisely described (using a procedural device, the deposit of a sample, that itself developed over the second half of the century)[81] in a way that enables a third party to reproduce the invention without undue experimentation, thereby satisfying the requirements of 35 U.S.C. § 112.[82]

Two unique exceptions, one for farmers and the other for researchers, distinguish the PVPA from the PPA and utility patents under the Utility Patent

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72. 7 U.S.C. § 2402(a) (1994).
73. *See id.* § 2321.
74. *Id.* § 2483(a)(1), (h)(1).
75. *See id.* § 2402.
76. *See id.* § 2402(a)(2).
77. *Id.* § 2402(a)(3).
78. *See id.* § 2402(a)(4).
79. *Id.* § 2422.
80. *See* 35 U.S.C. § 112 (1994).
81. *Id.* This device was originally developed for microbiological inventions but has been adopted for plants. Samples of seeds or plant cell tissue cultures are made freely available to the public upon the grant of the patent. *See In re* Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970); *see also* 37 C.F.R. §§ 1.801–09 (2003). These "descriptions" allow someone practiced in the field to grow a genetic duplicate of any deposited plant described in a utility patent. *See* Brief of Amici Curiae Biotechnology Industry Organization at 5, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
82. *See* Brief of Amici Curiae Biotechnology Industry Organization at 5, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

Act. The first exception allows a farmer who legally purchases and plants a protected variety to save the seed from these plants for replanting on his own farm.[83] The second exception permits a protected variety to be used for research.[84]

D. Decisions That Facilitated Issuance of the Plant Utility Patents

Two important decisions, one by the United States Supreme Court and the other by the Board of Patent Appeals, paved the way for patent protection for plants under 35 U.S.C. § 101. In the first of these decisions, *Diamond v. Chakrabarty*, the Supreme Court, in a 5–4 ruling, held that a live human-made microorganism was patentable under § 101 as a "manufacture" or "composition of matter."[85] Ananda Chakrabarty, a scientist, had developed a bacterium capable of breaking down components of crude oil.[86] The Supreme Court reasoned that the microorganism was a product of human ingenuity having a distinct name, character, and use.[87] In its decision, the Court rejected the argument that Congress's adoption of the PPA and PVPA was evidence of its intent to exclude living things from the scope of patentable subject matter under § 101.[88]

Five years later and in reliance on *Chakrabarty*, the Patent Board of Appeals and Interferences held in *Ex parte Hibberd* that 35 U.S.C. § 101 authorizes utility patent protection for sexually reproduced plants, specifically, corn varieties.[89] The Board concluded that *Chakrabarty* had established "that Section 101 includes man-made life forms, including plant life."[90] The Board rejected the argument that Congress implicitly carved out from the scope of

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83. *See* 7 U.S.C. § 2543 (1994). This section provides that "it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person . . . ." *Id.*

84. *See id.* § 2544. This section provides that "[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this Act." *Id.*

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

86. *See id.* at 305.

87. *See id.* at 309.

88. *See Chakrabarty*, 447 U.S. at 310–14. *See also In re* Arzberger, 112 F.2d 834, 835–36 (C.C.P.A. 1940). Well before *Chakrabarty*, the Patent and Trademark Office had ruled that bacteria are not "plants" for purposes of obtaining patent protection under the PPA. *See* 7 U.S.C. § 2401(a)(9) (1994) (defining "variety"). Likewise, the Department of Agriculture does not issue plant variety certificates for bacteria.

89. *See Ex Parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (1985).

90. *Id.* at 444.

35 U.S.C. § 101 the subject matter covered by the PPA and PVPA. Deeming the Court's analysis in *Chakrabarty* to be dispositive, the Board explained that neither the PPA nor the PVPA restricts or limits the scope of patentable subject matter under 35 U.S.C. § 101.[91] Nor, the Board reasoned, did protecting plants under 35 U.S.C. § 101 create irreconcilable practical conflicts with the PPA[92] or the PVPA.[93]

During the sixteen years following *Hibberd*, the PTO issued utility patents protecting sexually reproduced plants under 35 U.S.C. § 101. This practice went unchallenged until February 1998, when Pioneer Hi-Bred International, Inc., sued a small Iowa seed and supply company named Farm Advantage alleging infringement of patent rights.

III. THE DECISION: SEXUALLY REPRODUCING PLANTS ARE NOT EXCLUDED FROM THE SCOPE OF THE UTILITY PATENT ACT

A. Lower Court Proceedings

Pioneer brought suit before the United States District Court for the Northern District of Iowa.[94] Both parties moved for summary judgment, and the court granted Pioneer's motion, while denying Farm Advantage's motion.[95] The court rejected Farm Advantage's assertion that sexually reproducing plants, like the varieties of genetically engineered corn covered by the patents at issue, are not patentable subject matter under 35 U.S.C. § 101.[96] The court determined that established interpretative practice and congressional intent supported a broad reading of the provision.[97] It concluded that, in enacting the PPA and the PVPA, Congress neither expressly nor implicitly removed plants from 35 U.S.C. § 101's subject matter.[98] In particular, the district court noted

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91. *See id.* at 445.

92. *See* 1077 Off. Gaz. Pat. Office 24 (Apr. 21, 1987). In 1987, the PTO published a Notice in its Official Gazette stating that it "considers nonnaturally occurring non-human multicellular living organisms . . . to be patentable subject matter within the scope of 35 U.S.C. § 101."

93. *See Ex parte* Hibberd, 227 U.S.P.Q. (BNA) at 446–447.

94. *See* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply Inc., 49 U.S.P.Q. 2d 1813 (N.D. Iowa 1998).

95. *See id.* at 1822.

96. *See id.* at 1819–22.

97. *See id.* at 1816–17.

98. *See id.* at 1817–22.

that Congress did not implicitly repeal § 101 by passing the more specific PVPA because there was no irreconcilable conflict between the two statutes.

On interlocutory appeal, the United States Court of Appeals for the Federal Circuit unanimously affirmed the district court's decision.[99] Closely following the district court's reasoning, the Federal Circuit agreed with Pioneer that "the asserted conflict [between 35 U.S.C. § 101 and the PPA and PVPA] is simply the difference in the rights and obligations imposed by the two statutes."[100] The court also rejected Farm Advantage's argument that *Chakrabarty* "does not apply to plants because plants were intended to be excluded from the patent system, as evidenced by the enactment of other statutes to provide protection to plants."[101] Accordingly, the Federal Circuit held that sexually reproduced seeds are patentable subject matter under 35 U.S.C. § 101.[102] Farm Advantage then successfully petitioned for certiorari to the United States Supreme Court.[103]

B. Supreme Court Decision

On December 10, 2001, in a six to two opinion, the United States Supreme Court affirmed the Federal Circuit's decision and upheld Pioneer's seed patents.[104]

1. Majority Opinion

The Court examined the different rights and types of protection afforded agricultural plants under each of the three applicable intellectual property systems (PPA, PVPA, and Utility Patent Act) and concluded that the enactment of the PPA and the PVPA did not remove plants from the more

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99. *See* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 200 F.3d 1374 (Fed. Cir. 2000).
100. *Id.* at 1378.
101. *Id.* at 1376.
102. *Id.* at 1378.
103. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 200 F.3d 1374 (2000), *cert. granted*, 69 U.S.L.W. 3552 (U.S. Feb. 20, 2001) (No. 99–1996).
104. J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, 534 U.S. 124, 126 (2001). Justice Thomas was joined in the opinion by Chief Justice William Rehnquist and Justices Antonin Scalia, Anthony Kennedy, David Souter and Ruth Bader Ginsberg. Justices Stephen Breyer filed a dissenting opinion in which John Paul Stevens joined. Justice Sandra Day O'Conner took no part in the consideration or decision of the case. Justice Sandra Day O'Connor recused herself because of a possible connection to DuPont. *See* Richard A. Shanks & Joseph Mendelson, *Crops or Courts?*, 17 TEX. LAW. 23 (July 1, 2002).

general coverage of the Utility Patent Act.[105] The following discussion divides the Court's analysis into four parts.

Chakrabarty: The Court used the landmark decision in *Chakrabarty* as its point of departure, finding the language in 35 U.S.C. § 101 to be extremely broad.[106] The Court relied on the following language in *Chakrabarty*: "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."[107] The Court determined that the conclusion reached in *Chakrabarty* was that living things are patentable under 35 U.S.C. § 101 and that a manmade micro-organism fell within the scope of the statute.[108]

a. PPA: The Court noted that the PPA's text does not indicate that its protection for asexually reproduced plants was intended to be exclusive. The Court stated: "[t]he 1930 PPA conferred patent protection to asexually reproduced plants. Significantly, nothing within either the original 1930 text of the statute or its recodified version in 1952 indicates that the PPA's protection for asexually reproduced plants was intended to be exclusive."[109] On this point, the Court appears to have overreached. Neither Pioneer nor any lower court opinion had ever suggested this view of the PPA. There is no dispute that Congress had expressly rejected seed patenting when it passed the PPA.[110] Pioneer had argued simply that *Chakrabarty's* expansion of the breadth of 35 U.S.C. § 101, combined with Congress' subsequent inaction following *Hibberd*, confirmed congressional acceptance of the PTO's actions.[111]

b. PVPA: The Court made two points relative to the PVPA. The first was that the PVPA does not expressly deny 35 U.S.C. § 101 utility patent protection for sexually reproduced plants.[112] The Court noted that while the PVPA creates a statutory scheme, giving limited protection to plant varieties that are new, distinct, uniform, and stable, nowhere does it restrict the scope of patentable subject matter under 35 U.S.C. § 101.[113]

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105. *See J.E.M. Ag Supply, Inc.*, 534 U.S. at 132.
106. Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).
107. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 130 (quoting *Chakrabarty*, 447 U.S. at 308).
108. *See id.*
109. *Id.* at 132.
110. *See* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1566 (Fed. Cir. 1995).
111. *See* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 49 U.S.P.Q. 2d 1813, 1815 (N.D. Iowa 1998).
112. *See J.E.M. Ag Supply, Inc.*, 534 U.S. at 140.
113. *Id.* at 140.

The second point was that the PVPA did not alter 35 U.S.C. § 101's subject matter coverage by implication.[114] The Court noted that a repeal by implication requires that the earlier and later statutes be irreconcilable.[115] The Court found that differences in the requirements for, and coverage of, utility patents and PVPA plant variety certificates do not present irreconcilable conflicts because the requirements of a § 101 utility patent are more stringent than those for a PVP certificate, and the protections afforded by a utility patent are greater than those afforded by a PVP certificate.[116]

c. Congressional Inaction: The Court found it compelling that the PTO has assigned utility patents for plants for at least sixteen years, without any indication from either Congress or the agencies with expertise that coverage is inconsistent with the PVPA or the PPA.[117] Although the Court did not expressly rely on it, it is highly probable that a significant factor weighing in favor of affirming the decisions of the lower courts was the reliance by the biotechnology companies on the PTO's authorization of utility patent protection for sexually reproduced plants.[118]

2. Concurring Opinion

In his concurring opinion, Justice Scalia saw the case as presenting [a]n interesting and difficult point of statutory construction, seemingly pitting against each other two perfectly valid canons of interpretation: (1) that statutes must be construed in their entirety, so that the meaning of one provision sheds light upon the meaning of another; and (2) that repeals by implications are not favored.[119]

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114. *See id.* at 141–43.

115. *See id.* at 141–42.

116. *Id.* at 142.

117. *Id.* at 144–45.

118. This position was forcefully argued by the United States in its amicus brief to the Supreme Court in favor of Pioneer. The brief stated that "[g]iven the magnitude of the industry's reliance upon the current regime that allows protection under Section 101 as well as under the PPA and the PVPA, and given Congress's special concern for stability in interpreting patent law, this Court should be particularly hesitant to revisit *Chakrabarty's* analysis." Brief Amici Curiae United States in Support of Respondent at 15, *J.E.M. Ag Supply, Inc.* (No. 99–1996). The United States also noted that "[I]n 1992, the agriculture industry in the United States spent $400 million on research and development associated with plant breeding, as compared to $97 million in 1980. *Id.* (citing Economic Research Serv., U.S. Dep't of Agric., *Agricultural Research and Development: Public and Private Investments Under Alternative Markets and Institutions* (Agricultural Economic Rep. No. 735) 37, Table 10 (1996), *available at* http://www.ers.usda.gov/publications/aer735/.

119. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 146 (Scalia, J., concurring).

In Justice Scalia's view, the question before the Court was whether the term "composition of matter" included living things. He concluded that "there was no way in which 'composition of matter' could be regarded as a category separate from plants, but not separate from other living things."[120] The *Chakrabarty* decision, according to Justice Scalia, ruled that this issue was no longer an "open question." He opined that "the canon against repeal by implication comes into play, and I agree with the Court that it determines the outcome. I therefore join the opinion of the Court."[121]

3. Dissenting Opinion

In his dissent, Justice Breyer focused on congressional intent in enacting the PPA and PVPA, finding that Congress intended these statutes to exclude plant protection under 35 U.S.C. § 101.[122] Justice Breyer stated:

> I believe that the words 'manufacture' or 'composition of matter' do *not* cover these plants. That is because Congress intended the two more specific statutes to exclude patent protection under Utility Patent Statute for the plants to which the more specific acts directly refer. And, as the Court implicitly recognizes, this Court neither considered, nor decided, this question in *Diamond v. Chakrabarty*.[123]

This rationale adopts Farm Advantage's argument. Justice Thomas, writing for the majority, responded to the dissenting opinion as follows:

> Justice Breyer argues that *Diamond v. Chakrabarty* cannot determine the outcome of this case because it did not answer the precise question presented. But this simply misses the mark. *Chakrabarty* broadly interpreted the reach of § 101. This interpretation is surely germane to the question whether sexually reproduced plants fall within the subject matter of § 101. In addition, *Chakrabarty's* discussion of the PPA and the PPVA is relevant to petitioners' primary arguments against utility patent protection for sexually reproduced plants.[124]

Regardless of Congress' actual intent, the Supreme Court has clearly spoken: sexually reproducing plants are not excluded from the Utility Patent Act of 35 U.S.C. § 101.

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120. *Id.* at 146–47 (Scalia, J., concurring).
121. *Id.* at 147 (Scalia, J., concurring).
122. *See id.* at 147 (Breyer, J., dissenting).
123. *Id.* at 147 (Breyer, J., dissenting).
124. *Id.* at 131.

IV. IMPLICATIONS OF SUPREME COURT'S DECISION TO AGRICULTURAL COMMUNITY

The Supreme Court's decision in *J.E.M.* is significant to the agricultural community in several respects. First, the decision has numerous implications for biotechnology companies, producers, and society. Second, the decision fuels the international debate over the role of biotechnology in agriculture and intellectual property rights. Third, the decision places the burden squarely on Congress to determine whether changes will be made to the statutory protection of plant patents.

A. Implications of *J.E.M.* to Biotechnology Companies, Producers, and Society

The implications of the Supreme Court's decision in *J.E.M.* to the biotechnology and seed companies and to producers are immediately evident. Not as evident, but nevertheless significant, are the implications to society.

1. Protection of the Vested Interest of the Biotechnology Industry in Agriculture

The inventive activity encouraged by the availability of utility patent protection contributes to a thriving agricultural biotechnology industry.[125] At the time of the Supreme Court's decision in *J.E.M.*, over 1,800 utility patents had been obtained for seed and plant-related patents.[126] Examples include patents issued on corn plants expressing Bacillus Thuringiensis (Bt) insecticidal proteins;[127] herbicide-resistant crops, such as sugar beets containing the ROUNDUP READY TM gene;[128] sunflowers "conventionally" bred to contain high levels of the more healthful unsaturated oleic acid;[129] bananas, tomatoes, and other fruit recombitantly modified to contain edible vaccines;[130]

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125. "Biotechnology" is defined as "direct manipulation of genetic material in animals, plants, and microorganisms to produce new types of organisms or improve existing life forms." MODERN DICTIONARY FOR THE LEGAL PROFESSION (2d ed. 1996).
126. Brief of Amici Curiae American Seed Trade Association at 7, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
127. U.S. Patent No. 5,484,956 (issued Jan. 16, 1996).
128. U.S. Patent No. 6,204,436 (issued Mar. 20, 2001).
129. U.S. Patent No. 4,627,192 (issued Dec. 9, 1986).
130. U.S. Patent No. 5,861,277 (issued Jan. 19, 1999).

plants that produced nutritionally superior mixtures of dietary amino acids;[131] and maize with increased water stress tolerance.[132]

A decision by the Supreme Court in favor of Farm Advantage would have dealt a severe financial blow to biotechnology and seed companies.[133] Because sexual reproduction is a generational process, development of new and better plants takes many years and an enormous investment.[134] As no formula exists for selecting the proper plants to cross- and to self-pollinate, the breeding process often involves as much "art" as it does science.[135] Moreover, modern breeders employ costly advanced technologies (such as molecular analysis and gas chromatography) to assist in their creation of superior hybrids.[136]

At the same time, biotechnology companies are concerned with the ease with which plants can be copied.[137] Once a new plant line has been stabilized, further self-pollination can create thousands of replicas of the plant.[138] Thus, the plant breeder, after incurring the high cost of years of development, is faced with the possibility that others will simply "free ride" on its research.[139] Without some promise that the plant breeder will be able to protect its developments, the prospects for financial backing for risky research might be reduced or eliminated.[140]

2. Integration of the Plant Patent Statutory Scheme

The Supreme Court's decision arguably gives flexibility by allowing the three statutory systems (PPA, PVPA, and Utility Patent Act) to complement each other.[141] Despite the potential for broad protection of genetically

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131. U.S. Patent No. 5,508,468 (issued Apr. 16, 1996).

132. U.S. Patent No. 5,780,709 (issued July 14, 1998).

133. Brief of Amici Curiae American Seed Trade Association in Support of Respondent, at 2, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

134. Brief of Amici Curiae Cargill, Inc. in Support of Respondent, at 2, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

135. *See generally* ARNEL ROY HALLAUER, *Maize*, *in* PRINCIPLES OF CULTIVAR DEVELOPMENT (Walter R. Fehr ed., 1987).

136. Brief of Amici Curiae Cargill, Inc. in Support of Respondent at 18, *J.E.M. Ag Supply, Inc*. (No. 99–1996).

137. *See id.* at 18–19.

138. *See id.* at 18.

139. *See id.* at 19.

140. *See id.*

141. Additionally, it has been asserted that the decision is an affirmation by the United States Supreme Court of the importance of intellectual property at a time of major challenges to the underlying premise of strong intellectual property protection. These challenges are reflected in: The Qatar Declaration of November 14, 2001, concerning the interpretation of

engineered or otherwise improved plants by utility patents, the conventional plant breeder who discovers a distinctive new variety under cultivation or develops one by cross-breeding techniques is still free to secure more limited protection by fulfilling the less exacting requirements for a plant patent or PVPC. Although most biotechnology plant inventions are filed as utility patents,[142] the availability of utility patents for plants has not completely discouraged the conventional plant breeder from seeking PPA or PVPA protection.[143] "This development might presage a significant realignment in the seed industry's intellectual property portfolio strategy" with respect to maintaining PPA, PVPA, and utility patent protection for proprietary varieties.[144]

3. Encouragement of Further Biotechnology Development in Agriculture

The Supreme Court's decision helps create further incentives for plant inventors to research, develop, and market new plant products that will radically change American agriculture.[145] These changes include an expected shift in emphasis to "second wave" value products that include enhancing food, livestock, industrial, and pharmaceutical products.[146]

Whether biotechnology development in agriculture should be promoted is the subject of a vigorous debate. Proponents claim that biotechnology offers

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Trade Related Aspects of Intellectual Property Rights, or TRIPS, by the World Trade Organization; efforts to weaken the protections, such as they are, of the Hatch-Waxman law for the U.S. research-based pharmaceutical industry; the round of hearings on intellectual property and the antitrust laws to be launched early this year by the Federal Trade Commission; and the persistent underfunding of the United States Patent and Trademark Office resulting from the diversion of inventors' user fees to other totally unrelated government programs. *See* LEGAL BACKGROUNDER, *supra* note 6, at 3.

142. F.H. Erbishch & C. Velazquez, *Introduction to Intellectual Properties, in* INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY at 9 (F.H. Erbish & K.M. Maredia eds., 1998).

143. From 1930 to 1985, only 5,379 plant patents issued, while from 1985–2000, 11,337 issued. From 1971 to 1984, a total of 1,297 PVPA certificates were issued, while from 1985 to January 31, 1999, nearly the same length of time, 2,760 were issued. *See* PLANT VARIETY PROTECTION OFFICE, 1999 PROGRESS REPORT (Jan. 31, 1999).

144. Mark D. Janis & Jay P. Kesan, *The Future of Patent Law: U.S. Plant Variety Protection: Sound and Fury?*, 39 HOUS. L. REV. 727, 728 (2002).

145. *See* Brief of Amici Curiae Biotechnology Industry Organization at 12, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

146. Michael J. Phillips, The Future of Biotechnology, Lecture at the 2001 D.W. Brooks Lecture,College of Agriculture and Environmental Science, University of Georgia (Oct. 1, 2001) (transcript available at http://www.bio.org/foodag/weekly/DWBrooks%20Lecture%2010–1–01.pdf.

the three significant potential benefits: (1) radically increasing current levels of agricultural production, (2) dramatically improving the quality of health care, and (3) measurably contributing to a cleaner environment.[147] In response, opponents argue that these benefits are unproven and that biotechnology may in fact result in lower yields and may also endanger the environment and the health of consumers.[148]

i. Agricultural Production

The great hope for genetically engineered crops is that they will feed the world.[149] Biotechnology offers a potential answer to the great fear that with burgeoning populations, mass starvation is only a matter of time.[150] As populations have grown, the amount of arable land in the United States and elsewhere in the world has steadily decreased.[151] The growing world population)reaching over 6 billion people in the year 2000)has brought about the steady conversion of farmland into home and apartment sites, shopping centers, parking lots, and office buildings.[152] Despite this continuing decrease in arable land, food shortages have been avoided in large part by the increased productivity and yields achieved by American farmers.[153] Sustained

147. Brief of Amici Curiae Biotechnology Industry Organization at 1, *J.E.M. Ag Supply, Inc.* (No. 99–1996). Another touted benefit is the substantial contribution the biotechnology industry makes to the United State's economy: in 1999, for example, $9.9 billion in research and development were invested and the agricultural biotechnology sector generated $2.3 billion in revenues. *Id.* at 2.

148. In response to the world-wide resistance and criticism of agricultural biotechnology, the largest agricultural biotechnology companies are mounting a large public relations campaign, which includes setting up charitable foundations, backing aid for subsistence farmers, and donating valuable data and patents. *See* Justin Gillis, *Cultivating a New Image*, THE WASHINGTON POST, May 23, 2002, at E-1.

149. Christopher Hallowell et al., *Will the World Go Hungry?* Time Int'l., Nov. 1, 1997, *available at* http://www.time.com/time/reports/planet/food.html.

150. *Id.*

151. This phenomenon is particularly evident in the United States, where, in 1950, farm acreage totaled over 1.1 billion acres and by 1997, farm acreage had shrunk to just over 0.9 billion acres – a decrease of almost 20%. *See* National Agric. Statistics Serv., U.S. Dep't of Agric., Trends in U.S. Agriculture)Farm Numbers and Land in Farms, *at* http://www.usda.gov/nass/pubs/trends/farmnumbers.htm.

152. *See id.*

153. From 1940 to 1970, American farmers increased their per acre yield of corn by 150%, of wheat by 102%, and of soybeans per 64%. From 1970 to 2000, American farmers achieved further increases in per acre yields of corn by almost 90%, of wheat by 35%, and of soybeans by 42%. From 1940 to 2000, total harvested corn grown for grain increased from 2.2 billion bushels to over 9.9 billion bushels. Total harvested wheat increased from 0.8 billion bushels to over 2.2 billion bushels in the same period. *See* Brief of American Trade Seed Association at 11, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

productivity increases, many believe, depend on the development of biotechnology and its application to agriculture.[154]

However, some doubt the promises of higher yields by the biotechnology industry. These skeptics claim that the yields are actually lower in some cases,[155] and that the use of transgenic crops, such as B+ crops, will lead to insects that become resistant to insecticides, similar to the development of antibiotic-resistant bacteria.[156]

ii. Nutritional Value of Crops

Proponents of biotechnology foods point to benefits to health and nutrition.[157] In addition to higher yields, nutritionally-enhanced crops could provide more nutritious foods, which could be of special benefit to Third World countries.[158] Proponents also point out that an estimated 60 percent of all processed foods contain at least one genetically engineered component, and that no health problems attributable to a genetically engineered foods have been detected.[159]

Many do not share the belief that biotechnology can increase the nutritional value of foods. Consumer groups question whether potential risks to human health have been adequately studied.[160] Some consumers worry that unforeseen dangers, such as unknown food allergies, may occur in genetically engineered crops.[161]

iii. The Environment

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154. *See generally* Brief of Amici Curiae Biotechnology Industry Organization at 1, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

155. Ed Oplinger, Ph.D at the University of Wisconsin, conducted performance trials on Roundup Ready soybeans and concluded that on the average, the transgeneic soybeans yielded an average of four percent lower than conventional soybeans. *See* David Holzman, *Agricultural Biotechnology: Report Leads to Debate on Benefits Of Transgenic Corn and Soybean Crops*, GENETIC ENGINEERING NEWS, Apr. 15, 1999, at 29.

156. Bruce Rubenstein, *Growing Agro-Biotech Business Fuels Patent Battles, Dominance of a New Industry at Stake*, CORP. LEGAL TIMES, Feb., 1999, at 29.

157. *See* Brief of Amici Curiae Biotechnology Industry Organization at 1, *J.E.M. Ag Supply, Inc*. (No. 99–1996).

158. Researchers currently are working to genetically modify rice to add vitamin A. The genetically modified rice potentially could help the two hundred and fifty million children in Southeast Asia at risk for eye disease due to lack of vitamin A. *See The Campaign Against Genetically Modified Food*, 21 JUD./LEGIS. WATCH REP. 1 (2000).

159. *See* Doug McInnis and Gunjan Sinha, *Genes: They're What's for Dinner*, POPULAR SCIENCE, Apr. 2000 at 67.

160. *See id.*

161. *See id.*

Agricultural biotechnology promises to benefit the environment by lessening reliance on pesticides and other crop inputs.[162] One means of achieving remarkable results in crop yields is an increase in the use of chemical herbicides and pesticides.[163] However, environmental impact issues relating to the use of such chemicals are increasing.[164]

Not all share the view that the employment of biotechnology in agriculture benefits the environment. There is a concern that potential risks to the environment have not been adequately studied.[165] Some fear that genetically engineered crops could lead to an accidental release of genes into the environment that could destroy the delicate balance in an ecosystem.[166]

4. Facilitation and Promotion of Emerging Trends in Agriculture

Several dramatic changes and trends are occurring in the agriculture community. Although the causes of these changes are complex and varied, the issuance of utility patents to plant breeders has contributed, at least in part, to these changes and trends. By encouraging further biotechnology development in agriculture, the Supreme Court's decision in *J.E.M.* will contribute to and perhaps even accelerate these changes.

i. Genetic Erosion:

The first of these trends is genetic erosion. Allegedly caused by increased intellectual rights that restrict access to genetic resources, genetic erosion is

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162. *See* Brief of Amici Curiae Biotechnology Industry Organization at 2, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

163. An April 2000 U.S. Department of Agriculture publication entitled "Genetically Engineered Crops for Pest Management in U.S. Agriculture: Farm-Level Effects" summarizes numerous studies of enhanced corn, cotton, and soybean seeds. With respect to B+ cotton – cotton which has been genetically modified to express higher levels of B+ proteins, a natural insecticide – the publication reports that, in 1997, the farm-level effects included an increase in cotton yield, an increase in farm-level net returns, and a decrease in the use of certain insecticides. *See* J. FERNANDEZ-CORNEJO, ET AL., U.S. DEP'T OF AGRIC., AGRIC. ECONOMIC REP. NO. 786, GENETICALLY ENGINEERED CROPS FOR PEST MANAGEMENT IN U.S. AGRICULTURE: FARM-LEVEL EFFECTS (Apr. 2000), *available at* http://www.ers.usda.gov/publications/aer786/aer786fm.pdf. *See also* KEITH S. DELAPLANE, UNIVERSITY OF GEORGIA COLLEGE OF AGRICULTURAL AND ENVIRONMENTAL SCIENCES, PESTICIDE USAGE IN THE UNITED STATES: HISTORY, BENEFITS, RISKS, AND TRENDS (2000), *available at* http://www.ces.uga.edu/pubcd/B1121.htm.

164. *See* RACHEL L. CARSON, SILENT SPRING (Houghton Mufflin Company Boston 1962).

165. *See* McInnis and Sinha, *supra* note 159, at 66.

166. *See id.*

the loss of genetic diversity through extinction.[167] Diversification has helped stabilize American agriculture.[168] Diversification occurs where plant breeders have access to a wide range of genetic variability to develop healthier strains and meet changing conditions.

Diversification is disappearing, however.[169] Modern agriculture has become dependent upon a relatively small number of commercial crop species, some of which are dominated by a relatively small number of varieties within the species.[170] The lack of genetic variability or diversity within these crops means that crops react similarly to drought, disease, sex, and other factors, thus increasing the likelihood of large-scale crop failure.[171]

Genetic erosion has captured the attention of the international community, as the worldwide preservation of genetic diversity in the plant kingdom is an important international policy objective.[172] Some argue, however, while genetic diversification is important, the claim that genetic erosion is caused by the issuance of utility patents is unsupportable. A recent study notes "market and agronomic forces," rather than intellectual property rights, may be "the major factors leading to genetic erosion and the loss of genetic diversity, and "increased competition" resulting from the availability of intellectual property rights may "lead to more marked product differentiation among firms which, in turn, may enhance genetic diversity."[173] Some supporters of the theory

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167. *See* Peter J. Goss, *Guiding The Hand That Feeds: Towards Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 CAL. L. REV. 1395, 1402–03 (1996).

168. *See* Brief of Amici Curiae American Corn Growers Association & National Farmers Union at 14, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

169. *See id.*

170. *See* Cary Fowler, Unnatural Selection: Technology, Politics and Plant Evolution (International Studies in Global Change) 239–40 (Gordon and Breach eds. 1994) (citing to Table 12). The United States National Seed Storage Laboratory holdings suggest that since 1903 the United Sates has lost 94.1% of beet varieties, 96.1% of sweet corn varieties, 92.8% of lettuce varieties and 80.6% of tomato varieties. *Id*.

171. *See* Goss, *supra* note 167, at 1403.

172. Genetic Diversity is a specific aim of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, May 15, 2000, 39 I.L.M. 1027 (2000) (which the United States has not signed); United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (1992); Food and Agriculture Organization's International Undertaking on Plant Genetic Resources (a nonbonding agreement to which the United States is a signatory). Brief of Amici Curiae Delta and Pine Land Company at 10–11, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

173. CARLIENE BRENNER, OECD DEVELOPMENT CENTRE TECHNICAL PAPER NO. 133 – INTELLECTUAL PROPERTY RIGHTS AND TECHNOLOGY TRANSFER IN DEVELOPING COUNTRY AGRICULTURE: RHETORIC AND REALITY (1998), *available at* http://www.oecd.org/dataoecd/19/15/1922525.pdf.

even concede that the theory of genetic diversification is largely inapplicable to already-industrialized countries such as the United States.[174]

ii. Consolidation of the Seed Industry

Significant consolidation of the seed industry is occurring at a phenomenal rate. Between 1995 and 1998, approximately sixty-eight seed companies were either acquired by or entered into joint ventures with six large multinational corporations.[175] Some attribute this consolidation to utility patents.[176] They contend that utility patents will create an incentive for companies to acquire control of basic materials, to limit access to those materials, and to seek further patent protection as a means of continuing control.[177]

Some fear consolidation will lead to dramatic increases in the prices of seeds.[178] Since the seed company has an absolute monopoly on a patented variety, the price is not driven down by competition. Thus, the seed company can charge the maximum price the buyer is willing to pay for the new plant variety.[179]

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174. The charge that intellectual property rights may contribute to the narrowing of the genetic base of agricultural crops is most often made with reference to conditions in developing countries, rather than in developed nations such as the United States. This is because in most developed nations, due to land clearing, decades of commercial-scale farming, and the concentration of farmers' efforts on "cash crops," "genetic erosion" occurred long ago. *See, e.g.*, Jim Chen, *Diversity and Deadlock: Transcending Conventional Wisdom on the Relationship Between Biological Diversity and Intellectual Property*, 31 ENVTL. L. REP. 10625 (2001).

175. These six large multinational corporations include Monsanto, Aventis, Dow, AstraZeneca, Novartis and DuPont. JOHN L. KING, USDA, AGRICULTURE INFORMATION BULLETIN, CONCENTRATION AND TECHNOLOGY IN AGRICULTURAL INPUT INDUSTRIES (2001) *at* http://www.ers.usda.gov/publications/aib763/.

176. *See* Debra L. Blair, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 320 (1999).

177. *See id.*

178. *See* Brief of Amici American Corn Growers Association & National Farmers Union at 2, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

179. From 1985 to 1999, the cost of corn seed increased from $18.48 to $30.29 per planted acre. For cost of corn seed in 1985, s*ee* USDA, Economic Research Service, U.S. corn production costs and returns, 1975–95, *available at* http://www.ers.usda.gov/data/costsandreturns/data/history/Corn/H-USCorn.xls. For cost of corn seed in 1999, *see* USDA, Economic Research Service, U.S. corn production costs and returns, 1996–2001, *available at* http://www.ers.usda.gov/data/costsandreturns/data/recent/Corn/R-USCorn.xls. Similarly, the cost of soybean seed has increased from $12.92 per planted acre in 1985 to $19.25 per planted acre in 1999. For cost of soybean seed in 1985, s*ee* USDA, Economic Research Service, U.S. soybean production cash costs and returns, 1975–96, *available at* http://www.ers.usda.gov/data/costsandreturns/data/history/Soyb/H-USSoyb.xls. For cost of soybean seed in 1999, *see* USDA, Economic Research Service, U.S. soybean production costs and returns,

iii. Traditional Right to Save Seed

The issuance of utility patents has taken away the farmer's traditional right to save seed.[180] This development has two dimensions. The first is the economic consequence to farmers and seed companies. The second is the loss of a practice of historically important social utility.

The economic consequence to farmers and seed companies is obvious: every time a farmer replants with saved seed, the seed companies lose a potential sale, while restricting a farmer from saving seed compels the farmer to spend more money on seed. Less obvious, but no less important, is the social utility attached to a farmer's traditional right to save seed. Most plant breeders build upon the accumulated innovation of farmers who played a major role in ensuring a diverse genetic pool by expanding the germplasm base of modern agriculture through many years of experimentation and creation of thousands of new plant varieties.[181] This role has been facilitated by the ability to save seed and the exchange of this seed among farmers and breeders.[182]

iv. Seed Purchasing Agreements

The issuance of utility patents has also resulted in the increased use of seed purchasing agreements between the farmer and the seed company. As in *J.E.M.*, these agreements may limit the farmer to planting the seed for only a single crop year and prohibiting the farmer from storing or selling the seed.[183] The general concern with seed purchasing agreements is that they lead to the "industrialization" of farming by requiring farmers to use limited licenses with seed purchases and encouraging the use of contract production.[184]

This general concern is predicated upon several specific concerns. First, farmers actually become licensees of technology.[185] Second, the farmer must

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1997–2001, *available at* http://www. ers.usda.gov/data/costsandreturns/data/recent/Soyb/R-USSoyb.xls.

180. *See* Brief of Amici American Corn Growers Association & National Farmers Union at 2, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

181. *See id.* at 14–15.

182. *See id.*

183. *See* Brief for Petitioners at 5, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

184. *See* Neil D. Hamilton, *Reaping What We Have Sown: Public Policy Consequences of Agricultural Industrialization And The Legal Implications Of A Changing Production System*, 45 DRAKE L. REV. 289, 295 (1997).

185. *See* Brief for Petitioners at 5, *J.E.M. Ag Supply, Inc.* (No. 99–1996). Another example is Monsanto, which does not simply sell seed to farmers, but also requires farmers to buy licenses to use the company's technology. *See* Peter Downs, *Bad Seed*, THE PROGRESSIVE, Feb.1, 1999, *available at* 1999 WL 3680377. Monsanto is an agribiotech company engaged

agree to use the seed only once.[186] Many farmers[187] claim they cannot afford to purchase expensive bioengineered seed each year.[188] Third, these agreements forbid farmers' traditional practice of saving seed to replant the following year.[189] Fourth, they can mandate the conditions of post-harvest use and sale of the patented crop.[190] Fifth, they enable companies to force binding arbitration as a sole method of settling disputes.[191] Sixth, they also enable the patent holder to use local courts through a right of venue clause to enforce their ownership rights.[192] Seventh, these agreements also require acceptance of limited warranties that significantly narrow the liability of the patent holder or seed seller for any and all losses, injuries, or damages resulting from the use or handling of the seed.[193] Finally, they contain specific use restrictions on the seed.[194]

Seed companies argue these agreements are necessary to protect their intellectual property rights developed only after a substantial investment in time and money.[195]

v. Litigation with Farmers

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in the manufacturing and selling agricultural products including herbicides. It is also engaged in biotech research and development of crops. *See* Rhone-Polenc Argo S.A. v. Monsanto Co., 73 F.Supp. 2d 540 (M.D.N.C. 1999).

186. *See e.g.*, Brief for Petitioners at 5, *J.E.M. Ag Supply, Inc.* (No. 99–1996). Also, to use Monsanto Roundup Ready soybeans, for example, the farmer must agree to use the seed only once. *See also* Sylvia Carter, *One Potato, New Potato/ Farmers and Biotech Companies are Battling for Control*, NEWSDAY, Mar. 28, 1999, at A51, *available at* 1999 WL 8164254.

187. George Washington wrote "it is miserable for a farmer to be obliged to buy his seeds; to exchange seeds may, in some cases, be useful, but to buy them after the first year is disreputable." Brief for Petitioner at 48, *J.E.M. Ag Supply, Inc.* (No. 99–1996) (quoting George Washington letter to farm manager William Pierce, Nov. 16, 1791).

188. *See* Carter, *supra* note 186, at A51.

189. See *id*.

190. *See* Brief of Amici American Corn Growers Association & National Farmers Union at 25, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

191. *See id.* at 29.

192. *See id*.

193. *See id*.

194. *See id.*

195. *See* Brief of Amici Curiae Cargill, Inc. at 18–19, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

The issuance of utility patents has indirectly created defendant farmers.[196] Patents for modified plants rank second only to software patents for the number of legal challenges filed.[197] There were 8,200 cases in 1999 alone.[198] Monsanto has filed more than 475 lawsuits against farmers for patent infringement and violation of "technology user" agreements for saving seed or selling or trading to fellow farmers.[199] *J.E.M.* gives the biotechnology companies more confidence to enforce their intellectual property rights through litigation.

vi. The Changing Nature of Some Patent Infringement Claims

The patenting of sexually reproducing plants may also change the nature of patent infringement claims. Many patented seed varieties are from open pollinated crops whose pollen can infect neighboring farms planted with unpatented varieties. Such cross-pollination has occurred with the StarLink? genetically engineered corn variety patented by Aventis.[200] StarLink?, which does not have regulatory approval for human consumption, has reportedly contaminated cornfields across the country that were not planted with the variety, causing significant economic harm to many farmers.[201] The ultimate result of StarLink?-like cross pollination can be that a farmer who attempts to save his or her seed becomes an involuntary infringer of a patent if the genetic content of his seed has changed as a result of this biological pollution.[202]

B. International Debate

The Supreme Court's decision in *J.E.M.* fuels an intense international debate over the role of biotechnology in agriculture. This debate involves

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196. The proliferation of agricultural biotechnology litigation is not restricted to biotech companies versus farmers; the biotech companies themselves have extensive litigation. Dupont and Monsanto, the main U.S. makers of genetically modified seed, have agreed to license each others' biotechnology and dismiss all pending lawsuits against each other. For years, the two companies have battled each other in lawsuits over seed technology patent infringements, licensing agreements and claims of stolen technology. *See Dupont, Monsanto Sign Agreement, Settle Lawsuits*, FEEDSTUFFS, Apr. 15, 2002, at 5.

197. *See* Carter, *supra* note 186, at A51.

198. *See* RURAL ADVANCEMENT FOUNDATION INTERNATIONAL, IN SEARCH OF HIGHER GROUND (Sept. 2000), *available at* http://www.etcgroup.org/documents/occ_higherground.pdf.

199. *See* Higgenbotham v. Monsanto Co., No. 99–CV–03337 (CKK) (D.D.C. Am. Class Action Compl. filed Dec. 14, 1999).

200. *See* U.S. Patent No. 5,861,543 (issued Jan. 19, 1999).

201. *See* Brian O'Reilly, *Reaping A Biotech Blunder*, FORTUNE, Feb. 19, 2001, at 156.

202. *See id.*

issues such as global genetic diversity, the continued viability of important land races, north-south sea trade and appropriation, and industrial and rural agricultural concerns.[203] The key constituencies in the debate include biotechnology companies, First and Third World farmers, indigenous people, nations, environmentalists, scientists, and First and Third World consumers.[204] Although there are several constituencies, the dividing line in the debate is straightforward: developed countries versus developing countries.

The Supreme Court's decision comports with the position of developed countries, who want their technological innovations and investments to be granted strong intellectual property rights in developing countries to protect against piracy and to ensure monetary return on their investments.[205] The Supreme Court's analysis in *J.E.M.* reflects this market-oriented approach of developed countries.

On the other hand, the Supreme Court's decision is the antithesis of the view towards intellectual property rights in developing countries, especially as applied to agriculture. Developing countries prefer a system of intellectual property rights that supports and promotes the fair and equitable sharing of benefits arising from the use and development of genetic resources.[206] Developing countries are concerned intellectual property law favors technological innovation that has emerged from industrialized countries and disfavors farmers from gene-rich developing countries who, over generations, have contributed, approved, and preserved plant species.[207]

C. Places Burden on Congress to Effect Changes

The Supreme Court's decision places the burden on Congress to make changes to the availability or scope of plant patents. This is consistent with the Court's decision in *Chakrabarty*, where the Court noted that "Congress, not

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203. *See* ERAN BINENBAUM, ET AL., Int'l Food Policy Research Inst., South-North Trade, Intell. Prop. Jurisdictions, and Freedom to Operate in Agricultural Research on Single Crops, (Dec. 2000), Discussion Paper, *at* http://www.ifpri.org/divs/eptd/dp/papers/eptdp70.pdf. *See generally* United Nations Convention on Biological Diversity, June 5, 1982, S. Treaty.treaty doc. No. 103-20 (1993); General Agreement on Tariffs and Trade-Multilateral Trade Negotiations (the Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade and Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 (1994).

204. *See* BINENBAUM, *supra* note 203, at 4.

205. *See* Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 268–69 (1998).

206. *See id.* at 269.

207. *See id.* at 268–69.

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."[208] In *J.E.M.*, the Court noted that even with the PTO recognizing and regularly issuing utility patents for plants since *Hibberd*, Congress has failed to pass legislation indicating it disagrees with the PTO's interpretation of § 101.[209]

Congress, on the surface at least, tacitly favors the outcome reached by the Court in *J.E.M.* The Supreme Court believed expansion of 35 U.S.C. § 101 to include sexually reproduced plants is consistent with Congressional intent.[210] Moreover, Congress has traditionally favored expansion of intellectual property rights consistent with scientific development.

Given the significant stakes to the agriculture community and to society, as the science of biotechnology increases, the issues will become increasingly complex and the social costs increasingly higher, as they are becoming with transgenic animals.[211] If Congress elects to deliberate on the important policy considerations derived from the expanded use of utility patents, Congress needs to initially determine the value of biotechnology to agriculture. This will require an evaluation of the claimed values of biotechnology, including the increase in crop production and environmental and health benefits. These benefits will need to be weighed against the social costs of biotechnology to farmers. The impact of biotechnology on family farms is likely to be viewed in the context of the value placed by Congress on family farms in other contexts and social programs.[212] The costs and benefits to consumers and

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208. Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980).

209. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145 (2001).

210. *See id.* Citing Congressional support for its interpretation of the patent scheme set forth by Congress, the Supreme Court noted that "[i]n a 1999 amendment to 35 U.S.C. § 119, which concerns the right of priority for patent rights, Congress provided: 'Applications for plant breeder's rights filed in World Trade Organization (WTO) member country . . . shall have the same effect for the purpose of the right of priority . . . as applications for patents.'" *Id.*

211. John Quick, *Recent Developments in Health Law: Plants Patentable Under the Utility Patent Statute, PVA and PVPA*, 30 J. L. MED. & ETHICS 317, 318 (2002). Proponents of patent rights argue the benefits to society from research involving transgenic animals and the need for protection to enable the United States to become a leader in this field of research. *Id.* Opponents feel that creating such incentives will aggravate animal suffering and that larger farms will reap the benefits of this technology at the expense of family farms. *See generally* E.J. Hecht, *Beyond* Animal Legal Defense Fund v. Quig*: The Controversy over Transgenic Animal Patents Continues*, 41 AM. U. L. REV.. 1023 (1992) (discussing transgenic animal patents from an agricultural perspective).

212. *See* 29 U.S.C. § 213(a)(6) & (b)(12). Legislation affecting agriculture producers is often tailored to preserve and protect the family farm. *Id.* For example, current law exempts children in agriculture from the minimum-age and maximum-hour requirements designed to benefit the family farm. *Id.*

society in general will need to be carefully evaluated. Congress should also consider the international interests.

This evaluation will raise important issues regarding the relationships between producers and seed companies and whether the alleged benefits of genetically modified foods are worth the social risks to producers and consumers.

V. UNIQUE ISSUES ASSOCIATED WITH QUALIFYING PLANTS UNDER THE UTILITY PATENT ACT

The Patent Utility Act is the protection statute preferred by plant breeders.[213] Genetically engineered plants are often protected most effectively under § 101, rather than under the PPA or the PVPA,[214] because a utility patent generally affords greater protection to its holder than does a PVPA certificate.[215] The plant invention typically involves more than one plant variety and may relate to a whole species.[216] The inventor-breeder can claim the individual components of the variety, including DNA sequence, gene, tissue culture, seed, or specific plant part. The inventor-breeder can also claim methods using the variety to make other varieties or hybrids and any hybrid varieties created in the future resulting from use of its patented varieties.[217]

A. Satisfying Requirements of Section 101

Since the Utility Patent Act is the preferred protection statute by plant breeders, those who want protection should be aware of the qualifying requirements of 35 U.S.C. § 101 and unique issues associated with plant patent protection. As discussed, to qualify under the Utility Patent Act, the requirements of usefulness, novelty, and unobviousness over the prior art must

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213. *See* Janis & Kesan, *supra* note 144, at 771.

214. *See id*. It is asserted that although the PVP examination process is most likely to result in the receipt of a PVP certificate, it is a laborious, time-consuming and expensive process. *Id*. There are very limited reasons to justify the PVP regime of protection. *Id*. at 777 The PVP may be favored by small plant breeders and international obligations under the UPOV mandate the continuation of retaining PVP protection for new plant varieties. *Id*. at 778.

215. *See* Brief of United States at 24, *J.E.M. Ag Supply, Inc*. (No. 99–1996).

216. *See* ADELMAN, *supra* note 50, at 494–508.

217. *See* Brief of Amici American Corn Growers Association & National Farmers Union at 7, *J.E.M. Ag Supply, Inc.* (No. 99–1996).

be satisfied.[218] Satisfying these requirements has not proven difficult for the plant breeder. Nevertheless, as noted below, there are certain issues that the plant breeder must recognize. Moreover, the PTO cannot continue to expand the scope of patentable subject matter indefinitely.[219] A shrinking public domain and the realization that less is available for future inventors might cause courts to rule in favor of reducing the scope of patentable subject matter and narrowing the interpretation of current patents.[220]

1. Utility

Under § 101 of the Utility Patent Act, plant inventions must be "useful" to receive patent protection.[221] The question of how "useful" an invention must be to be patentable has been well-defined in the case law and presents little or no trouble to the average patentee.[222] According to the Federal Circuit, "[t]he threshold of utility is not high: An invention is useful under section 101 if it is capable of providing some identifiable benefit."[223] The PTO is not looking for something better, but rather for something that is different from the state of the art.[224] Outside of the chemical-patent field, the "utility" requirement has presented little or no obstacle to patenting[225] and has rarely, if ever, been raised as an obstacle to the patent of breeder's and biotechnician's efforts in the plant arena.[226] Since plants and seed are useful by their nature, there should be few problems to patenting sexually reproducing plants based on "utility."[227]

2. Novelty

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218. 35 U.S.C. § 101 (1994).
219. M.R. Carrillo-Heian, *Eat Your Vegetables and Be Sued for Patent Infringement*, 32 MCGEORGE L. REV. 957, 990 (2001).
220. *Id.*
221. 35 U.S.C. § 101 (1994).
222. *See* ADELMAN, *supra* note 50, at 181.
223. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999) (quoting 25 U.S.C. § 101 (1994)).
224. *See id.*
225. *See* ADELMAN, *supra* note 50, at 190.
226. *See* Geertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 J.L. & TECH. 143, 149 (1999).
227. 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, 213 (2001).

Under § 102, a person is entitled to a patent unless "the invention was known or used by others in the country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."[228] Thus, patents are barred when the invention is not new or "novel."[229] In essence, the novelty requirement means a person must be the first to invent something new under the United States patent system.[230]

Although simple in concept, the relationship of a claimed invention to the existing art in the public domain is among the most difficult and misunderstood aspects of a substantive patent law.[231] For a "reference" or "prior art" to invalidate a claim, "each and every element of the claimed invention must be disclosed in a prior art reference" in such a way that would enable others to practice the invention.[232] In other words, if someone of "ordinary skill in the art" would be able to discern the claimed invention from the prior art referenced, then the patent is said to be invalid due to "anticipation," because it is not new or novel.[233]

While the amount of litigation under § 102 (a) is considerable, the novelty requirement presents the same obstacle to patenting in the case of plants and seed produced by sexually reproducing as it would for inventors in any field.[234] The inquiry then is who is the first to invent something. [235]

3. Obviousness

Section 103 (a) provides

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[236]

Thus, obviousness under § 103 is a statutory bar to patent protection.[237]

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228. 35 U.S.C. § 102 (1984 & Supp. 2001).
229. *See* ADELMAN, *supra* note 50, at 203.
230. *See id.*
231. *See id.*
232. *See id.* at 205.
233. *See id.*
234. *See* Overwalle, *supra* note 226, at 152.
235. *See id.*
236. 35 U.S.C. § 103 (a) (1984 & Supp. 2001).
237. *See* ADELMAN, *supra* note 50, at 407–08.

On its face, the concern with this requirement as it relates to plant breeding is that traditional plant breeding techniques are obvious to an ordinary artisan skilled in the art of plant breeding.[238] However, this concern dissipates under the "sweat-of-the-brow" doctrine, which establishes a patentable invention if painstaking efforts or extensive experimentation are taken above and beyond existing art to achieve the inventive results.[239]

Another concern is where the patenting of a bioengineering process and the resulting genetically altered plant product is involved.[240] Section 103(b) addresses the problem of biotechnology processes. Under § 103(b),

> [b]iotechnological process using or resulting in a composition of a matter that is novel under section 102 and nonobvious under subsection (a) [of the statute] . . . shall be considered nonobvious if – (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person . . . . . [A biotechnological process is defined under the act as] a process of genetically altering or otherwise inducing single- or multi-celled organism to)(i) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism.[241]

Thus, under § 103(b), the claimed process and the claimed composition matter must be patented together for an invention to meet the requirement of nonobviousness under § 103(b).[242] The courts have not interpreted § 103(b) as it pertains to transgenically altered sexually reproducing plants, making it difficult to discern what interpretation the courts will give the statute in this context.[243] "In any case, Congress has expressed a clear intent that the nonobviousness requirement will not defeat biotechnological processes even if nonobviousness is defined in a more restrictive manner in terms of the transgenic organisms."[244] Therefore, the requirement of nonobviousness under § 103 does not appear to be a significant bar to the patenting of sexually reproduced organisms under the utility patent statutes.

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238. *See* Overwalle, *supra* note 220, at 152.
239. *See* ADELMAN, *supra* note 50, at 447.
240. *See id.* at 494.
241. 35 U.S.C. § 103(b) (1984 & Supp. 2001).
242. *See* Rives, *supra* note 227, at 217.
243. *Id.*
244. *Id.*

B. International Limitations

There is no unifying system for international intellectual property or patent law.[245] Patents issued by the PTO are effective only within the territory of the United States.[246] The United States patent law does protect somewhat against the import of nonpatented products produced abroad by a process patented in the United States.[247] Without foreign patent protection, however, the manufacture and sale of such products outside of the United States cannot be prohibited.[248] To obtain patent protection in foreign countries, an application must be filed in each country where protection is desired.[249] The United States is party to international agreements[250] facilitating this process.[251] Unlike the United States, most foreign countries offer no grace period for prior use and publication of the invention.[252] Foreign rights may be lost as a result of any prior commercial use or publication of the invention prior to filing of patent applications.[253] Thus, for an inventor who would like to pursue patent protection outside the United States, thousands of dollars in filing costs and attorneys' fees are required per jurisdiction without the guarantee that a patent will be granted.[254]

C. Multiple Applicants to the Same Plant Invention

A problem for plant breeders occurs when there is more than one claimant to the same invention.[255] When applications by multiple applicants to the same

245. *See* McManis, *supra* note 205, at 265.
246. *See* 35 U.S.C. § 271 (1994).
247. *Id.* at § 271(g).
248. *See* ADELMAN, *supra* note 50, at 813.
249. *See id.*
250. For an instructive article addressing biotechnology and international law, see Sean D. Murphy, *Biotechnology and International Law*, 42 HARVARD INT'L L. J. 47 (2001).
251. *See* 35 U.S.C. § 351 (1994).
252. *See* ADLEMAN, *supra* note 50, at 850-53.
253. *See id.*
254. *See* David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 105 (1995).
255. *See e.g.*, Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993) (an appeal from a three-way interference in which British, Israeli, and Japanese teams of inventors contested priority of invention of DNA that codes for human fibroblast beta-interferon).

invention are simultaneously pending, or a pending application interferes with the unexpired patent, the PTO Commissioner may declare interference.[256]

Plant breeders must always keep good and promptly witnessed records of all aspects of research in biotechnology to support subsequent applications for patent protection.[257] This need was illustrated in *Singh v. Brake,*[258] where the Federal Circuit overturned a Patent and Trademark Office Board of Patent Appeals and Interferences' decision awarding priority of invention in a DNA construct to Anthony J. Brake.[259] The issue was whether an inventor's testimony needs to be corroborated.[260] The Federal Circuit concluded that the inventor's laboratory notebook, not witnessed until several years after the fact, could provide corroboration of the inventor's testimony regarding conception but not reduction to practice.[261] The Federal Circuit determined the decision of the Board was not supported by substantial evidence and remanded so the Board could reweigh the sufficiency of the evidence and reach additional factual conclusions.[262]

D. Other Tools of Protection

1. Trade Secret Protection

Another important plant-protection tool long employed by plant breeders is trade secret law.[263] Until *Holden*, when the PTO reversed its stance on the issuance of utility patents for sexually reproducing plants, seed companies typically employed trade secrets to protect the parental line.[264] Trade secret protection still serves as a valuable tool in protecting the interest of seed producers.

In broad terms, a trade secret is virtually any type of confidential information offering a competitive advantage in the marketplace due to its

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256. *See* 35 U.S.C. § 135(a) (1994).
257. *See* Theodore A. Feitshans, *A Review of U.S. Intellectual Property Law Applicable to Inventions in Biotechnology: U.S. Intellectual Property Law Continues to Demonstrate its Adaptability to New Technology*, 6 DRAKE J. AGRIC. L. 7, 10 (2001).
258. 222 F.3d 1362 (Fed. Cir. 2000).
259. *See id*.
260. *Id.* at 1366.
261. *See id*. at 1370.
262. *See id*. at 1371.
263. *See* Brief for Respondents at 4, *J.E.M. Ag Supply, Inc.* (No. 99–1996).
264. *See* Blair, *supra* note 176, at 308–09.

secrecy.[265] The definition of a trade secret depends on a particular state since state law regulates trade secrets.[266] Today, however, some forty-two states have adopted the Uniform Trade Secret Act, thereby substantially harmonizing trade secret laws across the country.[267]

Under the Uniform Trade Secrets Act, a trade secret includes a formula, pattern, compilation, program, device, method, technique, or process that offers a competitive advantage, actual or potential, because it is not generally known and is not readily ascertainable by property means and is reasonably guarded by its owner to protect it secrecy.[268] "Not readily ascertainable" means information not available in trade journals, reference books, or other published materials.[269]

Trade secrets are different from patents in several ways.[270] First, unlike patents where the underlying purpose is to encourage disclosure to promote technological development, the heart of trade secret law is secrecy. Second, trade secrets are not restricted to certain types of subject matter. Third, a trade secret does not need to meet the rigorous criteria for patentability. In fact, trade secret law protects all inventions and information so long as they confer a competitive advantage, irrespective of whether the invention is new, obvious, or simplistic. As such, all patentable inventions are protectable as trade secrets; however, not all trade secrets are patentable. Fourth, unlike patents, trade secrets do not expire after a set period of time and fall into the public domain. They may be protected forever. Fifth, and most significantly, the owner of a trade secret does not enjoy an absolute property right in the trade secret that would exclude all others from using the secret.[271] Unlike other types of inventions, an intellectual property interest embodied in seed is self-replicating. This makes protection under trade secret law difficult because

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265. The definition of a trade secret invoked most often by courts is found at RESTATEMENT OF TORTS § 757, which states that a trade secret is "any formula, pattern, device or compilation of information which is used in one's business and which gives [the holder] an opportunity to obtain an advantage over competitors who do know or use it." RESTATEMENT OF TORTS § 757 (1939).

266. *See* DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW, 3A(1)(1992).

267. *See Corporate Counsel's Guide to Intellectual Property*, BUSINESS LAWS, INC. 4.003 (William A. Hancock ed., 1998).

268. *See id.* at 4.004.

269. *See* CHISUM & JACOBS, *supra* note 266, at § 3C(1)(c).

270. For a significant case involving trade secrets in the seed industry, see *Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226 (8th Cir. 1994) (shows that sexually reproducing inbred parental lines used to create hybrids can be protected by trade secret).

271. Goss, *supra* note 167, at 1416.

seeds can be acquired legally, genetically analyzed, and replicated indefinitely.[272]

2. Copyright Protection

17 U.S.C. § 102 provides that "[c]opyright protection subsists, in accordance with this title, in original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device."[273] Copyright protection has not yet been extended to genetically modified organisms, because the sequences incorporated into most genetically modified organisms are not original. As technology becomes more sophisticated, it is possible that artificial and original sequences of DNA will be protected through copyright.[274] There are several advantages to copyright law,[275] including the fact that copyrights afford protection for a longer period of time than does a patent,[276] and the existence in addition to patent protection, not as an alternative to it.[277]

VI. CONCLUSION

J.E.M. is a landmark case in the agriculture community because it affirmed the inclusion of sexually reproducing plants within the scope of the Utility Patent Act. The plant breeder now has three intellectual property plant protection statutes at its disposal, each with unique qualification criteria and scope. Of the three statues, the Utility Patent Act is the most significant in terms of accommodating and promoting the growth of biotechnology in agriculture.

The *J.E.M.* decision has significant implications for biotechnology and seed companies, producers, and consumers. The decision protects, sustains, and promotes the investment and economic stake of biotechnology products in the agriculture sector. The decision also validates and contributes to profound trends within the agriculture sector caused in whole or in part by the explosive

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272. *See id.* at 1417.
273. 17 U.S.C. § 102(a) (1994).
274. *See* Feitshans, *supra* note 257, at 27.
275. *See generally id.* at 27–28.
276. The duration of a copyright "in a work created on or after January 1, 1978, subsists from its creation and . . . endures for a term consisting of the life of the author and 70 years after the author's death." 17 U.S.C. § 302(a) (Supp. IV 1998).
277. Feitshans, *supra* note 257, at 27.

growth of biotechnology. These developments have altered the relationships producers have with seed companies, created additional economic pressures for producers, changed the nature of farming for producers, and exposed producers to new forms of liability. Whether consumers and society will benefit depends on the extent of the touted environmental, nutritional, and economic benefits from the growth of biotechnology products.

The Supreme Court has made it clear that Congress bears the burden to make changes concerning the role and development of biotechnology plant products within the intellectual property framework of the agriculture sector. If and when congressional action occurs, legislation should be predicated upon scientific and commercial development as well as a careful weighing of societal objectives, values, and concerns. Rather than being limited to the PPA and PVPA, the plant breeder now has the Supreme Court's backing in patenting its plant products under the general utility patent statute. Qualification issues for utility patents for the plant breeder are not significant; however, the plant breeder should be cognizant of international limitations and the problem of multiple applications to the same plant invention. Also, the plant breeder should be aware of other tools of intellectual property protection for plant inventions, including trade secrets and copyrights.