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Plants, Patents, and Seed Innovation in the Agricultural Industry

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Plants, Patents and Seed Innovation in the Agricultural Industry

Summary

Agricultural research and seed distribution systems within the United States have become increasingly privatized. Private plant breeders have turned to the intellectual property system on the grounds that research and development expenses should be recovered. Intellectual property laws allow innovators to appropriate the benefits of their inventions by excluding others from reproducing and selling the protected subject matter.

In recent years, plant breeders have pursued intellectual property rights through three different statutes. The Patent Act of 1952 allows inventors to obtain utility patents, which pertain generally to technological products and processes. The Plant Patent Act of 1930 additionally provides for plant patents, awarded for distinct and new varieties of plants that have been asexually reproduced. Finally, the Plant Variety Protection Act (PVPA) of 1970 provides for the issuance of plant variety protection certificates for new, distinct, uniform and stable plant varieties that have been sexually reproduced.

Due to the overlap among these three statutes, some legal uncertainty existed as to whether plant breeders could obtain multiple, concurrent intellectual property rights. In its 2001 decision in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the U.S. Supreme Court confirmed that an innovative plant may be awarded a utility patent, even though it may also be subject to protection under one of the plant-specific statutes.

Response to the *J.E.M. v. Pioneer* decision has been mixed. Some observers believe that by enacting more specific legislation for plant innovation, the intent of Congress was to foreclose utility patent protection for such inventions. In addition, some commentators have asserted that the possibility of utility patents for seed-bearing plants effectively eliminates certain PVPA provisions that favor farmers and scientific researchers. Others have been more favorably disposed towards this overlap between intellectual property regimes, observing that the rights and responsibilities presented under the three statutes differ.

Should Congress have an interest in legislating in this area, a variety of options are available. If the availability of utility patents for plants is deemed sound, then no action need be taken. Alternatively, if legislative activity is deemed prudent, Congress could impose new restrictions upon the subject matter eligible for utility patents, introduce infringement exemptions within the utility patent statute, or encourage the agricultural industry to develop guidelines on permissible uses of patented plant innovations.

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Plants, Patents and Seed Innovation in the Agricultural Industry

The U.S. agricultural industry is increasingly innovative. Crops that produce insecticide, are nutritionally enhanced or generate increased yields are among the many examples of recent agricultural inventions.[1] An increasing number of these improvements derive from private investment in research and development, as compared to government-sponsored programs.[2] Whether the research and development employs conventional breeding methods or the latest biotechnologies, agricultural research and development can be costly and time-consuming.[3]

Firms that expend such resources upon agricultural research and development ordinarily seek to appropriate the benefits of their innovation. The problem of reaping the rewards of innovation is especially acute for plants. Many engineered plants are self-replicating, living entities that are distributed in large quantities. They therefore present an easy target for copyists.[4] Innovators have therefore turned to intellectual property for protection. At present, at least three intellectual property regimes are available for plants: utility patents, plant patents and plant variety protection certificates.[5]

Many commentators believe that the availability of robust intellectual property rights will encourage innovation in the agricultural industry.[6] Others are concerned that strong intellectual properties in plants may unduly restrict access to plants by farmers and consumers.[7] As the U.S. agricultural industry employs 2.1 million people, produces goods valued at approximately $200 billion, and accounts for

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[1]Cliff D. Weston, "Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol," 4 *Journal of Small and Emerging Business Law* (2000), 377.

[2]Mark D. Janis, "Sustainable Agriculture, Patent Rights, and Plant Innovation," 9 *Indiana Journal of Global Legal Studies* (2001), 91.

[3]Mark D. Janis & Jay P. Kesan, "Weed-Free I.P.: The Supreme Court, Intellectual Property Interfaces, and the Problem of Plants," *Cincinnati Law Review* (2001).

[4]Janis, *supra* note 2.

[5]Peter J. Goss, "Guiding the Hand That Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation," 84 *California Law Review* (1996), 1395.

[6]Andrew F. Nilles, "Plant Patent Law: The Federal Circuit Sows the Seed to Allow Agriculture to Grow," 35 *Land and Water Law Review* (2000), 355.

[7]Joseph Mendelson III, "Patently Erroneous: How the U.S. Supreme Court's Decision in *Farm Advantage* Ignores Congress and Threatens the Future of the American Farmer," 32 *Environmental Law Reporter* (2002), 10698.

exports worth approximately $53 billion, the balance of rights and responsibilities between plant breeders, farmers and consumers raises important issues for the U.S. economy.[8] Agricultural intellectual property further raises issues about availability of the food supply, sustainable agriculture and the rights of farmers.[9]

This report offers an overview of the availability of intellectual property rights for plants, focusing upon the seed industry. It initially offers an introduction to seed innovation. The report then reviews the three intellectual property regimes applicable to plant innovation: utility patents, plant patents and plant variety protection certificates. It then details a 2001 decision of the U.S. Supreme Court, *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*,[10] which held that sexually reproducing plants may be subject to utility patents. The ramifications of *J.E.M. v. Pioneer* upon the agriculture industry are then explored. The report closes with concluding comments on possible legislative responses to the *J.E.M. v. Pioneer* decision as well as implications of the decision for intellectual property rights generally.

Seed Innovation in the United States

In the early United States, seed innovation was performed exclusively by individual farmers.[11] These farmers employed traditional methods of screening and saving seeds that resulted in plants with superior properties. Selection for features such as faster growth, larger seeds or sweeter fruits dramatically changed many domesticated plant species compared to their wild relatives.[12] Intra-farm trade in seeds resulted in the selection of a set of plants deemed suitable for large-scale agricultural production.[13]

In the early nineteenth century, the U.S. government began to assist farmers in obtaining more plant varieties. Secretary of the Treasury William H. Crawford requested in 1819 that ambassadors and military officers retrieve seed from around the world and supply that seed within the United States.[14] In 1839, Commissioner

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[8]CRS Report RL30753, *Agricultural Support Mechanisms in the European Union: A Comparison with the United States*, by Geoffrey S. Becker (statistics for 2001).

[9]Janis, *supra* note 2.

[10]534 U.S. 124 (2001).

[11]Nathan A. Busch, "Jack and the Beanstalk: Property Rights in Genetically Modified Plants," 3 *Minnesota Intellectual Property Review* (2002), 3. *See also* A. Fenwick Kelly, *Seed Planning and Policy for Agricultural Production: The Roles of Government and Private Enterprise in Supply and Distribution* (Bellhaven 1989); N.P. Louwaars, ed., *Seed Policy, Legislation, and Law: Widening a Narrow Focus* (Food Products 2002).

[12]Robert Tripp, *Seed Provision and Agricultural Development: The Institutions of Rural Change* (Heinemann 2001).

[13]Busch, *supra* note 11.

[14]Nelson Klose, *America's Crop Heritage: The History of Foreign Plant Introduction by the*
(continued...)

of Patents Henry Ellsworth obtained federal funding for the collection and distribution of new plant varieties to farmers.[15] The collection and distribution efforts were eventually assigned to the predecessor agency of the U.S. Patent and Trademark Office (USPTO), the Patent Office. By 1855, the Patent Office distributed on an annual basis one million packages of seeds to U.S. farmers free of charge.[16]

Two laws enacted in 1862 increased the involvement of the federal government in seed innovation and distribution. First, Congress established the U.S. Department of Agriculture (USDA).[17] This legislation required the USDA to "collect new and valuable seeds and plants; to propagate such as may be worthy of propagation; and to distribute them among agriculturalists."[18] Second, the Federal Land Grant Act of 1862 established state agricultural colleges.[19] After the Civil War, the development and testing of new varieties of domestic crop species was conducted by the land grant colleges in conjunction with the USDA. The resulting seeds were gratuitously distributed to U.S. farmers.[20]

As the nineteenth century progressed, private seed companies emerged that began to supplant the government as the principal source of seed innovation and distribution.[21] Although the reasons for this transition are complex, commentators have pointed to the increasing scientific understanding of plant biology as one contributing cause. Advanced plant breeding techniques involved increasingly sophisticated equipment and scientific expertise beyond the capabilities of most farmers.[22] In addition, in the words of Secretary of Agriculture James Wilson, the USDA seed distribution program was increasingly regarded as one of "unwieldy, unnecessary, and extravagant proportions" that was "an infringement of the rights of

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[14](...continued)
Federal Government (Iowa State College Press, Ames, Iowa, 1950), 26.

[15]*Ibid* at 39.

[16]Jack Ralph Kloppenburg Jr., *First the Seed: The Political Economy of Plant Biotechnology, 1492-2000* (Cambridge University Press, Cambridge 1998), 51.

[17]Act of May 15, 1862, ch. 72, 12 Stat. 387.

[18]*Ibid.*

[19]Act of July 2, 1862, ch. 130, 12 Stat. 503, 503-05.

[20]*See* Rick Weiss, "Seeds of Discord: Monsanto's Gene Police Raise Alarm on Farmer's Rights, Rural Tradition," *Washington Post* (3 Feb. 1999), A6.

[21]*See* H. Peter Loewer, *Seeds: The Definite Guide to Growing, History and Lore* (Hungry Minds, Inc. 1996); Robert Tripp & Derek Byerlee, "Public Plant Breeding in an Age of Privatization," 57 *Natural Resource Perspectives* (June 2000) (available at http://www.odi.org.uk /nrp/57.html).

[22]*See* Busch, *supra* note 11.

citizens engaged in legitimate trade pursuits."[23] In 1924, the gratuitous distribution of seeds by the USDA was terminated.[24]

The U.S. seed industry grew considerably following the Great Depression and through the World War II era. [25] As the industry grew, so did the number of techniques available to develop new seeds and plant varieties.[26] Through hybridization,[27] breeders were able to obtain progeny that are genetically stable and tend to be more productive than either of the parents. The science of cytogenics – the branch of genetics that studies cellular components concerned with heredity – has allowed breeders to cross plants of distantly related species.[28] A wild grass may provide disease-resistant genes to a new wheat variety, for example. Breeders have also employed tissue culture techniques, through which cells, tissues, and whole plants are grown under sterile conditions. Tissue culture techniques allow scientists to reproduce varieties of many crops from a single cell.[29] Additionally, various laboratory techniques have provided opportunities for inducing mutations, which serve as the basis for new crop varieties.[30]

Today, a well-known method for developing new plants is biotechnology. The techniques of biotechnology allow for the transfer of genes between species.[31] The result has been genetically modified or transgenic crops. Such crops may feature beneficial traits, including resistance to herbicides, insects, viruses or bacteria, or enhanced consumer characteristics such as longer shelf-life or higher nutrient content. Critics of this technology have also emerged, however, citing among other concerns potential detrimental effects to human and animal health and the environment.[32]

Until relatively recently, the seed industry was characterized by small, independent and often family-owned firms.[33] This industry structure began to change rapidly in the 1970's. Mergers and buy-outs, often from companies with interests in chemicals, food processing or other fields, led to consolidation within the seed

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[23]J. Sterling Morton, *Report of the Commissioner of Agriculture for the Year 1893*, H.R. Exec. Doc. No. 53-1 (2d Sess. 1894), 389-91.

[24]*See* Kloppenburg, *supra* note 16, at 71.

[25]*Ibid.*

[26]Colin Tudge, *Food Crops for the Future* (Oxford Press, 1998).

[27]*See* Tripp, *supra* note 12, at 32-33.

[28]*Ibid.*

[29]*Ibid.*

[30]*Ibid.*

[31]*Ibid.*

[32]*See* CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation and Issues*, by Donna U. Vogt & Mickey Parish.

[33]*See* Tripp, *supra* note 12, at 37.

industry.[34] This trend accelerated in the mid-1990's. Between 1995 and 1998, over 60 seed companies either were acquired by or entered into joint ventures with a handful of large multinational corporations.[35] Still, there are many small family seed businesses in operation. For example, over 300 companies produce corn seed in the United States.[36]

Through the university system, agricultural experimental stations and other programs, state and federal governments continue to play a role in seed innovation. Private firms now serve as the primary source of innovation in the modern seed industry, however.[37] Such firms rationally seek to obtain a return on their investment in research and development. In the case of plant research and development, appropriating the benefits of innovation can be particularly challenging.[38] Many plants are self-replicating, living entities that are often distributed in large quantities.[39] Detection of copying can also prove difficult for biological entities. Experience suggests that misappropriated plants may simply be sold under a different name in the plant trade than the name under which it was originally marketed.[40]

In order to recover the expenses associated with research and development, private plant breeders have turned to the intellectual property system. Intellectual property laws allow innovators to appropriate the benefits of their inventions by excluding others from reproducing and selling the protected subject matter. This exclusive position may allow the patent proprietor to charge a supracompetitive price for a limited period of time. As a result, the patentee may be in a position to recover the expenses associated with innovation and earn a profit.[41] In recent years, plant breeders have pursued intellectual property rights through three different statutes: the Patent Act of 1952, the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. This report reviews these three statutes next.

Utility Patents on Plants

Introduction to Utility Patents

When lay persons use the term "patent," they are most often referring to the intellectual property right more technically known as a "utility patent." Utility

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[34]*Ibid.*

[35]John L. King, *Concentration and Technology in Agricultural Input Industries*, U.S. Department of Agriculture, Agriculture Information Bulletin Number 763 (March 2001).

[36]Tripp, *supra* note 12, at 37.

[37]*Ibid.*

[38]Janis, *supra* note 2.

[39]Ibid.

[40]Kelly, *supra* note 11, at 37.

[41]*See* CRS Report RL31132, *Multinational Patent Acquisition and Enforcement: Public Policy Challenges and Opportunities for Innovative Firms*, by John R. Thomas, at 2-6.

patents pertain generally to technological products and processes. Utility patents are governed by the Patent Act of 1952, codified in Title 35 of the U.S. Code.[42]

Utility patent rights do not arise automatically. Inventors must prepare and submit applications to the USPTO if they wish to obtain utility patent protection.[43] USPTO officials known as examiners then assess whether the application merits the award of a utility patent.[44]

In deciding whether to approve a utility patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[45] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the Patent Act of 1952. To be patentable, an invention must be useful, novel and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[46] To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other knowledge within the public domain.[47] A nonobvious invention must not have been readily within the grasp of a person of ordinary skill in the technical field in which the invention arises, judged at the time the invention was made.[48]

If the USPTO allows the utility patent to issue, the proprietor obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[49] These rights are not self-enforcing. A patentee bears responsibility for monitoring its competitors to determine whether they are using the patented invention or not. Patent proprietors who wish to compel others to observe their intellectual property rights must usually commence litigation in the federal courts.

The maximum term of utility patent protection is ordinarily set at 20 years from the date the application is filed.[50] The patent applicant gains no enforceable rights until such time as the application is approved for issuance as a granted patent,

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[42]P.L. 82-593, 66 Stat. 792 (codified at Title 35 U.S. Code).

[43]35 U.S.C. § 111.

[44]35 U.S.C. § 131.

[45]35 U.S.C. § 112.

[46]35 U.S.C. § 101.

[47]35 U.S.C. § 102.

[48]35 U.S.C. § 103.

[49]35 U.S.C. § 271(a).

[50]35 U.S.C. § 154(a)(2). Although patent term is based upon the filing date, the patentee gains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

however. Once the utility patent expires, others may employ the patented invention without compensation to the patentee.

Protection of Innovative Plants Via Utility Patents

Section 101 of the Patent Act of 1952 stipulates that a "process, machine, manufacture, or composition of matter" may be the subject of a utility patent.[51] The statute neither expressly includes nor excludes plants or any other biological subject matter. Nonetheless, certain doctrines developed by the courts traditionally led to difficulties in procuring utility patents on plants. In particular, the requirements that plant inventors provide complete written descriptions of their inventions, along with the "product of nature" doctrine, were seen as posing obstacles.[52]

Under the Patent Act of 1952, each utility patent is required to disclose the protected invention so that skilled individuals can readily practice it.[53] For mechanical, electrical or chemical technologies, diagrams or textual illustrations may fully convey the workings of the patented machine, compound or circuit. This technique may be less effective for plants because a drawing or written description is often not enough. An actual sample of a plant is needed in order to reproduce it.

The "product of nature" doctrine arises from judicial precedent stating that naturally occurring substances discovered in the wild may not be patented.[54] Suppose, for example, that a metallurgist unearths a mineral that was not previously known to exist. Longstanding case law establishes that a utility patent cannot claim the mineral itself. However, significant artificial changes to a product of nature may render it patentable.[55] To continue the hypothetical, suppose that the metallurgist discovers that certain compounds within the mineral have valuable heat-resistant properties. She then develops a purified form of these compounds. A utility patent may be awarded claiming the isolated compounds.

The distinction between products of nature and artificial inventions may seem clear at first glance. Difficulties have arisen, however, with respect to organisms that have been modified through biotechnology or more traditional techniques. Even though a "living invention" was extensively altered from its natural state through human intervention, some have viewed the organism as a product of nature outside the patent system.

For many years, the written description requirement and the product of nature doctrine led to uncertainties about the practical availability of utility patents for

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[51]35 U.S.C. § 101.

[52]*See generally* John M. Golden, "Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System," 50 *Emory Law Journal* (2001), 101.

[53]35 U.S.C. § 112.

[54]*See, e.g., Ex parte Latimer*, 1889 Comm'r Dec. 13 (1889).

[55]*See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) (claiming a purified and isolated DNA sequence encoding erythropoietin).

plants. The level of these concerns is demonstrated by the congressional enactment of two specialized statutes, the Plant Patent Act in 1930[56] and the Plant Variety Protection Act of 1970,[57] to provide intellectual property rights for plants. However, two developments subsequent to those statutes confirmed the availability of utility patents for plants.

First, the USPTO has provided another mechanism for plant-related inventions to fulfill the written description requirement. Inventors are allowed to deposit plant samples in a national public depository and refer to this deposit in their patent applications.[58] The USPTO has stipulated that, in order to meet the pertinent legal requirements, the selected depository must be under an obligation to maintain the plant in a permanent collection and to supply samples to anyone seeking them once the patent issues.[59]

Second, legal developments at the U.S. Supreme Court rendered the product of nature doctrine of less significance to artificially modified organisms. In 1980, the Court's decision in *Diamond v. Chakrabarty* held that a genetically engineered microorganism could be patented.[60] In that case, the Supreme Court reviewed a USPTO decision rejecting a patent application claiming an artificially generated bacterium. The USPTO had earlier ruled that living things could not be subject to protection under the utility patent statute.

The Supreme Court reversed the USPTO decision. The Court reasoned that the utility patent statute was drafted in broad terms, including "manufacture" and "composition of matter," that encompassed the artificial bacterium for which a patent was sought.[61] The Court further rejected the argument that because genetic technology was unknown at the time the 1952 Patent Act was enacted, Congress could not have intended that artificial organisms be the subject of utility patents. The Court instead concluded that Congress used broad language to define the scope of patentable subject matter precisely because technological advances often produce unforeseeable inventions.[62]

Following *Diamond v. Chakrabarty*, the USPTO concluded that plants and plant parts could also be subject to utility patent protection. In 1985, the USPTO Board of Patent Appeals and Interferences held that plants should be considered constituted either "manufactures" or "compositions of matter" within the meaning of § 101 of

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[56]Townsend-Purnell Plant Patent Act, 46 Stat. 376 (1930) (codified at 35 U.S.C. §§ 161-164).

[57]Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified at 7 U.S.C. §§ 2321-2583).

[58]37 C.F.R. §§ 1.801 - 1.809. *See also* U.S. Patent & Trademark Office, *Manual of Patent Examining Procedure* § 2402.

[59]37 C.F.R. § 1.803.

[60]447 U.S. 303 (1980).

[61]447 U.S. at 308-10.

[62]447 U.S. at 309.

the Patent Act, and were therefore eligible for patenting.[63] The USPTO has subsequently issued approximately 1,800 utility patents on plants.[64]

Plant Patents

For many years, the product of nature doctrine and the written description requirement were thought to prevent plants from being the subject of utility patents. With the Townsend-Purcell Plant Patent Act in 1930,[65] Congress addressed both of these concerns. The Plant Patent Act expressly stated that the work of plant breeders could be the subject of a new form of intellectual property right, the plant patent. Plant patents were further subject to a relaxed written description requirement. The written description of plant patents need only be "as complete as is reasonably possible."[66]

Plant patents may issue for distinct and new varieties of plants that have been asexually reproduced. Asexual reproduction results in a plant that is genetically identical to its parent. Typical asexual reproduction techniques include grafting, budding, the use of cuttings, layering and other methods. Plants that are produced through seeds, which involves sexual reproduction, are excluded. Also excluded from the Plant Patent Act are tuberpropagated plants or plants found in an uncultivated state.[67]

The acquisition and enforcement of plant patents is accomplished in a manner very similar to utility patents. Plant patents are issued by the USPTO provided that the novelty and nonobviousness requirements are met. Applicants must submit an application featuring color drawings that disclose all the distinctive characteristics of the plant capable of visual representation. If approved, a plant patent enjoys a term of 20 years from the date of filing.[68] Plant patents are infringed if another entity asexually reproduces the plant, or uses, sells, or imports into the United States the plant so reproduced. The USPTO has issued approximately 13,000 plant patents since 1930, including 584 plant patents in 2001, as compared to 548 plant patents in 2000 and 421 plant patents in 1999.[69]

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[63] *In re Hibberd*, 227 USPQ 443, 444 (1985).

[64] *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 122 S. Ct. 593, 596 (2001).

[65] Townsend-Purnell Plant Patent Act, 46 Stat. 376 (1930) (codified at 35 U.S.C. §§ 161-164).

[66] 35 U.S.C. § 162.

[67] 35 U.S.C. § 161.

[68] 35 U.S.C. §§ 161, 154(a)(2).

[69] *U.S. Patent and Trademark Office, U.S. Patent Statistics, Calendar Years 1963-2001* (available at www.uspto.gov).

Plant Variety Protection Certificates

A third intellectual property possibility for plants is the Plant Variety Protection Act, or PVPA.[70] The PVPA provides for the issuance of plant variety protection certificates that act similarly to utility and plant patents. Plant variety protection certificates exclusively pertain to sexually reproduced plants, however, including most seed-bearing plants. Fungi and bacteria are ineligible for certification. The plant must be clearly distinguishable from known varieties and stable, in that its distinctive characteristics must breed true with a reasonable degree of reliability.[71]

A key distinction between the plant patent and plant variety protection regimes is the manner in which the inventor has reproduced the protected plant. Asexual reproduction, which results in a plant genetically identical to its parent, forms the basis of plant patent protection.[72] Certification under the PVPA instead depends upon sexual reproduction, which results in a distinct plant that combines the characteristics of its parents.[73]

An example illustrates this distinction. Suppose that inventor Johnny Peachpit cultivates a unique orange tree growing in his orchard. The tree bears seedless oranges of excellent color and taste. Peachpit's nurturing of the tree is by itself insufficient to support a plant patent, and because the tree does not reproduce sexually it is ineligible for a PVPA certificate. But if Peachpit is able to reproduce the tree asexually, through the use of budwood or other techniques, then he would be able to pursue plant patent protection. Suppose further that Peachpit experiments with soybeans, eventually arriving at a variety that grows well in cooler climates. Because soybeans reproduce sexually, Peachpit may be able to obtain a plant variety certificate under the PVPA.

Unlike utility and plant patents, which are issued by the USPTO, plant variety protection certificates are administered by the USDA.[74] To be entitled to a certificate, the plant must be new, distinct, uniform and stable.[75] Although no written description requirement exists in the PVPA, applicants must submit 2,500 seeds to the USDA.[76] The PVPA does not impose a nonobviousness requirement.[77]

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[70]This statute may be found in 7 U.S.C. § 2321 and subsequent sections. The PVPA allows the United States to comply with the International Convention for the Protection of New Varieties of Plants, an agreement the United States joined in 1981.

[71]35 U.S.C. § 2402(a).

[72]35 U.S.C. § 161.

[73]7 U.S.C. § 2402(a).

[74]7 U.S.C. § 2321.

[75]7 U.S.C. § 2402(a).

[76]U.S. Department of Agriculture, Plant Variety Protection Office, General Information (available at http://www.ams.usda.gov/science/PVPO/pvp.htm).

[77]Janis, *supra* note 2.

If allowed to issue by the USDA, the term of a plant variety protection certificate is 20 years (25 years for trees and vines).[78] The holder of a plant variety certificate obtains the right to "exclude others from selling the variety, or offering it for sale, or reproducing it, importing, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom."[79]

An important difference between the utility and plant patents, on the one hand, and plant variety protection certificates, on the other, is the availability of two infringement exemptions under the PVPA. The PVPA includes an exemption that broadly states that the "use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement."[80] In addition, the PVPA grants farmers the right to plant new crops of seeds descended from protected seeds that were legitimately purchased.[81] In contrast, neither the utility nor the plant patent statutes contain these exemptions. Such activities may constitute infringements that may expose researchers and farmers to legal liability, including damages and an injunction.[82] The USDA has issued nearly 5000 plant variety protection certificates in total, including 495 certificates in 2001.[83]

Interfaces in Intellectual Property for Plants

The existence of three intellectual property statutes applicable to plant innovation has resulted in complex issues of interface between the plant-specific statutes and the utility patent system. In particular, experience has demonstrated that innovators have sought concurrent protection of plant innovation under the different regimes. For example, the innovator of a seed-bearing plant could possibly procure rights under all three statutes. Such an innovator could assert that the plant was useful, novel and nonobvious, and file a utility patent application. He could also demonstrate that the plant was new, distinct, uniform and stable, and therefore assert entitlement to a plant variety protection certificate. Finally, he could produce a cutting or otherwise asexually reproduce the plant, and assert an entitlement to plant patent protection.

Seed-bearing plants are most commonly the subject of overlapping rights under the PVPA and the utility patent statute. The significant legal distinctions between these statues appear to motivate innovators to seek multiple rights. In contrast to utility patents, plant variety protection certificates have been viewed as easier to

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[78]7 U.S.C. § 2483(b).

[79]7 U.S.C. § 2483(a).

[80]7 U.S.C. § 2544.

[81]7 U.S.C. § 2543.

[82]35 U.S.C. § 271.

[83]U.S. Department of Agriculture, *Progress Report of the Plant Variety Protection Office* (Jan. 31, 1999); U.S. Department of Agriculture, *Minutes of the Plant Variety Protection Board Meeting* (Nov. 14-15, 2001) (available at http://www.ams.usda.gov/science/PVPO/brdmin.htm).

obtain.[84] The legal requirements for plant variety protection certificates appear less strict than for utility patents.[85] In particular, the USDA does not apply a nonobviousness requirement when assessing applications for plant variety protection certificates.[86] Furthermore, some commentators have viewed the USDA as more accessible to the agricultural industry than the USPTO, which must interact with many sorts of inventions and industries.[87]

Although plant variety protection certificates may be easier to obtain than utility patents, they are generally viewed as providing less substantial rights.[88] Seed replanting by farmers, as well as experimental uses by scientific researchers, are expressly declared not to infringe the rights afforded by a plant variety protection certificate.[89] These acts would ordinarily constitute infringement under the utility patent statute.[90] As a result, some innovators of seed-bearing plants view utility patent protection as even more valuable than the distinct intellectual property right specifically designed for such plants.[91]

Critics of this system of concurrent protection content that by enacting more specific legislation for plant innovation, the intent of Congress was to foreclose utility patent protection for such inventions.[92] In addition, they assert that the possibility of utility patents for seed-bearing plants effectively eliminates the infringement exemptions for research and seed replanting available under the PVPA.[93] Others were more favorably disposed towards this overlap between intellectual property regimes, observing that the rights and responsibilities presented under the three statutes differ.[94]

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[84]Janis & Kesan, *supra* note 3.

[85]*Ibid.*

[86]*Ibid.*

[87]John R. Thomas, *American Bar Association Preview of United States Supreme Court Cases* (Sept. 24, 2001), issue 1 at 4.

[88]Janis & Kesan, *supra* note 3.

[89]*Ibid.*

[90]*See* 35 U.S.C. § 271(a) (stating that any use of an invention subject to a utility patent is an infringement).

[91]Janis & Kesan, *supra* note 3.

[92]Mendelson, *supra* note 7.

[93]Elisa Rives, "Mother Nature and the Courts: Are Sexually Reproducing Plants and Their Progeny Patentable Under the Utility Patent Statute of 1952?," 32 *Cumberland Law Review* (2001-2002), 187.

[94]Nilles, *supra* note 6, at 355.

The *J.E.M. v. Pioneer* Litigation

The *J.E.M. v. Pioneer* Decision

These competing views about the availability of intellectual property rights for plant innovation were ultimately presented to the U.S. Supreme Court. On December 10, 2001, the Court issued its decision in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*[95] There the Court held that plants could be subject to protection under the utility patent statute.

The plaintiff in that litigation, Pioneer Hi-Bred ("Pioneer"), sold hybrid corn to farmers. Pioneer owns numerous utility patents on its hybrid corn. Each Pioneer seed corn bag included a tag bearing a limited patent license that authorized the use of the seed only for crop production.[96] Farm Advantage, an agricultural supply dealer, allegedly sold bags of Pioneer's corn without Pioneer's permission.[97] Pioneer brought suit against Farm Advantage in the U.S. District Court for the Northern District of Iowa.[98] Pioneer asserted that the Farm Advantage sales infringed seventeen of Pioneer's utility patents.

Among Farm Advantage's defenses was that the PVPA was the exclusive statute for obtaining intellectual property rights in seed-bearing plants. Both the trial court and the U.S. Court of Appeals for the Federal Circuit rejected Farm Advantage's argument, holding that a plant protected under the PVPA may also be claimed in a utility patent.[99]

In its 2001 decision, the Supreme Court affirmed the result of the lower courts. Justice Thomas wrote the decision for the majority. He initially observed that § 101 of the 1952 Patent Act employed broad language, including the words "manufacture" and "composition of matter," to define what subject matter could be subject to a utility patent. These terms include artificially generated plants and plant parts, the majority reasoned.

The majority next rejected arguments that congressional enactment of specialized legislation evidenced the congressional intent that living plants could not be the subject of utility patents. Justice Thomas found no specific statement in the legislative history of the utility patent statute or the PVPA suggesting that utility patents could not issue on plants. Instead, he explained, these statutes illustrated only that "Congress *believed* that plants were not patentable under § 101, both because

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[95]122 S. Ct. 593 (2001).

[96]122 S.Ct. at 597.

[97]*Ibid.*

[98]*See Pioneer Hi-Bred International, Inc. v. J.E.M. Ag Supply, Inc.*, 49 U.S.P.Q.2d (BNA) 1813 (N.D. Iowa 1998).

[99]*See Pioneer Hi-Bred International, Inc. v. J.E.M. Ag Supply, Inc.*, 200 F.3d 1374 (Fed. Cir. 2000).

they were living things and because in practice they could not meet the stringent description requirement. Yet these premises were disproved over time."[100]

The majority opinion further observed that the USPTO had assigned utility patents for many years without objection from Congress or the USDA. Justice Thomas explained that "[i]n the face of these developments, Congress has not only failed to pass legislation indicating that it disagrees with the USPTO's interpretation of § 101, it has even recognized the availability of utility patents for plants."[101] In support of this latter assertion, Justice Thomas cited 1999 amendments to the patent laws that appeared to acknowledge that utility patents could issue on seed-bearing plants.[102]

Justice Thomas also observed that a particular legal or property interest is often the subject of multiple statutes. For example, computer software may qualify for protection under both the copyright and patent laws. Justice Thomas concluded that merely because these laws may be of different scope does not suggest that some of them are inapplicable.

Justice Scalia wrote a brief concurring opinion that agreed with the majority. According to Justice Scalia, the issue before the Court had been settled by *Diamond v. Chakrabarty*, which held that living things may be the subject of a utility patent.[103]

Justice Breyer wrote a dissenting opinion that Justice Stevens joined.[104] Justice Breyer believed that Congress intended the two plant-specific statutes to exclude protection under the utility patent statute. Justice Breyer reasoned that allowance of broader utility patents on plants would effectively override the more narrowly tailored rights under the Plant Patent Act and PVPA.[105]

Justice Breyer also distinguished *Diamond v. Chakrabarty* from the current case. According to Justice Breyer, the bacteria at issue in *Diamond v. Chakrabarty* was not a "plant" within the meaning of either the Plant Patent Act or the PVPA. As a result, Justice Breyer concluded that *Diamond v. Chakrabarty* had not addressed the issue of whether utility patents were available for subject matter protectable under the Plant Patent Act or PVPA.[106]

The Supreme Court decision in *J.E.M. v. Pioneer* removed any legal uncertainty that the USPTO may grant utility patents on plants and plant parts. The Supreme

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[100]122 S.Ct. at 600.

[101]122 S. Ct. at 606.

[102]Justice Thomas cited 35 U.S.C. § 119(f), which allows applicants seeking utility patents to obtain the benefit of a filing date of certain foreign plant breeder's rights. *Ibid.* For more on foreign priority under the patent law, see Thomas, *supra* note 41, at 19-20.

[103]122 S.Ct. at 606.

[104]122 S.Ct. at 607.

[105]122 S.Ct. at 608-10.

[106]122 S.Ct. at 607-08.

Court's holding is binding upon the USPTO, which must continue its current practice, as well as the lower courts. Provided that they fulfill the statutory requirements for patenting, including novelty, nonobviousness and written description, plants and plant parts may be subject to utility patents in the same manner as other inventions.

Commentary on the *J.E.M. v. Pioneer* Decision

That utility patents offer plant breeders greater proprietary rights than plant patents or plant variety protection certificates is uncontroversial. Disagreement has arisen, however, over the propriety of the *J.E.M. v. Pioneer* holding and its effect upon the agricultural industry. Critics of the Supreme Court's opinion argue that allowing utility patents to issue on seed will harm research and development, promote industry concentration and limit the traditional right of farmers to save seed. In contrast, other observers find these concerns overstated and believe that limited intellectual property rights for plants would negatively impact the agricultural industry.

Critics of the *J.E.M. v. Pioneer* decision contend that the availability of utility patents will diminish access to the number of plant breeders for research. Joseph Mendelson III, Legal Director for the International Center for Technology Assessment and the Center for Food Safety, asserts that agriculture involves the screening and manipulation of the genetic components of plants. The larger the pool of genetic resources, according to Mendelson, the greater the options possessed by a plant breeder. Mendelson believes that as new varieties are subject to utility patent protection, plant breeders possess fewer genetic characteristics and raw materials.[107]

Other studies have echoed these concerns. A forum at the National Academy of Sciences provided, among others, the following account:

> Even when ownership of a technology is not in doubt, academic researchers sometimes find they are shut out from using inventions whose rights are controlled by private companies. At Iowa State University, for example, plant breeders have been rebuffed a couple of times when they approached a company about licensing a technology. "We were refused, even though the company is licensing to many other companies," said Patricia Swan, vice provost for research and advanced studies at Iowa State University. "The company indicated that [it] did not want to license to us because [it] did not believe that universities were capable of managing and looking after the intellectual property in the way that it should be looked after."[108]

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[107]Mendelson, *supra* note 7.

[108]National Academy of Sciences, National Research Council, *Intellectual Property Rights and Plant Biotechnology* (1997).

Also notable is a 1999 survey of public plant breeders by Steven C. Price, a member of the University of Wisconsin faculty.[109] Price queried whether the proprietary interests of private companies interfered with research by universities and other entities within the public sector. According to Price, 48% of respondents indicated that they had experienced difficulty in obtaining genetic stocks from private companies, 45% indicated that these difficulties interfered with their research, and 23% reported that these difficulties interfered with the training of graduate students. It should be noted that the Price survey did not specify the extent to which the stated difficulties were specifically attributable to utility patent protection, vis-a-vis plant variety protection certificates, trade secrets or other techniques.

Critics have also asserted that the availability of utility patents on plants has promoted consolidation within the seed industry.[110] These observers believe that many recent corporate mergers were motivated by a desire to acquire control of proprietary genetic materials. In addition, critics claim that utility patents on plants place a barrier to entry into the seed industry. According to these commentators, dominant firms with entrenched patent portfolios now enjoy increasing control over access to genetic materials, research pathways and seed prices.[111]

Detractors of *J.E.M. v. Pioneer* further argue that the availability of utility patents on seed will limit the traditional right of farmers to save seed.[112] Farmers have long gathered seed from their own harvest to replant, trade or sell. Utility patent protection allows innovative seed companies to condition the sale of seed upon a farmer's agreement not to replant descendants of the purchased seed. If farmers disregard this restriction, they could be subject to charges of patent infringement.

In contrast to these critics, other observers believe that seeds are appropriately the subject of utility patents. Some commentators believe that utility patents will best encourage research and development in biotechnology by providing intellectual properties commensurate with protection available in other fields of endeavor.[113] Further, if less rigorous intellectual property rights are available for plants than for other types of innovations, it is argued that some actors may shift their research and development efforts away from plants and into other technologies.[114]

Commentators further observe that if plant innovations are excluded from the utility patent system, innovators will likely intensify their efforts to secure alternative

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[109]Steven C. Price, "Public and private plant breeding," 17 Nature/Biotechnology (Oct. 1999) no. 10 at 938.

[110]Mendelson, *supra* note 7.

[111]*See* John Quick, "Intellectual Property: Plants Patentable Under the Utility Patent Statute, PVA, and PVPA," 30 *Journal of Law, Medicine and Ethics* (Summer 2002), 317.

[112]Mendelson, *supra* note 7.

[113]Quick, *supra* note 111.

[114]Joseph Straus, "Patent Protection for New Varieties of Plants Produced by Genetic Engineering – Should 'Double Protection' be Prohibited?," 15 *International Review of Industrial Property & Copyright Law* (1984), 426.

forms of protection.[115] Some types of plant innovation may be protected under the trade secret law.[116] Technological substitutes that limit plant reproduction, such as hybridization and genetic use restriction technologies, may also be available.[117] These alternatives may well impose costs that are not socially productive. Maintaining a trade secret may require expensive security measures, for example. Further, unlike the subject matter disclosed in an issued patent instrument, the subject matter of a trade secret is not circulated to the general public. As a result, others cannot use this information to generate additional innovation.[118]

Other experts observe that the utility patent statute and the PVPA are not overlapping because they present different sets of rights and responsibilities. The utility patent statute imposes the written description and nonobviousness requirements, for example, while the PVPA does not. As explained by Mark Janis, a member of the University of Iowa College of Law, "the PVPA requires relatively low-quality disclosure as compared to the utility patent regime, and in exchange confers relatively low-level protection as compared to the utility patent regime."[119] As the statutes are not wholly duplicative, Professor Janis believes there is no reason to restrict plant breeders to one regime or another.[120]

Supporters of the *J.E.M. v. Pioneer* decision also point to experience suggesting that patent attorneys are sometimes able to circumvent restrictions on patent-eligible subject matter through the artful drafting of patent applications.[121] These drafting techniques focus upon one part of each utility patent, the specific definitions of the patented invention known as the "claims." Each utility patent application, and resulting granted utility patent instrument, must contain one or more claims.[122] In order to maximize their scope of protection, most utility patents contain multiple claims that define the invention in different ways.

Given the ability of patent attorneys to draft a variety of claims, a utility patent directed towards a plant may have a number of claims in addition to the plant as a whole. A particular utility patent might also claim a tissue culture, a method of breeding the plant, a plant part, such as pollen or seeds, or other different aspects of

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[115]Janis & Kesan, *supra* note 3.

[116]*See Pioneer Hi-Bred International, Inc. v. Holden Foundation Seeds, Inc.*, 35 F.3d 1226 (8th Cir. 1994) (adjudicating claim of misappropriation of trade secrets concerning proprietary seeds).

[117]Janis & Kesan, *supra* note 3.

[118]*See* David Friedman, William Landes & Richard Posner, "Some Economics of Trade Secret Law," 5 *Journal of Economic Perspectives* (1991), 61.

[119]Janis, *supra* note 2.

[120]Ibid.

[121]*See* John R. Thomas, "Of Text, Technique and the Tangible: Drafting Patent Claims Around Patent Rules," 17 *John Marshall Journal of Computer and Information Law* (1998), 219.

[122]35 U.S.C. § 112.

the invention.[123] Not all of these claims appear to be directed towards a plant *per se*. As a result, even if *J.E.M. v. Pioneer* had been decided differently, plant breeders might still be able to obtain substantial intellectual property protection through the utility patent system.

Legislative Issues and Options

The *J.E.M. v. Pioneer* decision confirms the current USPTO practice of allowing utility patents to issue on seeds. Competing views have arisen as to the propriety of this practice and its impact upon the agricultural industry. Should Congress have an interest in legislating in this area, a variety of options are available.

If the availability of utility patents for plants is deemed sound, then no action need be taken. Alternatively, Congress could impose new restrictions upon the subject matter eligible for utility patents. The utility patent statute might specify that plants or plant varieties are not eligible for protection.[124] Another option is to compel inventors to make an exclusive choice among one of the three intellectual property options. Under this system, a plant breeder could obtain either a utility patent, plant patent, or plant protection certificate, but not two or three of these intellectual properties.

Another option would be to introduce an experimental use exception in the utility patent statute.[125] Such an exception could be specific to plants in the manner of the existing provision within the Plant Variety Protection Act.[126] Alternatively, this legislation could be general in nature. The following provision, introduced in the House of Representatives in 1990 but not enacted, is an example of a general experimental use exception:

> [I]t shall not be an act of infringement to make or use a patented invention solely for research and development purposes unless the patented invention has primary purpose of research or experimentation. . . . [I]f the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention . . . .[127]

Legislation pending before the 107th Congress appears to bear upon this possibility. The Genomic Research and Diagnostic Accessibility Act, H.R. 3967, would introduce the following language into the utility patent statute:

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[123]Janis, *supra* note 2.

[124]*Ibid.*

[125]Carla R.D. Bourne, "Will § 101 Patents Have Utility for Plants?," 3 *San Joaquin Agricultural Law Review* (1993), 155.

[126]*See* 7 U.S.C. § 2544.

[127]Patent Competitiveness and Technological Innovation Act of 1990, H.R. 101-960 (2d Sess. 1990).

> It shall not be an act of infringement for any individual or entity to use any patent for or patented use of genetic sequence information for purposes of research. This paragraph shall not apply to any individual or entity that is directly engaged in the commercial manufacture, commercial sale, or commercial offer for sale of a drug, medical device, process, or other product using such patent for or patented use of genetic sequence information.[128]

This provision appears to apply to the plant breeding industry to the extent the research involves a patented genetic sequence of a plant.

Another option would be to encourage the plant breeding industry to develop guidelines for plant researchers. These guidelines could articulate those research uses of patented plant inventions that the plant breeding industry deems appropriate.[129] It should be noted, however, that these voluntary guidelines would not necessarily bind all patent owners. Researchers might still be subject to suit by patent proprietors who did not chose to comply with such guidelines.

In considering legislative options, attention should be paid to the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement").[130] The TRIPS Agreement forms one component of the international agreements forming the World Trade Organization (WTO). As a WTO member, the United States has agreed to maintain certain minimum standards of intellectual property protection.

Several of the provisions of the TRIPS Agreement are pertinent to patenting plants. Article 27 of the TRIPS Agreement allows WTO members to exclude plants from the utility patent system if they have enacted a specialized regime for plant variety protection. With both plant patents and plant variety protection certificates available, the United States would be eligible to take advantage of this exception.

Article 27 of the TRIPS Agreement further requires that patent rights must be "enjoyable without discrimination . . . as to the field of technology . . . ." In addition, Article 30 of the TRIPS Agreement allows members to provide "limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Unless a plant-specific experimental use exception is considered sufficiently limited to qualify under Article 30, such a provision could be judged to violate Article 27's requirement that all technologies be treated identically. As the patent statutes of many WTO members include a general experimental use exception, it is unlikely that such a provision would be considered to violate the TRIPS Agreement.

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[128]H.R. 101-960 (2d. Sess. 1990).

[129]*See* Janis, *supra* note 2.

[130]Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15,1994, WTO Agreement, Annex 1C, in *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations* 321, 334 (World Trade Organization, 1999), 33 I.L.M. 81.

Concluding Observations

In *J.E.M. v. Pioneer*, the U.S. Supreme Court opted not to reconfigure the current menu of intellectual property options in the plant breeding field. Plants will continue to be subject to utility patents, plant patents and plant variety protection certificates. A developed empirical record, attentive to the unique structure and climate of innovation of the agricultural industry, may be the best mechanism for determining the preferred interface between intellectual properties in plant innovation.

The impact of *J.E.M. v. Pioneer* may be most immediately felt with regard to the plant variety protection regime. As utility patents offer more robust rights than plant variety protection certificates, plant breeders might decline to seek plant variety protection certificates in favor of utility patents for their more commercially important inventions. It is possible that the PVPA may be relegated to a secondary, "petty patent" regime, employed for inventions with less marketplace significance or for inventions that do not meet the more rigorous standards of the utility patent statute. The PVPA may deserve renewed attention to determine whether that statute remains responsive to the current needs of the agricultural industry.

Supreme Court approval of multiple intellectual property alternatives for plant breeders offers an additional lesson. The boundaries between various federal intellectual property regimes have not always been sharply drawn. Innovators sometimes may obtain concurrent protection through overlapping intellectual property regimes. As a result, proposed legal reform of one intellectual property alternative – be it patent, copyright, trademark or a related regime – may wish to account for other options available to innovators in particular industries.