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Will § 101 Patents Have Utility for Plants?

by

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Will § 101 Patents Have Utility for Plants?

Traditionally, two forms of federal intellectual property protection existed for developments in plant varieties. In the 1980's, for the first time a utility patent was issued for a genetic development in a field crop. Nearly a decade later, the debate continues over what effect these utility patents will have on farming and agricultural research. The following comment examines the use of utility patents for plants, which may alleviate or exacerbate problems with the two traditional forms of plant variety protection. The author urges the agricultural community to lobby Congress for statutory solutions before the issues are relegated to litigation, which would unnecessarily add to the confusion and conflict.

INTRODUCTION

In 1985, the Patent and Trademark Office Board of Appeals and Interferences granted a utility patent[1] for a genetic development in corn. The patented subject matter included the seed, plants and tissue cultures of the "new" plant.[2] The agricultural biotechnology industry viewed the event as a landmark which would transform the industry,[3] because the broad legal protections of a utility patent had been assumed to be unavailable for plants.[4] Previously, those seeking legal protection for a genetically new plant had to choose between two other forms of federal protection.[5]

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[1] 35 U.S.C.A. § 101 (West 1984); § 101 establishes the right to protect one's inventions or discoveries from unauthorized use by others. Commonly when the term "patent" is used a § 101 utility patent is what is meant. The full text of § 101 states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

[2] *Ex Parte Hibberd*, 227 U.S.P.Q. (BNA) 443 (PTO Bd. Pat. App. & Int. 1985).

[3] Tim Beadsley, *US Patent Rights March On*, 317 Nature 568 (1985).

[4] Utility patents had been granted for methods and processes of treating and breeding plants, but never for a plant itself. Technically, some of the claims related to processes did, in fact, amount to claims on a plant, but they were merely a consequence of the process patent. *Hibberd* was the first true utility patent for a plant. Nicholas Seay, *Protecting the Seeds of Innovation: Patenting Plants*, 16 AIPLA Q.J. 418, 427 (Nos. 3 & 4, 1988-89)..

[5] Plant Patents, 35 U.S.C.A. § 161 (West 1984) and Plant Variety Protection Certi-

If viewed for more than profit potential, § 101 protection may not prove to be such a boon for the agricultural world.[6] In practice, the use of utility patents may have a significant chilling effect on both public and private research, and it decreases a farmer's ability to use, legally, seed saved from the previous year's crop.

This comment will examine the traditional forms of plant variety protection and the extension of the utility patent to plants. A compromise will be proposed which lessens the potential research and farming harm of utility patents for plants. Statutory exemptions for farmers and researchers are recommended. Such exemptions could be modeled on existing statutory schemes.

I. Traditional Legal Protection for Plants

The days of generous Johnny Appleseed - walking across the countryside giving away new varieties of apple trees, or any other kind of income-producing plant - are long gone. The world of agriculture is now thoroughly enmeshed with the world of intellectual property[7] rights.[8] Statutory schemes, such as patents, trademarks and copyrights, were created to protect intellectual property by restricting unauthorized access.[9] Without such restrictions, the ability to profit from inventions and artistic creations would surely be lost; consequently, the economic incentive underlying the creation of most intellectual property would be lacking.[10] Economic return must be considered since research and development expense, whether for a new plant variety or a new manufacturing process, can be prohibitive.

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fication, 7 U.S.C.A. § 2402 (West 1988). Patents are exclusively provided by federal law.

[6] For a generally pessimistic view of the effect of genetic engineering on world agriculture and food supply see Edward Yoxen, The Gene Business: Who Should Control Biotechnology? (1984) which predates the judicial decisions to be discussed in this comment. The recent developments may limit even further the access to biotechnology advances.

[7] Intellectual property, as opposed to tangible property, is that which is created by the mind and is not reduced by individual consumption. William Lesser, *Needed Reforms in the Harmonization of U.S. Patent Law*, Agricultural Biotechnology at the Crossroads: Biological, Social & Institutional Concerns 120, 121 (National Agricultural Biotechnology Council Report 3, 1991).

[8] *See generally* Owen Rogers, *Germplasm and How to Protect It*, 26(4) HortScience 360 (1991) and Agricultural Biotechnology at the Crossroads: Biological, Social & Institutional Concerns (National Agricultural Biotechnology Council Report 3, 1991).

[9] Lesser, *supra* note 7, at 120-121.

[10] *Id.*

Of the three basic intellectual property rights - copyrights, patents and trademarks - patents are most frequently utilized in agriculture. In general, a patent is a legal grant of a seventeen-year monopoly to produce an invention.[11] The patentee benefits through the power to grant permission for others to produce the invention in exchange for royalty payments.[12] A civil infringement action can be brought by the patentee against anyone believed to be using, producing or selling the patented item without benefit of a license.[13] Both equitable relief and damages are available.[14]

In recent years, the legal and policy implications resulting from the choice of intellectual property protection have become more complex for those in the specialized agricultural area of plant breeding. Traditionally, there have been two methods of obtaining federal intellectual property protection for new plant varieties. The oldest method is a special patent available for a narrow range of plants.[15] The second method is certification of plant varieties with the United States Department of Agriculture (USDA).[16]

A. Plant Patents

In 1930, Congress passed the Plant Patent Act[17] to provide a special patent for new plant varieties.[18] Except for the specialized subject matter, patents granted under the Plant Patent Act ("plant patents") are governed by the same code sections as utility patents. Thus, the duration, definition of infringement and forms of infringement action are identical to those of utility patents.

The Plant Patent Act addressed two issues which had caused the Patent and Trademark Office to refuse to grant traditional utility patents for plants.[19] First, the popular misconception that all plant vari-

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[11] 35 U.S.C.A. § 154; Patents are provided for constitutionally. U.S. CONST. art. I, § 8, cl. 8.

[12] Lesser, *supra* note 7, at 121-122.

[13] 35 U.S.C.A. §§ 271, 281 (West 1984, Supp. 1992).

[14] Treble damages may be awarded as well as attorney's fees. 35 U.S.C.A. §§ 283-85 (West 1984).

[15] 35 U.S.C.A. § 161 (West 1984).

[16] 7 U.S.C.A. § 2402 (West 1988).

[17] 35 U.S.C.A. §§ 161-64 (West 1984).

[18] As of 1989, over 6000 plant patents had been issued. Robert Jondle, *Overview and Status of Plant Proprietary Rights*, Intellectual Property Rights Associated with Plants 5, 7 (ASA Special Publication No. 52, 1989).

[19] Diamond v. Chakrabarty, 447 U.S. 303, 312-13 (1980); Seay, *supra* note 4, at 419-20.

eties were natural occurrences had been replaced by the recognition that human technology was responsible for many new plant varieties.[20] Second, plant patent applications were exempted from the utility patent requirement that every application include a precise written description of the item or process to be protected.[21] Instead, grant of a plant patent requires that the application description be "as complete as is reasonably possible."[22]

Still, the range of plants protected by the Plant Patent Act is very narrow. A plant patent may be granted to one who "invents or discovers and asexually reproduces[23] any distinct new variety of plant, including cultivated sports,[24] mutants, hybrids, and newly found seedlings, other than a tuberpropagated plant[25] or a plant found in an uncultivated state."[26]

A plant patent only grants "the right to exclude others from asexually reproducing the plant or using the plant so reproduced."[27] For example, a researcher may use a legally obtained sample of the patented variety to develop another distinct variety through sexual reproduction. The plant patent is not infringed because, while asexually propagated plants are genetic clones (i.e. identical to the parent plant), seeds of such a plant will not reproduce an identical offspring.[28] Farm-

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[20] *Id.*

[21] 35 U.S.C.A. § 112 (West 1984); the requirement was considered impossible for plants because some varieties were distinct in ways that defied accurate written description. For example, a rose might only differ in its shade of color.

[22] 35 U.S.C.A. § 162 (West 1984).

[23] Asexual reproduction essentially means reproduction is accomplished through vegetative parts rather than by seed. A new plant is started from root, stem or leaf material of a parent by any of various means including the following: rooting stem cuttings (grapes), budding or grafting stem pieces onto a rootstock (fruit trees), layering stems (apple rootstocks), setting runners (strawberries), root cuttings (blackberries), or through tissue culture techniques under aseptic lab conditions (garlic). JOHN MILTON POEHLMAN, BREEDING FIELD CROPS 26 (2d ed. 1979).

[24] A plant or part of a plant which shows an unusual or singular deviation from the normal or parent type; mutation. THE RANDOM HOUSE COLLEGE DICTIONARY 1271 (rev'd ed. 1980).

[25] Plants reproduced by roots or tubers such as potatoes. POEHLMAN, *supra* note 23, at 26.

[26] 35 U.S.C.A. § 161 (West 1984).

[27] 35 U.S.C.A. § 163 (West 1984).

[28] POEHLMAN, *supra* note 23, at 26; Most sexually propagated plants are, genetically, highly heterozygous. This means that those plants result from the mating of two distinct parent plants which often differ by many genes. Thus, at reproduction many different types of gametes (eggs and sperms) will result. This phenomenon can be understood by remembering that seeds are produced by the fusion of eggs and sperms.

ers must have true clones because they want a crop which has the exact properties and characteristics of the parent.[29] Therefore, they must buy plants from an authorized source to prevent infringement. This is not as great an economic burden as it might at first appear. Crops produced by asexually reproduced plants (for example apples, grapes, and oranges) generate crops for many years as opposed to crops from sexually reproduced plants (for example wheat, soybeans, and rice) which require new seed for each crop. This distinction is important to note as consideration is given to the economic effects of applying traditional utility patent protection to new varieties of agricultural plants.

In addition to using patented varieties in sexual reproduction, researchers may also take advantage of naturally occurring mutations which occur in patented varieties. While the mutations may be slight, the patent office may issue a separate patent to a plant breeder who stabilizes the mutation, causing it to appear in successive generations. For example skin color mutations have occurred frequently in the Gala apple variety resulting in many "new" patented varieties of apples which produce different colors of the original Gala apple.[30]

B. Plant Variety Protection Certification

Most field crops - including wheat, soybeans, rice and barley - are produced through sexual reproduction (i.e. seeds);[31] thus, they are ineligible for a plant patent. In 1970, Congress passed the Plant Variety Protection Act[32] ("PVPA"), to provide plant breeders who develop sex-

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The seed-producing plant (the egg donor) may or may not be the source of the pollen (sperms). Just as no human child is genetically identical to either parent, neither are seeds produced by the male and female parts of many plants. For example, if one saves a seed from an apple core and is able to cultivate it, the fruit on the resulting tree will not have the same genetic characteristics (size, color, taste) as the fruit from which the original seed was taken. POEHLMAN, *supra* note 23, at 13-27.

[29] For example, a farmer who planted an apple orchard with seedlings grown from seeds of Golden Delicious apples would not get a crop of Golden Delicious apples, but rather a mixed variety of apples reflecting the diverse genetic background of the Golden Delicious variety. In order to ensure the quality of the crop, the farmer must plant apple rootstocks taken directly from other Golden Delicious apple trees. An analogy can be made to human reproduction. Traditional sexual reproduction results in a fetus which reflects the diverse genetic background of both biological parents. The only means of obtaining a true clone is by developing two humans from the same initial cell. This occurs with identical twins.

[30] C. S. Walsh and R. Volz, *'Gala,' and the Red 'Gala' Sports: A Preliminary Comparison of Fruit Maturity*, 44 FRUIT VARIETIES JOURNAL 18 (No. 1, 1990).

[31] POEHLMAN, *supra* note 23, at 13.

[32] 7 U.S.C.A. §§ 2321-2582 (West 1984).

ually reproduced plants with a form of intellectual property right similar to a plant patent.[33] Technically, the protection provided by the PVPA is not a patent, but instead a certification by the USDA.[34] A Plant Variety Protection ("PVP") certificate may be granted to "[t]he breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety . . ."[35]

A key to certification is having stability in the variety; the seed must reproduce a plant of the same essential, distinctive characteristics.[36] For example, a PVP certificate would not be issued on a variety of wheat unless breeding trials demonstrated that the wheat crop produced had the same essential genetic characteristics as the parent. As discussed earlier, it had been believed that such stability was only possible through asexual reproduction methods, however, by 1970 it had been proven that true-to-type reproduction by seed was possible in many varieties.[37]

The PVP certificate is infringed if one sells, ships, exchanges, imports, exports or reproduces, either sexually or asexually, a protected variety. Packaging that contains any PVP-certified seed must be specifically marked as containing a protected variety.[38] PVP certificates are valid for eighteen years.[39] Certificate holders may bring civil infringe-

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[33] The PVPA was intended to "stimulate private plant breeding research and to provide better seed cultivars to farmers and gardeners." Over 2100 PVP certificates had been issued as of 1989. Jondle, *supra* note 18, at 6 & 7; H.R. REP. NO. 1605 91st Cong., 2d sess. 3, reprinted in 1970 U.S.C.C.A.N. 5082, 5083.

[34] *Id.*

[35] 7 U.S.C.A. § 2402 (West 1988).

[36] 7 U.S.C.A. § 2401(a)(3) (West 1988).

[37] Diamond, 447 U.S. at 313; Earlier (see *supra* note 28) the fact that the seeds from an asexually propagated plant do not yield a genetically identical plant was discussed. Many sexually reproduced field crops, such as wheat and soybeans, are not genetically heterozygous, however. Instead, they are genetically homozygous for almost all characteristics. This means that these plants result from many generations of self-pollination (the egg and pollen-producing plants are the same). Through this process, heterozygosity is eliminated merely by chance or through selection of uniform plants by a plant breeder. The result is a "true-to-type" seed or one which when planted results in a plant with genetic characteristics identical to the seed parent. For instance, if one saved grains of wheat from one year's crop and planted them, the resulting wheat plants would be genetically identical to the previous year's plants. POEHLMAN, *supra* note 23 at 13-27.

[38] 7 U.S.C.A. § 2541 (West 1988); The Secretary of the USDA may issue a cease and desist order to prevent false marking of a variety. 7 U.S.C.A. § 2568 (West 1988).

[39] 7 U.S.C.A. § 2483(b) (West 1988).

ment actions equivalent to those of patent holders.[40] Civil actions for both injunctions and damages are available.[41]

The PVPA provides two important types of exemptions to certificate infringement. First, farmers may save enough seed from the current year's crop to replant the following year, provided the original seed was obtained from an authorized source.[42] Further, farmers may sell saved seed for which they have no use to other growers whose primary occupation is farming.[43] The second exemption to infringement is granted to researchers.[44] A PVP-certified variety may be used and reproduced in the course of research without violating the certification. As a result, a plant breeder may legally use a protected variety to produce a further improved variety of the same species.

For example, a breeder develops a high-yield variety of wheat (Variety 1) and obtains PVP certification. Another plant breeder obtains some Variety 1 seed through an authorized source. The researcher then undertakes to use Variety 1 in a series of crossing experiments which results in a second new variety (Variety 2) which has both high-yield and drought tolerance characteristics. Variety 2 may effectively eliminate the market for Variety 1, but the PVP certification has not been infringed by the researcher's actions. Indeed, even seemingly insignificant plant variations may not infringe a PVP certificate. As with plant patents, the differences necessary to obtain a separate certification for a "new" variety are very slight.[45]

II. Traditional § 101 Utility Patents Applied in a New Way

In the 1980's, plant patents and PVP certification were joined by a "new" form of intellectual property protection for plants. Judicial decisions resulted in the granting of traditional utility patents to living organisms.

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[40] 7 U.S.C.A. § 2561 (West 1988).

[41] 7 U.S.C.A § 2563-64 (West 1988). As will be seen *infra* section III. D, most PVP litigation never reaches trial resulting in a scarcity of reported cases.

[42] 7 U.S.C.A. § 2543 (West 1988).

[43] *Id.*

[44] 7 U.S.C.A. § 2544 (West 1988).

[45] See *supra* note 30 and accompanying text.

A. Chakrabarty's Bacterium

In 1980, the Supreme Court opened the window of patent opportunity to living organisms in *Diamond v. Chakrabarty*.[46] Chakrabarty, a microbiologist, invented a unique bacterium capable of altering the components of crude oil. Chakrabarty believed the bacterium could help combat oil spills.[47] The Patent Office Board of Appeals upheld the patent examiner's rejection of the patent claims because of a longstanding policy that living organisms could not be patented.[48] The Supreme Court found no such limitation in patent law, but instead looked to legislative history and found that "anything under the sun that is made by man"[49] can be patented.

The court undertook a traditional statutory construction analysis in its opinion. It looked first to the words of the statute to find that living organisms are not explicitly excluded from utility patents.[50] Next the court examined the legislative history of patent law, especially the 1952 recodification, and again found no basis for excluding living organisms.[51] Finally, the court rejected petitioner's argument that existence of the plant patent or PVP certification reflected congressional belief that living organisms could not be granted a utility patent.[52] Instead, the court indicated that those Acts reflected limitations in human understanding of how new plant varieties could be produced.[53] In dictum, the court stated that any dangers or dilemmas which their decision posed for genetic research should be addressed by the legislative branch.[54]

B. From Bacterium to Maize

Patent examiners resisted *Chakrabarty*'s sweeping statement by insisting that the creation of the plant patent and PVP certification preempted the grant of utility patents to plants.[55] The Patent and Trademark Office Board of Appeals and Interferences, however, read

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[46] 447 U.S. 303 (1980).

[47] *Id.* at 305.

[48] *Id.* at 306.

[49] *Id.* at 309 quoting S. REP. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. REP. No. 1923, 82d Cong., 2d Sess., 6 (1952).

[50] Diamond, 447 U.S. at 308.

[51] *Id.* at 308-09.

[52] *Id.* at 311.

[53] *Id.* at 311-14.

[54] *Id.* at 316-18.

[55] Hibberd, 227 U.S.P.Q. at 444.

Chakrabarty as controlling.[56] In 1985, the Board granted a utility patent to Molecular Genetics, a Minnesota biotechnology company, for a variety of corn which had been genetically altered to overproduce tryptophan, an amino acid added to animal feed as a dietary supplement. The resulting corn eliminates the need for supplementing the feed.[57] Under its utility patent, Molecular Genetics can preclude anyone else from developing any other variety of corn with the same tryptophan-producing gene.[58] Molecular Genetics announced its intention to introduce the gene into a wide range of corn varieties to make it marketable in all regions of the United States.[59] The company could have protected its innovative plants and seeds with a PVP certification, but the farmers and researchers exemptions would have prevented the exclusive control allowed by a utility patent.

III. Benefits and Costs of Utility Patents for Plants

A. Incentive for Commercial Research

Utility patents provide obvious advantages for private researchers. Biotechnology companies can obtain all-inclusive protection for new plant varieties and effectively preclude any unauthorized use for seventeen years.[60] One advantage is the likelihood that utility patents will be granted in a new area due to the operation of the description requirement.[61] The patentee submits a series of "claims" which set forth the parameters of the invention, and thus, establishes the extent of the patentee's rights in future infringement actions.[62] In new areas of patenting, broad claims are usually granted because of the nature in which patent examiners consider applications.[63] Patent examiners must have a basis, such as prior knowledge or prior inventions, for rejecting a patent claim.[64] If the claim arises in a new area, it is unlikely that any specific reason for rejecting the claim will exist.[65] Therefore, pioneers in an

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[56] *Id.*

[57] Beardsley, *supra*, note 3; Marjorie Sun, *Plants Can Be Patented Now*, 230 SCIENCE 303 (1985).

[58] *Id.*

[59] Beardsley, *supra* note 3.

[60] 35 U.S.C.A. § 154 (West Supp. 1992).

[61] 35 U.S.C.A. § 112 (West 1984).

[62] Terence J. Centner, *Policy Issues Regarding Property Rights in Biological Inventions*, 24(3) HORTSCIENCE 426, 428 (1989).

[63] Lesser, *supra* note 7, at 125.

[64] *Id.* and 35 U.S.C.A. § 102 (West 1984).

[65] Lesser, *supra* note 7, at 125.

area can expect broad claims to be successful.[66]

If the primary purpose of intellectual property laws is to provide economic incentive for creative endeavors,[67] then utility patents can be viewed as an important means of stimulating research. Further, increased competition amongst breeders may ensure that research is concentrated on areas previously neglected as competitors seek to maximize profits by satisfying marketplace deficiencies.[68] Such an effect was seen after the PVPA was enacted in 1970. Plant breeders, who had previously concentrated on a fairly exclusive group of species, diversified their research.[69]

Commercial researchers will not necessarily benefit by the use of utility patents to the exclusion of public or university researchers. As public universities struggle to fill funding gaps created by increasing budgetary constraints, they too may utilize available intellectual property rights.[70] Although the use of plant patents and PVP certification are not the norm at public universities, some have begun to restrict release of the plant varieties their researchers develop. For example, some universities grant nonexclusive licenses to distribute new varieties in return for a royalty paid on each plant sold.[71]

B. The Research Policy Debate

Underlying the utility patent debate is the issue of whether intellectual property law, in general, serves the goals and policies of research. Law professor Rebecca S. Eisenberg has written extensive articles outlining the competing theories on the benefits and harms of various forms of intellectual property rights.[72] The basic debate centers on

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[66] Those seeking a broad claim do face some difficulties, however. The requirements of 35 U.S.C.A. § 112 (West 1984) that a patent disclose the best process for making and using the invention and give a written description apply to patent applications for living organisms. (See *supra* note 19.) For a detailed discussion of the obstacles presented by § 112 see Edward Lentz, *Adequacy of Disclosures of Biotechnology Inventions*, 16 AIPLA Q. J. 314 (No. 3 & 4, 1988-89).

[67] Lesser, *supra* note 7, at 121.

[68] David W. Davis & James J. Luby, *Some Current Options in the Use of Plant Variety Protection in Horticulture*, 23(1) HORTSCIENCE 15, 17 (1988).

[69] Jondle, *supra* note 18, at 6.

[70] Davis & Luby, *supra* note 68.

[71] Jondle, *supra* note 18, at 13.

[72] Rebecca Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987) [hereinafter Eisenberg, *Proprietary Rights*]; Rebecca Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) [hereinafter Eisenberg, *Patents and the Progress of Science*].

whether scientific progress is better served by free access to all discoveries or by exclusive rights.[73] One view holds that scientific progress consists of continuous refinements and additions to past discoveries and inventions. Without free access, the ability to move science forward is stifled.[74] The other view is that commercial firms will only justify spending corporate resources on research if a strong economic incentive exists.[75] Indeed, absent patent laws, commercial researchers would probably resort to secrecy.[76]

Plant breeders are specifically concerned about whether utility patents will restrict access to germplasm, the vegetative materials of a species which represent its collective hereditary potential.[77] One group of researchers concluded that the primary effect will probably be more formalized exchanges of germplasm information in both public-to-private and public-to-public situations.[78] One possible solution is licensing agreements. Patent holders could sell the right to perform research involving a patented item. Such a compromise preserves the economic benefit of restricted access without resorting to absolute secrecy. Drawbacks of such a solution are additional costs and research delays while negotiating to obtain such licenses.[79] In addition, research licensing does not eliminate the possibility that valuable information might be withheld indefinitely. A researcher or corporation determined to have a monopoly in a particular area might resort to complete secrecy for key methods and processes rather than obtaining any form of public intellectual property protection.

C. The Existing Utility Patent Research Exemption

The PVPA specifically provides a research exemption,[80] and, thus, avoids problems presented by utility patent protection which provides

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[73] Eisenberg, *Patents and the Progress of Science*, *supra* note 72, at 1047-48.

[74] *Id.* at 1055.

[75] Roger A. Kleese, *Proprietary Rights - Private Industry*, Intellectual Property Rights Associated with Plants, 59 (ASA Special Publication No. 52, 1989) recounts Molecular Genetics, Inc.'s pragmatic analysis of which crops held the best profit potential and thus, were worth the investment of research funds. Molecular Genetics, Inc. is the company which obtained the first utility patent for a plant. See *supra* notes 2, 55.

[76] John H. Barton, *Patenting Life*, 264 SCIENTIFIC AMERICAN 40 (March 1991).

[77] POEHLMAN, *supra* note 23, at 465. *See generally* Rogers, *supra* note 8; *Workshop Summary Report*, Intellectual Property Rights Associated with Plants, 178-80 (ASA Special Publication No. 52, 1989); Davis & Luby, *supra* note 68, at 17.

[78] *Workshop Summary Report*, *supra* note 75, at 179.

[79] Eisenberg, *Patents and the Progress of Science*, *supra* note 72, at 1056.

[80] 7 U.S.C.A. § 2544 (West 1988). See *supra* note 44 and accompanying text.

no statutory research exemption. A very limited research exemption for utility patents has developed through case law.[81] The exemption, known as the experimental use defense, arose out of cases where infringement-action defendants argued that they were not guilty of infringement since they were not using the patented item commercially.[82]

Those charged with patent infringement often raise the experimental use defense, but it is rarely successful.[83] *Northill Co. v. Danforth*[84] is a representative case. The defendant claimed that he only experimented with a patented anchor, and that others actually manufactured the infringing anchors. His defense was rejected because the court found that the foundries were acting as the defendant's agents, and that the experimental use defense could not be claimed when the ultimate purpose was commercial.[85]

In 1984, the Court of Appeals for the Federal Circuit took a very strict approach to the experimental use defense in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*[86] The plaintiff held a utility patent on the active ingredient in a sleeping pill.[87] Prior to the expiration of the seventeen-year patent, a drug manufacturer began to test the ingredient as required for its application to market a generic equivalent when the patent expired.[88] The court held that the experimental use defense did not apply, even though: (1) the tests were mandated by the FDA and (2) requiring the manufacturers to wait until the patent had expired to perform the tests would essentially extend the patent for several years.[89] The court held that any use for commercial benefit, even when the plaintiff could show no lost sales or damages, was an infringement.[90]

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[81] Historically, Supreme Court Justice Story is credited with the creation of the experimental use defense to charges of utility patent infringement. Prior to his elevation to the Supreme Court, Justice Story opined that constructing and using a patented item simply for philosophical purposes or to test whether it would actually work could not be an infringement. Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q.J. 457, 458-459 (1988-89); Eisenberg, *Patents and the Progress of Science*, *supra* note 72, at 1023.

[82] *Id.*

[83] Eisenberg, *Patents and the Progress of Science*, *supra* note 72, at 1023.

[84] 51 F. Supp. 928 (N.D. Cal., S.D. 1942).

[85] *Id.* at 929.

[86] 733 F.2d 858 (Fed. Cir. 1984).

[87] *Id.* at 860.

[88] *Id.*

[89] *Id.* at 863-64.

[90] *Id.* at 861.

The chilling effect of such a restrictive view was quickly manifested. Johnson & Johnson sent stern warning letters to researchers at universities, competing companies, and federal laboratories stating that use of its patented cells which produce monoclonal antibodies[91] might constitute infringement regardless of whether the research led to a product that was to be sold.[92] Some patent attorneys and researchers saw this as the realization of their worst fears following the *Roche v. Bolar* decision.[93]

In response to the overwhelmingly adverse reaction to the result in *Roche v. Bolar*, Congress quickly amended patent law. They excluded from infringement the use of patented items in the performance of tests and preparation of information required by a federal law regulating such pharmaceuticals.[94] Thus, a pharmaceutical research exemption was created.

D. Utility Patent Fallout for Farmers

Ultimately, research aimed at producing new varieties of plants should benefit farmers by providing hardier, higher yielding crops. PVP certification served that purpose very well by causing vigorous expansion of research into new areas.[95] While the effects on research of routinely obtaining utility patents for new plant varieties are unknown, increased utilization of such patents for crop varieties will initially increase production costs for farmers. Farmers have little incentive to use any but the most hardy and high-yielding varieties.[96] Unlike the PVPA, utility patents provide no saved seed exemption.[97] Therefore, when farmers use patented varieties, they will not have the legal right

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[91] A human cell culture composed of a single, cancerous cell strain. This cell line is used to elucidate the origin of human disease reaction. MONROE STRICKBERGER, GENETICS 638 (3d ed. 1985).

[92] Jeffrey Fox, *Patents Encroaching on Research Freedom*, 224 SCIENCE 1080 (8 June 1984).

[93] *Id.*

[94] 35 U.S.C.A. § 271(e)(1) (West Supp. 1992).

[95] Jondle, *supra* note 18, at 5-6; 458 new varieties of soybeans have been developed since the passage of the PVPA. Dan Kirkpatrick, *Enforcing the Letter of the Law*, SEED WORLD 8 (December 1991).

[96] Barton, *supra* note 76, at 41.

[97] As noted earlier, plants patented under the plant patent are all asexually produced and thus, do not contain a saved seed exemption either. However, once a farmer purchases the initial planting stock such as fruit trees he can expect many years of production for his investment as opposed to the one crop production given by a purchase of seed.

to save seed from one year's crop to replant the following year. One view is that the increase in production costs will eventually be offset by the increased yield from new, improved varieties.[98]

One author has raised the intriguing question of what may happen with a crop which produces a grain, for instance wheat, but also produces true-to-type[99] seed.[100] Obviously, the farmer's purchase of the original seed from an authorized source gives him the right to produce a crop and sell the resulting grain. How can the patentee police whether the grain is sold as food or as seed? Selling for food would not be an infringement, while selling for seed surely would be since such sales would reduce the number of consumers of seed from licensed dealers.[101]

Another perspective is provided by the seed industry. Many seed companies view utility patents as a way to avoid what is perceived as widespread abuse of the PVPA's saved seed exemption. Under the PVPA, farmers who do not use their saved seed have the right to sell it to other farmers.[102] This aspect of the PVPA's saved seed exemption is looked upon with disfavor by the seed industry.

For example, Asgrow Seed Company, an Upjohn subsidiary, has instituted an aggressive enforcement policy involving the use of field agents to locate and report farmers who appear to be violating the saved seed exemption by selling more than would be necessary to replant their own farmland.[103] Asgrow has initiated at least eighteen suits, most of which have ended in settlement favorable to the company.[104] In *Asgrow Seed Company v. Winterboer*,[105] defendant farmers took the position that they could sell their soybean crop as saved seed as long as such sales were to other farmers.[106] The district court's grant of summary judgment for Asgrow has been reversed. The Court of Appeals held that the saved seed exemption does not give farmers a blanket right to sell saved seed. However, the percentage of crop sold is not the determining factor, rather on remand the district court is to look at

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[98] Barton, *supra* note 76, at 41.

[99] See *supra* note 37.

[100] Seay, *supra* note 4, at 440.

[101] *Id.*

[102] 7 U.S.C.A. § 2543 (West 1988).

[103] Kirkpatrick, *supra* note 95, at 8-9.

[104] *Id.*

[105] No. 92-1048, 1992 U.S. App. LEXIS 33382, (Fed. Cir. Dec. 21, 1992), *rev'g* 795 F.Supp. 915 (N.D. Iowa 1991).

[106] *Id.*; Dan Kirkpatrick, *Recent Rulings Could Affect Future PVP Cases*, SEED WORLD 9 (December 1991).

the extent to which impermissible marketing may have been used by the Winterboers in the farmer-to-farmer sales.[107]

One report indicates that seventy-seven percent of Ohio farmers who farm more than 1,000 acres buy seed from other farmers, while forty-four percent of those with 100 to 250 acres do so.[108] Seed companies surely view such figures bitterly since each farmer might be buying from authorized dealers instead. However, the American Seed Trade Association[109] supports some type of saved seed exemption for all three types of plant protection.[110] The Association's position may be motivated by mere public relations, or it may truly reflect a commitment to providing farmers with new varieties in a cost-effective way.

Delta and Pine Land Co. v. Peoples Gin Co.[111] provides another example of problems that have arisen under the PVPA saved seed exemption. A cooperative gin was found to have violated the exemption by allowing member farmers to tell the gin that their cottonseed should be saved and then sold to any other member farmer who needed it the next season.[112] The court held that this type of brokering by a cooperative was not within the farmer-to-farmer sales envisioned by the PVPA. Rather, person-to-person transactions are necessary.[113]

IV. Possible Statutory Solutions

Plant breeders, both private and public, have begun to seek utility patents for their products. The Patent and Trademark Office reported that in Fiscal Year 1986 seventy-three applications for utility patents on plants were filed. In 1987, the number increased to 137. By 1988, 235 such applications had been filed.[114] The agricultural industry will not be comfortable with the use of utility patents, however, until questions surrounding research and saved seed exemptions are resolved. For instance: will federal courts be willing to find implied exemptions; will utility patent holders vigorously enforce their rights against researchers

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[107] Asgrow Seed Company v. Winterboer, No. 92-1048, 1992 U.S. App. LEXIS 33382 at *16 (Fed. Cir. Dec. 21, 1992).

[108] Centner, *supra* note 62, at 428.

[109] An organization representing members of the American seed industry.

[110] William Schapaugh, *The Seed Trade's View on Proprietary Rights*, Intellectual Property Rights Associated with Plants, 19 (ASA Special Publication No. 52, 1989).

[111] 546 F. Supp. 939 (N.D. Miss., 1982), *aff'd*, 694 F.2d 1012 (5th Cir. 1983).

[112] *Id.* at 942.

[113] *Id.* at 944.

[114] Charles F. Warren, *Issues and Challenges in the Administration of the Patent Law with Regard to Plants by the Patent and Trademark Office*, Intellectual Property Rights Associated with Plants, 147 (ASA Special Publication No. 52, 1989).

and farmers? Attempts to resolve these issues could be relegated to infringement litigation with the resulting answers, consequently, being less than efficient and, in all likelihood, confusing.

The only efficient means of resolving these issues is through legislative action. The PVPA, as well as the pharmaceutical research exemption,[115] provide precedent for such action. Further, many nations provide research exemptions in their regular patent laws.[116] A variety of suggestions have been made as to how the United States could do the same.[117] In fact, some form of exemption is needed to serve the Constitutional goal of "promot[ing] the progress of . . . useful arts."[118] Therefore, Congress has no legitimate excuse and, perhaps a constitutional mandate, to provide a research exemption to the utility patent.

Unfortunately, utility patent law has long existed without any research exemption (excepting the recent pharmaceutical research exemption) which makes it unlikely that Congress will suddenly initiate the creation of one. Farmers and researchers must convince Congress of the harsh predicament facing agriculture. The ill-effects will only increase if Congress procrastinates on this issue. Entire realms of research could be removed from general access for up to seventeen years. Farmers may experience significant harm without a saved seed exemption. Production costs will rise leaving farmers to hope they can recover the difference through increased yields or price. For example, if a particular company produced a gene which increased drought tolerance and then patented that gene for an entire species, such as soybeans, both researchers and farmers could suffer.

However, a special exemption for biotechnology, or even more specifically plant breeding, does seem possible. When presented with a narrow pressing issue, such as pharmaceutical research, Congress has acted decisively.[119] The agribusiness and university communities need to lobby Congress and make the need for a specific research exemption a pressing issue.

A utility patent saved seed exemption could be created which allows companies to profit without subjecting farmers to unreasonable production costs. A feasible exemption would allow farmers to save, but not

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[115] See *supra* note 94 and accompanying text.

[116] Barton, *supra* note 76, at 43.

[117] Such suggestions range from blanket research exemptions to exemptions which allow research after a specified time. See, Barton, *supra* note 76, at 43; Centner, *supra* note 62, at 427; Eisenberg, ***Patents and the Progress of Science***, *supra* note 72, at 1078.

[118] Israelsen, *supra* note 81, at 475 *citing* U.S. Const., Art. I, § 8, cl. 8.

[119] 35 U.S.C.A § 271(e)(1) (West Supp. 1992).

sell, seed. Such a compromise is also frequently suggested as a solution to the PVPA saved seed exemption problem.[120] Farmers would retain the right to replant from their own crop if the original utility-patented seed was obtained from an authorized dealer. No sales of saved seed would be allowed. Congress should undertake to create such an equitable system before the courts are embroiled further in infringement disputes.

V. Conclusion

Increased utility patent protection offers an opportunity to invigorate biotechnology research. However, Congress must act to ensure that all researchers and farmers can benefit. Scientific progress, especially in the area of plant breeding, relies on the availability of past progress to move forward. New inventions that might refine or advance a particular plant species should not be excluded from further testing and research for periods of seventeen years. Profit potential should not take precedence over increased farm production and subsequent improvement in the availability of food. Economic incentive plays an important role in agricultural research; however, it should not be cast as the dramatic lead. Intellectual property rights in the world of agriculture should function to enhance farming. A proper balance between free research access, proprietary rights, and production costs is needed to accomplish that goal.

Carla R. D. Bourne

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[120] *Workshop Summary Report*, *supra* note 75, at 185. If such a change was made to the PVPA saved seed exemption, utility patents might not be widely utilized for plants since one of the primary problems with the PVPA would be eliminated. Kirkpatrick, *supra* note 95, at 9.