Patent Pools and Antitrust Concerns in Plant Biotechnology

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No single company or organization . . . has the resources to develop any significant fraction of the genetic information present in an organism. If proprietary information is not freely available or licensed in an affordable manner, researchers will be precluded from using these protected nucleic acids to develop new therapeutics and diagnostics.[1]

Genetic inventions are both legally patentable and increasingly patented.[2] Innovations in research and market dynamics are driving new patent applications for genetic inventions. The increase in biotechnology patent applications has surpassed all other types of patent applications.[3] Genetic innovations and advances in plant biotechnology cut across medical, agricultural, and industrial fields. Because genes control all life processes, patents on genes can function as "gatekeepers" on subsequent innovations.[4] This Article looks at how gene patents, and in particular plant patents, pose antitrust concerns. Then, it compares patent pools to other congressional, administrative, and self-help remedies.

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[1] JEANNE CLARK ET AL., U.S. PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 3 (2000), *available at* http://www.uspto.gov/web/offices/pac/dapp/ opla/patentpool.pdf (last visited Feb. 14, 2005).

[2] ORGANISATION FOR ECON. CO-OPERATION AND DEV., GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES 8 (2002), *available at* http://www.oecd.org/dataoecd/42/21/2491084.pdf (last visted Feb. 14, 2005) [hereinafter OECD].

[3] *Id.*

[4] Lorelei P. Westin, *Genetic Patents: Gatekeeper To The Promised Cures*, 25 T. JEFFERSON L. REV. 271, 281 (2002).

Worldwide patents on genes and plants are on the rise. The United States Patent and Trademark Office (PTO) listed 9456 patents that include the term "nucleic acid" in 2002.[5] The Japanese Patent Office has granted 5652 patents since 1996.[6] Between 1998 and 2002, the European Patent Office (EPO) received 30,000 patent applications.[7] In 2001 alone over 5000 DNA patents were granted by the PTO.[8]

Though the use of plant utility patents is recent, there have been 3771 utility patents granted on plants since 1995.[9] It is estimated that 40 percent of gene patents relate to micro-organisms, plants and/or animals, and 60 percent of patents relate to human or animal DNA sequences.[10] In the United States in 1999, 52 percent of the gene patents were owned by genomic and pharmaceutical companies, 23 percent were held by universities, and 19 percent were owned by non-profit research organizations.[11]

Patents on plant genetic inventions have pharmaceutical, industrial, and agricultural applications.[12] Patents on plants, however, include both genetic inventions as well as plants produced through sexual propagation (traditional breeding).[13] Biotechnicians and plant breeders merge their efforts to test and introduce new varieties.[14] The global market for commercial crop seed was estimated at $15 billion in 1990.[15] The annual

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[5] OECD, *supra* note 2, at 8.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] Search of PTO database, query of utility patent claims for "seed" and "plant" since 1995, *at* http://www.uspto.gov (last visited Feb. 14, 2005).

[10] OECD, *supra* note 2, at 38.

[11] *Id.*

[12] For a comprehensive listing of approved field tests, state by state, including their intended application, see Information Systems for Biotechnology (ISB), Field Test Releases in the U.S. Blacksburg, VA: Virginia Polytechnic Institute and State University (Virginia Tech) (Virginia Tech's searchable database), http://www.isb.vt.edu/cfdocs/fieldtests1.cfm, (last visited Feb. 14, 2005).

[13] *See* J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001) (the Supreme Court extended the scope of the utility patent to include sexually produced plants).

[14] Mark Hannig, *An Examination of the Possibility to Secure Intellectual Property Rights for Plant Genetic Resources Developed by Indigenous Peoples of the NAFTA States: Domestic Legislation Under the International Convention for Protection of New Plant Varieties*, 13 ARIZ. J. INT'L. & COMP. L. 175, 185 (1996).

[15] The commercial global market for seed had an annual estimated value of $30 billion in 2004. The U.S. seed industry accounts for about 20 percent of this market. *See* AMERICAN SEED TRADE ASSOCIATION, *at* http://www.amseed.com/about_statistics.asp (last visited Mar. 8, 2005).

world market for medicines derived from medicinal plants was estimated at $43 billion.[16] Because the diversity of genetic resources lies outside the United States, genetic advancements in plant varieties require access to plant germplasm from around the world.[17]

Historically, access to and management of plant genetic diversity was based on a "common heritage" approach.[18] However, in response to the rise in patents in the United States and Europe, the Convention on Biological Diversity and subsequent international treaties have put an end to the common heritage regime.[19] This change affords states intellectual property rights over all plant genetic diversity within their borders.[20]

In addition to medicine and research, gene and plant patents impact genetic conservation and food security. Farmers have bred plants through the mass selection of seeds since agriculture began.[21] The exchange of seed among farmers and the lack of explicit proprietary rules were common to agriculture before the 20th century, and remain the dominant approach to seed management for the majority of farmers worldwide.[22] In reaction to the United States and Europe patenting their plants, less developed countries replaced the common heritage regime with sovereign control over plant genetic resources. Countries with vast plant genetic resources have now closed access to plant material

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[16] Hannig, *supra* note 14, at 192 n.75.

[17] *Id.*

[18] *Id.*

[19] Article 15 of the Convention on Biological Diversity recognizes sovereign rights of States over their natural resources. *See* Convention on Biological Diversity, June 5, 1992, art. 15, 1760 U.N.T.S. 76, *available at* http://www.biodiv.org/doc/legal/cbd-en.pdf (last visited Feb. 6, 2005) (entered into force on Dec. 23, 1993); *see also* Gregory Rose, *International Law of Sustainable Agriculture in the 21st Century: The International Treaty on Plant Genetic Resources for Food and Agriculture*, 15 GEO. INT'L ENVTL. L. REV. 583 (2003); S. Johnston, *Conservation Role of Botanic Gardens and Seed Banks*, 2 REV. EUR. COM.& INT'L ENVTL. L. 172, 177-78 (1993); International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, *available at* ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf (last visited Feb. 17, 2005) (codifying 35 crops as common heritage and extending intellectual property to all other plants) [hereinafter ITPGR].

[20] ITPGR, *supra* note 19.

[21] Hannig, *supra* note 14, at 185.

[22] Stephen B. Brush, *The Demise of 'Common Heritage' and Protection for Traditional Agricultural Knowledge*, *available at* http://law.wustl.edu/ centeris/confpapers/ PDFWrdDoc/StLouis1.pdf (last visited Feb. 15, 2005) (paper prepared for conference on biodiversity, biotechnology, and the protection of traditional knowledge, St. Louis, Mo, April 4-5, 2003).

and are seeking to secure lucrative licensing arrangements with pharmaceutical firms. One example is the Merck/INBio agreement.[23] With the introduction of patented crops, farmers have had to sign licensing agreements with forum selection clauses, gag rules, and provisions preventing growers from saving, using, selling, and exchanging seed.[24] Growers now face patent liability for infringement because of patented pollen cross-pollinating with their non-patented seed crops.[25] Licensing arrangements and transaction costs constitute new hurdles to plant conservation, variety development, and medical and agricultural research.

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[23] "Merck Pharmaceuticals contracted with INBio, a private nonprofit biodiversity institute created by the Costa Rican government, to 'bioprospect' the species-rich Costa Rican lands." Rory J. Radding, *Interfaces Between Intellectual Property and Traditional Knowledge and Folklore: A U.S. Perspective*, *available at* http://library.lp.findlaw.com/articles/file/00310/008753/title/Subject/topic/Intellectual%20Property_Genetics/filename/intellectualproperty_1_748 (last visited Feb. 15, 2005). In exchange for Costa Rican screening and research services, and extracts from Costa Rican plants, insects, and microorganisms, "Merck provided US $1.3 million as an initial sum, plus a share of any royalties on commercial products developed from these accessions." *Id.*; *see also* Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 958 (1996).

[24] Labels on seed bags inform purchasers that they are entering into legal agreements with seed companies, which typically provide that the purchaser abide by specific use restrictions on the seed. *See* 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 ENVTL. L. REP. 10698, 10708 (2002).

[25] Percy Schmeiser says he never wanted gene-altered canola on his 1400 acres in Western Canada. *See* Monsanto Canada Inc. v. Schmeiser, [2002] F.C. 309. But he was sued by Monsanto in 1998 after his conventional canola fields were contaminated with the company's Roundup Ready Canola. In 2000, a judge agreed with Monsanto, and held Percy liable for over $180,000 Canadian. "I can tell you stories that go on forever. It goes beyond bullying tactics," says Rodney Nelson, who also outlines his saga on his website. *See* Sally Deenan, *Non-GM Farmers Pay* (Oct. 9, 2003), available at http://www.non-gm-farmers.com/news_print.asp?ID=749 (last visited Feb. 15, 2005); Nelson Farm, *at* http://www.nelsonfarm.net (last visited Feb. 15, 2005). Nelson's family grows soybeans and wheat on 8000 acres outside of Amenia, North Dakota. He says his family has spent more than $200,000 in attorney fees and other costs fighting Monsanto after it accused the family farm of saving Roundup Ready soybean seeds from their 1998 crop and planting them in 1999. Monsanto continued its lawsuit, but finally dropped it in the autumn of 2001. Several farmers have unsuccessfully alleged violations of the Sherman Antitrust Act and Racketeer Influenced and Corrupt Organizations Act (RICO). Additionally, they have also claimed that the company committed negligence, fraud and deceit, breach of implied warranty of merchantability, and breach of implied duty of good faith and fair dealing. *See, e.g.*, Massey v. Monsanto Co., No. 299CV218-P-B, 2000 WL 1146705 (D. Miss. June 13, 2000); Blades v. Monsanto Co., No. 00-CV-4034-DRH, 2001 WL 775980 (S.D. Ill. 2001).

The rise in plant and biotechnology patents has closely mirrored changes in U.S. patent law. In 1980, the Supreme Court put an end to the traditional bar against patenting living organisms. *Diamond v. Chakrabarty* extended the scope of the utility patent to include genetically engineered bacteria capable of digesting spilled petroleum.[26] In 1985, PTO further extended the scope of the utility patent to include non-genetically engineered plants. In *Ex parte Hibberd*, the Board of Patent Appeals made an agency determination, that a corn variety produced through traditional breeding was patentable subject matter.[27] In 2001, the Supreme Court confirmed the patentability of sexually propagated plants in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l*, Inc.[28] In doing so, the Court eliminated the farmer seed saving provision and the research exemption reserved in the Plant Variety Protection Act.

In 1993, the PTO first considered a proposal to patent gene fragments, also known as Express Sequence Tags (ESTs). The application was rejected for lack of novelty, non-obviousness, and utility.[29] In 1995, the Patent Commissioner issued new Guidelines for Examining Applications for Compliance with the Utility Requirement, which lowered the utility standard of proof.[30] The 1995 Guidelines resulted in a "gold rush" in the biotechnology industry.[31] In 1997, the PTO announced that it would

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[26] 447 U.S. 303, 305 (1980). *Chakrabarty* was distinct from *Hibberd* in that *Chakrabarty* concerned the use of genetically engineered organisms, not sexually propagated plants.

[27] 227 U.S.P.Q. 443 (Bd. Pt. Of Patent App. and Interferences) (1985).

[28] 534 U.S. 124 (2001). Previously, only asexually propagated plants could be patented, and only under the Plant Patent Act.

[29] Leslie Roberts, *Gene Patents: Rumors Fly Over Rejection of NIH Claim*, 257 SCIENCE 1855, 1855 (1992).

[30] Mary Breen Smith, Comment, *An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 766-67 (2002). "If the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., 'a specific utility') and that assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility." Utility Examination Guidelines, 60 Fed. Reg. 36,263 (July 14, 1995).

[31] Eliot Marshall, *Companies Rush to Patent DNA*, 275 SCIENCE 780, 780-81 (1997). At the time over a half million partial gene sequences were pending. By 1990, a single company, Incyte Pharmaceuticals, Inc., had filed applications on 1.2 million partial gene fragments. Hyseq, had patents pending for 900,000 gene discoveries. Pfizer reportedly paid $15.75 million to Incyte Pharmaceuticals for access to their DNA database and SmithKline Beecham has paid $125 million to Human Genome Sciences for access to its genetic information. *See Corporate Agreements*, BIOVENTURE VIEW (Nov. 1994). "Currently three million gene-related patent

grant patents for ESTs based upon the usefulness in locating their complete gene sequence in a given DNA sample.[32]

I

ANTITRUST CONCERNS IN PLANT PATENTS

A patent holder may incur liability under sections 1 or 2 of the Sherman Antitrust Act.[33] Section 2 of the Sherman Act mandates imprisonment or monetary penalties for every person who monopolizes any part of trade or commerce.[34] Section 1 of the Sherman Act imposes antitrust liability for multi-firm conduct.[35] Fraudulent procurement and patent enforcement,[36] bad faith or sham patent enforcement,[37] and monopoly power[38] all constitute illegal activities under the Sherman Act.[39]

As lawsuits for patent infringements increase, so does the likelihood of antitrust counterattacks.[40] Antitrust counterattacks

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applications have been filed with the USPTO—more than there are genes in the human body." Brian O'Reilly, *There's Still Gold In Them Thar Pills*, FORTUNE, 58 (July 2001).

[32] Joshua C. Benson, Note, *Resuscitating the Patent Utility Requirement, Again: A Return to* Brenner v. Manson, 36 U.C. DAVIS L. REV. 267, 278 (2002); May Mowzoon, Comment, *Access Versus Incentive: Balancing Policies in Genetic Patents*, 35 ARIZ. ST. L.J. 1077, 1088 (2003). These Guidelines were amended in 1999 in the Revised Interim Utility Guidelines, which replaced the 'credible utility' of the 1995 Guidelines with the requirement of "specific, substantial, and credible utility."

[33] 15 U.S.C.A. §§ 1-2 (2004).

[34] Section 2 reads in part,

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court . . . .

Id. § 2.

[35] Section 1 reads in part, "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." *Id.* § 1. Licensing arrangements between corporations that restrain trade could give rise to antitrust liability.

[36] *See* Walker Process Equip., Inc. v Food Mach. & Chem. Corp., 382 U.S. 172, 176-77 (1965).

[37] *See* Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 992 (9th Cir. 1979).

[38] The Supreme Court ruled that control of 75 percent of a relevant market constituted monopoly power. United States v. E.I du Pont de Nemours & Co. 357 U.S. 377, 391 (1956).

[39] Richard G. Schneider et al., *The Antitrust Counterattack in Patent Infringement Litigation*, A.B.A. SEC. ANTITRUST L. 49-56 (1994).

[40] *Id.* at 89.

may take the form of counterclaims in the patent infringement cases, or they may appear as new suits filed after invalid patent infringement claims are dismissed.[41] For example, a person may file a claim under the Clayton Act, which provides victims of antitrust injuries with a private cause of action and treble damages.[42] To date, defensive claims of antitrust have not met with success.[43]

Legal scholars have argued that patents on genes and on plants pose a potential "tragedy of the anti-commons," where numerous property rights claims hinder subsequent research and development.[44] However, interviews with U.S. firms showed little evidence that intellectual property (IP) rights or negotiations have broken down or that research has slowed.[45] However, patent thickets, royalty stacking, and reach-through rights are recognized concerns for the industry.[46] This environment is likely to become more complex as IP protection extends to include the informational nature of genetic inventions such as database protection, and copyright and patents for software.[47] Collective actions, like the formation of consortia and patent pools, are emerging to overcome transaction costs associated with the increasing complex patent environment.[48]

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[41] *Id.*

[42] 15 U.S.C.A. § 15 (2004).

[43] Monsanto Co. v. Scruggs, 249 F. Supp. 2d 746 (N.D. Miss. 2004). Scruggs alleged antitrust and patent misuse as an absolute defense to Monsanto's infringement action. *Id.* at 748. Scruggs argued that Monsanto implemented a seed cartel through its vast web of contractual agreements with seed partners (of which there were close to three hundred). *Id.* at 752. Focusing on the grower agreements and dealer incentives, the Court did not find anticompetitive behavior. *Id.* at 753.

[44] *See generally* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698-701 (1998). Other scholars have argued that plant genetic resources suffer from a "tragedy of the commons," where genetic resources leave the South as the common heritage of mankind and return as individually owned commodities for sale at prices that inhibit many citizens of the LDCs from having access to them. *See also* James O. Odek, *Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 149 (1994).

[45] *See* John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (S. Merrill et al. eds., 2003) (describing a study consisting of interviews with executives and researchers at biotechnology and pharmaceutical firms, research personnel and administrators at several universities).

[46] OECD, *supra* note 2, at 60.

[47] *Id.*

[48] *Id.*

"Patent thickets" arise when there are multiple patent holders controlling various components of a product.[49] As a result, the product's price is higher than if a single firm controlled the inputs. Reach-through claims refer to patents on "upstream" technologies[50] used in the research process itself.[51] Upstream patent claims are on the rise at the EPO and PTO.[52] Upstream patent claims can result in royalty stacking[53] and blocking patents.[54] Royalty stacking has resulted in unreasonable royalties in biotechnology, in some cases exceeding 20 percent.[55] Blocking patents arise when improvement patents and pioneer patents cannot be exploited without infringing upon each other.[56]

Since no technologies can yet substitute for genes and genes cannot be improved upon, genetic patents have been "true gatekeeper patents."[57] In the making of Golden Rice, public and private researchers navigated over seventy patents to raise the level of vitamin A in rice.[58]

Other actions can also trigger antitrust concerns in genetic and plant innovations, such as grantback provisions, tying arrangements, and package licensing. Grantback provisions that assign subsequent innovations to the licensor suppress innovations.[59] Tying arrangements, in which a seller refuses to sell one product without being "tied" to another, are illegal.[60] Additionally, pack-

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[49] *Id.* at 61.

[50] "Upstream" describes technologies that involve several patents in a single process. An example would include a patented Express Sequence Tag used to identify a specific gene sequence used to confer a specific trait, such as herbicide resistance.

[51] OECD, *supra* note 2, at 63.

[52] *Id.*

[53] Royalty stacking is where so many parties have partial ties or interests in so many elements that it is difficult for researchers or product developers to operate. *Id.*; *See also* Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 441 (2003).

[54] *See generally* Steven C. Carlson, Note, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359 (1999).

[55] *See* OECD, *supra* note 2, at 15.

[56] *See* Robert P. Merges, *A Brief Note on Blocking Patents and Reverse Equivalents: Biotechnology as an Example*, 73 J. PAT. & TRADEMARK OFF. SOC'Y. 878, 878-79 (1991).

[57] Westin, *supra* note 4, at 282.

[58] OECD, *supra* note 2, at 63.

[59] The Supreme Court has previously upheld grantback provisions against a per se illegality challenge. Transparent-Wrap Mach. Corp. v. Stokes & Smith Co., 329 U.S. 637, 648 (1947).

[60] To establish per se illegality of tying, the elements include: (1) presence of a tying arrangement between two distinct products or services; (2) evidence of sufficient market power by the seller, which results in coercion on a significant number

age licensing can trigger antitrust problems if a licensee can prove that it requested and was refused the opportunity to license particular patents, or that a licensor "held hostage" an entire research endeavor.[61] Furthermore, because genes are required for all crop breeding, genetic innovations may also raise antitrust concerns under the "essential facilities doctrine."[62]

Gatekeeper patents in genetic innovation have already impacted public research. For example, after a patent was granted on the hemachromatosis gene, 30 percent of the 119 U.S. laboratories surveyed reported discontinuing a genetic test for the disease.[63] Additionally, "[a] 2002 study found that 47 percent of geneticists had been denied requests from other faculty members for information, data, or materials regarding published research."[64] Moreover, gatekeeper patents have hindered plant variety development. At universities, public breeders are reticent or prohibited from releasing new plant varieties without Material Transfer Agreements protecting their intellectual property.[65] Additionally, in one study, nearly 50 percent of public plant breeders had difficulty obtaining genetic stocks.[66] Furthermore, in that study, one-fourth of breeders responded that graduate student training has been harmed.[67]

Finally, gatekeeper patents also have decreased the availability of plant varieties. Between 1995 and 1998, approximately sixty-

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of buyers; and (3) substantial amount of commerce in the tied product. *See* Eastman Kodak Co. v. Image Technical Services, Inc., 504 U.S. 451, 461-62 (1992); Betaseed Inc. v. U. and I. Inc., 681 F.2d 1203, 1215 (9th Cir. 1982) (citing Northern Pacific Railroad v. United States, 356 U.S. 1, 5-6 (1958)).

[61] *See* Hensley Equip. Co. v. Esco Corp., 383 F.2d 252, 265 n.24 (5th Cir. 1967); McCullough Tool Co. v. Well Surveys, Inc., 343 F.2d 381, 408-10 (10th Cir. 1965).

[62] Under the "essential facilities doctrine" the plaintiff must show: (1) control of an essential facility by a monopolist, (2) inability of competitors to duplicate practically the facility, (3) refusal by the monopolist to give competitors access to the facility, and (4) feasibility of providing such access. MCI Communications Corp. v. AT&T Co., 708 F.2d 1081, 1132-33 (7th Cir. 1983).

[63] Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 78 (2002); *see also* James B. Kobak, Jr., *Intellectual Property, Competition Law and Hidden Choices Between Original & Sequential Innovation*, 3 VA. J.L. & TECH. 6 (1998).

[64] Andrews, *supra* note 63, at 80.

[65] In the USDA IFAFS project, *The Public Seed Initiative*, grower cooperators had to sign MTA's to work with Cornell plant varieties, and were prohibited from selling or exchanging seed with others without MTA's.

[66] Steven C. Price, *Public And Private Plant Breeding*, 17 NATURE BIOTECH. 938 (1999) (letter to editors).

[67] *Id.*

eight seed companies either were acquired by or entered into joint ventures with six large, multinational corporations (Monsanto, Aventis, Dow, AstraZeneca, Novartis, and DuPont).[68] In 2000, ten companies controlled 30 percent of the commercial seed market worldwide, and just five vegetable seed companies controlled 75 percent of the global vegetable seed market.[69] Seminis, the world's largest vegetable seed corporation, eliminated 25 percent of its product line (2000 varieties were acquired through mergers and acquisitions that lacked IP protection).[70] Of the 5000 non-hybrid vegetable varieties available in 1981, 88 percent had been dropped by 1998.[71] Seed prices, in turn, have risen dramatically in response to increasing royalties.[72]

Antitrust law prevents patent holders from using their monopoly power as a sword instead of a shield.[73] Restraining trade through excluding or impeding innovation can lead to antitrust liability. Many plant patents are for traits for herbicide resistance, resulting in vertical integration of agricultural inputs provided by a single firm.[74] Additionally, since plant patents extend to pollen carrying the patented traits, plant and gene patents can

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[68] Between 1998 and 2001, there were over $34 billion in mergers and acquisitions by these six corporations. The largest patent holders are the most active in purchasing and collaborating with each other. In 2000, Monsanto purchased Holden Foundation Seeds for $1 billion, the remaining 60 percent of DeKalb Genetics, Asgrow, Agracetus, and Cargill's seed division. Over a five year period, Monsanto acquired, merged with, or obtained an interest in DeKalb (1998), Calgene (1997), Asgrow (1996), First Line Seeds Limited (1998), Holden's Foundation Seed (1997), Plant Breeding International (1999), Agracetus, and Ecogen. DuPont paid $7.7 billion to acquire remainder of Pioneer. DuPont is now the world's largest seed company. Novartis, the merger of Ciba-Geigy and Sandoz, owns Northrup King, Rogers Seed Co., Funk Seeds International, and others, then merged with Astra Zeneca to form Syngenta. *See generally* Mendelson, *supra* note 24.

[69] *Earmarked for Extinction? Seminis Eliminates 2,000 Varieties*, Rural Advancement Foundation International, July (2000), *available at* http://www.etcgroup.org/article. asp?newsid=25 (last visited Feb. 15, 2005).

[70] *Id.*

[71] *Id.*

[72] Total seed expenditures by U.S. farmers rose from about $500 million in 1960 to over $6.7 billion in 1997. Similarly, when measured as a share of total farm expenditures, seed expenditures increased from 2 percent in 1970 to 4 percent in 1997. *See* JORGE FERNANDEZ-CORNEJO, U.S. DEP'T OF AG., THE SEED INDUSTRY IN U.S. AGRICULTURE: AN EXPLORATION OF DATA AND INFORMATION ON CROP SEED MARKETS, REGULATION, INDUSTRY, STRUCTURE, AND RESEARCH AND DEVELOPMENT (2004) (Agriculture Information Bulletin 786).

[73] Atari Games Corp. v. Nintendo of Am. Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990).

[74] For example, the patent on the herbicide Roundup, owned by Monsanto, has expired. Roundup is the most widely used herbicide in the world. Monsanto crop

secure unheralded horizontal control over plant breeding technology. This is analogous to releasing a patented virus and suing the sick for infringement.

For example, in the case of Canadian canola grower Percy Schmeiser, the Monsanto Company alleged that Schmeiser had infringed their patent on canola after they tested his seed and found their patented gene.[75] Two lower courts found that Percy had infringed the patent.[76] Those courts stated that it did not matter whether Schmeiser had ever used the patent (grown plants to resist herbicide application).[77] The Canadian Supreme Court heard his case in January, 2004. It ruled that the patent was valid, but that the patent did not extend to the entire plant and therefore no infringement had occurred.[78] There are several similar cases in the United States. Those cases have been settled, with provisions preventing the parties from discussing the case.[79]

II

Remedies

There are government and private sector solutions to the antitrust threats to innovation in biotechnology and plant patents. Surveyed U.S. biotech firms held that "working solutions," such as changing the types of contracts negotiated and the formation of consortia and patent pools are emerging to overcome transaction costs associated with the increasing complex patent environment.[80] Other remedies include legislation, administrative changes, self-regulation, and self-help.

"Patent pools are private contractual agreements whereby rival patentees transfer their rights into a common holding company for the purpose of jointly licensing their patent portfolios."[81] First, patent pools consolidate the patent rights

varieties have the trait for resistance to Roundup. This trait effectively extends the monopoly power on the expired patent.

[75] Monsanto Canada Inc. v. Schmeiser, [2002] F.C. 309.

[76] *Id.*

[77] *Id.*

[78] Schmeiser v. Monsanto Canada Inc., [2004] S.C.R. 34. The Supreme Court of Canada confirmed the patent eligibility of "living" inventions. The Court held that Schmeiser had not used the patent. *Id.*

[79] Tony Rausch and Rodney Nelson are two farmers who have violated their agreement not to speak about their cases. *See generally* Nelson Farm website *at* http://www.Nelsonfarm.net (last visited Feb. 15, 2005).

[80] OECD, *supra* note 2, at 60.

[81] Carlson, *supra* note 54, at 367; *see* Merges, supra note 54, at 878-79.

into a central, independent entity. Second, patent pools establish a method for valuing the patents and for dividing up royalty streams generated through licensing revenues.[82] The U.S. Department of Justice (USDOJ) and the Federal Trade Commission (FTC) 1995 guidelines grant an exception to the antitrust laws by permitting holders of blocking patents to pool their patents and jointly set royalty rates.[83] The guidelines suggest that patent pools may promote technological development by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation.[84] The guidelines pose two overarching questions: (1) whether the proposed licensing program is likely to integrate complementary patent rights; and (2) if so, whether the resulting competitive benefits are likely to be outweighed by the competitive harm posed by other aspects of the pool.[85]

Patent pools have enjoyed a mixed history in the United States. The first patent pool was implemented in 1856, for sewing machines.[86] In 1902, the Supreme Court ratified the dominance of patent law over federal antitrust law.[87] The absolute freedom of patentees to collude through patent pools ended in 1912.[88] In 1945, Justice Hugo Black wrote of the glass blowing patent pool: "The history of this country has perhaps never witnessed a more completely successful economic tyranny over any field of industry than that accomplished by these appellants."[89] The Court compelled the glass cartel members to license their patents at "standard royalties and without discrimination or restriction[.]"[90] The Manufacturers Aircraft Association,[91] the As-

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[82] Carlson, *supra* note 54, at 368.

[83] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 105 (April 6, 1995) [hereinafter the 1995 Guidelines].

[84] *Id.* at 462-63.

[85] CLARK, *supra* note 1, at 7.

[86] Library of Congress, *Inventor of the Sewing Machine*, *at* http://memory.loc. gov/ammem/today/jul09.html, (last visited Feb. 15, 2005).

[87] *See* E. Bement & Sons v. Nat'l Harrow Co., 186 U.S. 70 (1902).

[88] Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 49 (1912).

[89] Hartford-Empire v. United States, 323 U.S. 386, 436-37 (1945) (Black, J., dissenting).

[90] *Id.* at 419.

[91] *See* George Bittlingmayer, *Property Rights, Progress, and the Aircraft Patent Agreement*, 31 J.L. & ECON. 227, 230-32 (1988).

sociated Radio Manufacturers,[92] and the MPEG LA patent pools[93] are all patent pools approved by the USDOJ that have subsequently led to critical standard setting in their respective industries.

Patent pools have diverse organizational forms, ranging from informal understandings that look like multiparty cross-licensing arrangements, to pools that are institutions in their own right and behave in some respect like joint ventures.[94] The central entity in a patent pool can manage the pools by assessing the various patents relative values or by affording each patent an equal share. The challenges in organizing a patent pool include: (1) the initial transaction costs of building relationships between patent holders, (2) setting a royalty breakdown among the various patent holders, and (3) avoiding antitrust sanctions.[95] Royalty allocation can make or break the patent pool.[96] For example, the MPEG LA patent pool contains hundreds of patents worldwide and forty-six U.S. patents.[97] MPEG LA offers a package license to firms whose products implement the MPEG-2 standard. Each patent in the MPEG LA pool is valued equally.[98] In addition, the USDOJ does not directly analyze the characteristics of the selected patents for validity or tying, but rather evaluates the lawfulness of the pool based on the License Administrator's representations.

The advantages of using a patent pool for genetic innovation and plant patents include: (1) overcoming the problems associated with blocking and stacking patents, (2) prompting further

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[92] *See* Bradley J. Levang, Comment, *Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229, 236-37 (2002).

[93] *See* Letter from Joel I. Klien, Acting Assistant Attorney General, to Gerrard R. Beeney, Esq., partner, Sullivan & Cromwell (June 26, 1997), *available at* http://www.usdoj.gov/atr/public/busreview/1170.pdf (last visited Feb. 15, 2005).

[94] Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1895 (2002).

[95] Levang, *supra* note 92, at 237.

[96] *See* RSA Data Sec., Inc. v. Cylink Corp., No. 96-20094 SW, 1996 WL 107272, 3-4 (N.D. Cal. 1996) (resolving breakup of pool that dissolved due to dispute between partners over licensing practices); Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 75 (1994).

[97] *See* Dana J. Parker, *Everybody into the Pool!*, EMEDIA PROF'L (Sept. 1998), *available at* http://www.findarticles.com/p/articles/mi_m0FXG/is_n9_v11/ai_21041392 (last visited Feb. 15, 2005); *see also* Mark A. Lemley, *Antitrust and the Internet Standardization Problem*, 28 CONN. L. REV. 1041, 1067, 1074 (1996).

[98] Parker, *supra* note 97.

innovation and simplifying the process of obtaining patents for research, (3) reducing licensing transaction costs, (4) distributing risks, and (5) spillover effects such as increasing the sharing of technical information not disclosed in the patents.[99] Moreover, patent pools can provide settlement options that increase smaller firms' chances of survival alongside larger firms.[100]

Plant patent pools could potentially provide a one-stop licensing resource for plant developers. However, that is not the case. The parties in control of genetic resources include life-science corporations, universities, international and national seed banks, governments, and farmers. Each party has both vastly different investments at risk and different products to contribute to the pool. Some of those investments are protected by patents and most are protected as trade secrets. The difficulty in evaluating these different contributions explains why plant breeding has been widely supported, with breeders exchanging new varieties for access to raw germplasm in a common heritage regime. Additionally, a majority of plant developers (including farmers and public breeders) continue to exchange varieties without proprietary restrictions. Finally, without a single international patent system, pool participants would have to navigate multiple national patent systems.[101]

Patent pools can result in trade restricting practices. For example, when patents that are legally blocking but factually competitive are pooled, the pool provides a direct means for restoring monopoly prices in an otherwise competitive market.[102] For this reason alone, scholars have argued that "the [US]DOJ and the FTC should not adopt a per se rule of legality for the pooling of blocking [gene] patents."[103]

Patent pools can also violate antitrust laws by preserving potentially invalid patents[104] through tying or by "bringing horizon-

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[99] Carlson, *supra* note 54, at 378; Ralph T. King, Jr., *What Bull Market? A Biotech Investor Never Quits Trying*, WALL ST. J., Jan. 5, 1999, at A1, *available at* http://www.aidsinfobbs.org/articles/wallstj/99/002 (last visited Feb. 15, 2005).

[100] *See* United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 420 (1956).

[101] Chetan Gulati; Note *The "Tragedy of the Commons" in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology Patent Office*, 4 YALE HUM. RTS. & DEV. L. J. 63, 93-94 (2001).

[102] Carlson, *supra* note 54, *at* 385-86.

[103] *Id.* at 386.

[104] *E.I. Du Pont de Nemours & Co.*, 351 U.S. at 419-20; *see also* United States v. Singer Mfg. Co., 374 U.S. 174, 177 n. 2 (1963).

tal competitors into collusion."[105] Package licensing can harm the public by requiring consumers to purchase all the pool patents in a bundle regardless of whether the patents are needed or valid.[106] Other concerns include the high formation costs of biotech patent pools. Genetic innovations are difficult to valuate. Once a DNA fragment is found to be immensely valuable, it will be that much more difficult to incorporate it into a patent pool.[107] In addition, participation in a patent pool would necessarily be limited to larger corporations and institutions, making it very difficult for individual plant breeders and smaller seed companies to access genetic resources. It is difficult to imagine farmers participating in patent pools. As raw genetic resources are granted patent-like protection through the World Trade Organization (WTO), access to basic crop genetic resources could be tied to certain patent pools, and severely restrict public plant breeding.

Governments have undertaken several activities to rebalance both monopoly rights and the public interest in biotechnology. Those activities include banning gene patents, requiring compulsory licenses for gene patents, creating a research exemption, and applying public pressure to place gene fragments into the public domain. For example, the European Patent Convention article 53(a) prohibits patents for inventions that are contrary to "ordre public" or "morality."[108] Additionally, article 27 of the WTO Trade-Related Aspects of Intellectual Property Rights Agreement includes the same exemption and also allows countries to disallow patents on plants and animals if they have a sufficient *sui generis* system in place.[109] The Genome Research and Diagnostic Accessibility Act of 2002 proposed an exception to patent exclusionary rights when genetic sequence information is used

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[105] Carlson, *supra* note 54, at 388.

[106] *Id.* at 390.

[107] Levang, *supra* note 92, at 249-50.

[108] European Patent Convention Art. 53(a) (2000); *see also* Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 256-57 (2000).

[109] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 27 (a)(b), 33 I.L.M. 81 (1994). The question of what a sufficient *sui generis* system looks like is not clear. The USDA Plant Variety Protection Act, which preserves the farmer seed saving and research exemption has been held up as an example of a *sui generis* system. *See* Brush, *supra* note 22.

for research or genetic diagnostic testing.[110] Congress has already enacted a law requiring that patent applications become public after eighteen months as a way to combat submarine patents.

Congress has the power to compel compulsory licensing of patents both in the WTO and in U.S. patent law. Congress could require compulsory licenses for gene patents. Currently, there are no compulsory licenses for patents in the United States.[111] Government pressure in the biotechnology sector has been minimal, and it has only succeeded in placing a handful of gene fragments into the public domain.[112]

Administrative solutions include raising or lowering the bar for admission of patent claims and encouraging ex-parties and inter-parties reexaminations. Eliminating incentives for patent approval may promote greater scrutiny in approving patent applications. After gene-related patents flooded the PTO, the agency responded by raising the standard for utility and announced new stricter guidelines for granting patents on ESTs.[113]

The PTO could revisit the written description and enablement requirements for gene innovations and patents. Currently, the requirement is satisfied with a deposit in an official repository. Deposits arguably do not provide "fair notice" of the "metes and bounds" of the invention,[114] nor do they disclose the subject matter in a way that a person of ordinary skill in the art may make and practice the invention.[115]

Finally, regarding examinations, since 1999, the PTO has allowed both ex-parties and inter-parties to request reexaminations in which the validity and scope of an issued patent can be challenged.[116] Reducing the costs of reexamination and curbing the estoppel limitations on reexamination would encourage

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110 Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2d Sess. 2002).

111 Mowzoon, *supra* note 32, at 1099.

112 National Institutes of Health collaborated with the Wellcome Trust to provide significant backing for a public consortium did several pharmaceutical companies agree to place any of their SNP sequences into a public domain library. *See* Ken Garber, *Homestead 2000: The Genome*, SIGNALS (Mar. 2000).

113 *See* Utility Examination Guidelines, 66 Fed. Reg. 1092-02, 1093 (Jan. 5, 2001).

114 *See* Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677 (Fed. Cir. 1990).

115 Westin, *supra* note 4, at 274.

116 *See generally* Qin Shi, *Reexamation, Opposition, or Litigation? Legislative Efforts to Create a Post-Grant Patent Quality Control System*, 31 AIPLA J. 433 (2003).

greater third-party policing of gene and plant patents.[117] The administration could also expand the existing procedure within the patent office so that any third party can ask for a patent to be reexamined.[118]

Patent holders can also employ cross-licensing arrangements to avoid antitrust violations. Cross-licensing arrangements do not employ a central entity to hold the patents. Instead, firms holding overlapping patents execute licenses to gain access to one another's patented technology. For example, DuPont and Monsanto struck a comprehensive settlement that gives them access to critical aspects of each other's technology.[119] When cross-licenses are executed royalty free, no direct economic harm is created.[120] However, cross-licensing can be set up such that "explicit or implicit barriers" restrict extending licensing rights to outside parties.[121] In the United States, the diaper industry is currently dominated by Procter & Gamble and Kimberly Clark, who have settled mutual legal disputes through a cross-licensing arrangement that holds the rest of the industry at bay.[122] The 1995 Federal Antitrust Guidelines give similar treatment to cross-licensing agreements and patent pools.[123]

Other self-regulatory remedies include giving technology away in a good faith effort to restore the common heritage regime for plant improvement and defensive licensing strategies. Monsanto and Syngenta gave away genetic data on the rice plant to public researchers valued at $60 million.[124] In March of 2004, Monsanto and DuPont agreed to make a vast amount of information about corn genes available to the government and to academic scientists in an effort to "accelerate improvement of one of the

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[117] *Id.*

[118] *See* 35 U.S.C. §§ 302, 303 (2002); Manual of Patent Examination Procedure, 37 C.F.R. 1.20 (2004).

[119] Justin Gillis, *Cultivating a New Image: Firms Give Away Data, Patent Rights on Crops*, WASH. POST, May 23, 2002, at E1.

[120] *See* George L. Priest, *Cartels and Patent License Arrangements*, 20 J.L. & ECON. 309 (1977) "[S]ince the cross-licensing makes each firm a competitor of the other, the two must agree to restrain sales to avoid competing away the patent rents." *Id.* at 357. *See, e.g.*, United States v. Singer Mfg. Co., 374 U.S. 174 (1963); United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377 (1956); *see also* Klien, *supra* note 93.

[121] John Barton, Professor, Stanford Univ., Statement at the Hearings on Global and Innovation-Based Competition Before the Fed. Trade Comm'n 49 (1995).

[122] Carlson, *supra* note 54, at 370.

[123] U.S. DEP'T OF JUSTICE, *supra* note 83.

[124] Gillis, *supra* note 119.

nation's most important crops."[125] Self-help measures are also available. Farmers around the world have established plant registries that defensively document traditional varieties as prior art to attack patent validity.[126] Similarly, in the computer programming realm, the Free Software Foundation (the GNU Project)[127] employs defensive licenses to protect their software innovations. Authors of the software copyright it and then provide a General Public License (GPL) so that users can copy, distribute, and modify the software.[128] The GPL stipulates that any patent or copyright derived from free software must be licensed for everyone's free use.

In sum, with the demise of the common heritage regime of plant exchange and the increasing use of patents to protect plant varieties, creative solutions will be required to continue conserving and developing new plant varieties for food, medicine, and industry. Patent pools and compulsory licensing arrangements are encouraged by the USDOJ and FTC in the 1995 guidelines. Plant patent pools would offer central clearinghouses for access to upstream patents and genetic innovations, but may also protect invalid patents and restore monopolies in otherwise competitive markets. Cross-licensing arrangements would likely restrict outside parties' access to genetic resources, especially farmers. Defensive licensing and contributing to the common heritage of plants are two approaches for maintaining wide access and collaborative plant development. Administrative and congressional remedies would inevitably retard investment in further innovation. However, without adequate self-regulation to balance the public interest in conservation, medicine, research, and food security, political solutions will be necessary. Patent pools, in concert with a continued effort to maintain and promote the

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[125] Andrew Pollack, *Seed Concerns Donate Data on Corn Gene*, N.Y. TIMES, March 17, 2004, at C4.

[126] The Farmer Cooperative Genome Project is an Oregon model for farmers working with national seed banks, public breeders, and landrace collections to register varieties in the public domain as common heritage as well as develop new varieties suitable for organic production methods. *See generally* FARMERS COOPERATIVE GENOME PROJECT, *at* http://www.fcgp.org (last visited Feb. 15, 2005).

[127] The GNU Project has developed an operating system which is free software, the GNU system. *See* GNU PROJECT, *GNU Operating System-Free Software Foundation*, *at* http://www.gnu.org (last visited Feb. 15, 2005).

[128] *See* GNU PROJECT, *GNU General Public License*, *at* http://www.gnu.org/copyleft/gpl.html (last visited Feb. 15, 2005).

common heritage management of plant genetic material, offer the most potential for preventing patent thickets and other consequences of the "tragedy of the anti-commons."