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Legal Issues Related to the Use and Ownership of Genetically Modified Organisms

by

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I. OVERVIEW

The genetic modification of crops (primarily corn, soybeans, cotton, and canola) has developed significantly as a new agricultural technology in recent years.¹ American farmers have adopted crops engineered to be resistant to particular herbicides (the “Roundup Ready” crops) and the European Corn Borer (the so-called Bt crops).² Similarly, the prospect of genetic modification of plants to produce pharmaceuticals (so-called bio-pharmaceutical crops), such as proteins designed as a vaccine for hepatitis B, is a distinct possibility in the near future.³

While the adoption of genetically modified crops has advanced rapidly in the United States,⁴ certain world markets will not accept Genetically Modified Organisms (GMOs),⁵ and some United States grain processors have announced that they would not purchase grain containing GMOs until it is approved in particular world markets.⁶ This injects tremendous uncertainty into seed purchase transactions and product sales at or after harvest.⁷ This uncertainty also creates

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1. Scientists first announced in 1973 that they had developed the capability of modifying genetic material. See SHELDON KRIMSKY, *GENETIC ALCHEMY* 13, 72-73, 339 (1982).

2. Herbicide-tolerant soybeans were introduced in 1996 and were used on “17 percent of the soybean acreage in 1997,” rising to “68 percent in 2001.” JORGE FERNANDEZ-CORNEJO & WILLIAM D. MCBRIDE, U.S. DEPT’ OF AGRIC., AGRIC. ECON. REP. NO. 810, ADOPTION OF BIOENGINEERED CROPS iv (2002). “Herbicide-tolerant cotton expanded from 10 percent of cotton acreage in 1997 . . . and reached 56 percent in 2001. . . . Bt corn grew to 8 percent of U.S. corn acreage in 1997 and 26 percent in 1999, but fell to 19 percent in 2000-01.” *Id.* Bt cotton acreage grew “from 15 percent of U.S. cotton acreage in 1997 to 37 percent in 2001.” *Id.* Genetic modification is also occurring in animals such as genetically modified hogs designed to be free of intestinal disease and genetically modified cattle designed to be immune to hoof-and-mouth disease.

3. Some bio-pharmaceuticals are in production at the present time. The United States Department of Agriculture (USDA) has stated that bio-pharmaceutical crops were grown on thirty-four sites in the United States in 2002.

4. See generally KRIMSKY, *supra* note 1.

5. A GMO, as referred to in this article, is a plant that contains genetic material from other species such as bacteria. The process is different from crossbreeding in which plants within the same species are bred.

6. The European mistrust of biotechnology stems from the long history of natural organic agricultural practices, the loss of the small family farm, a fear of monopoly control of their agriculture by foreign corporations, and secrecy and propriety protections built into the American way of doing business.

7. Producers who grow GMO varieties should be prepared to segregate their crop by using their own separate storage or by arrangement with the elevator or other purchaser. This is particularly necessary in light of the lack of a two-track grain marketing system in the United States and the fact that outlets for GMO grain may not be as conveniently located as the local elevator (which may not be equipped to implement a two-track marketing scheme). Relatedly, the pric-

numerous legal issues for farmers, particularly those that do not choose to raise GMO crops. The basic legal issues for producers of both GMO and conventional crops generally rest in contract law or common law theories related to land use conflicts. Relatedly, the intellectual property right protection of genetically modified and conventional crops by seed companies raises the specter of producers being prosecuted for violation of the intellectual property rights of the owners of the technology. The patenting of seeds coupled with a no-replant policy also raises antitrust concerns.

II. CONTRACT-BASED LIABILITY ISSUES

A. Application of U.C.C. Article 2 to the Sale of GMOs

The proliferation of GMOs in crop agriculture gives rise to numerous contract-based legal issues, especially those involving the existence of warranties in sales transactions. Article 2 of the Uniform Commercial Code (U.C.C.) governs the law of sales of goods.⁸ If a farmer is a “merchant” with respect to the sale of goods, liability may arise for breach of an implied warranty.⁹ However, an express warranty may be created irrespective of whether the seller of the goods is a merchant.¹⁰

ing of GMO grain is likely to be based on supply and demand considerations. That could mean that producers can expect a discount for GMO crops and a premium for non-GMO crops.

8. Under U.C.C. Article 2 (2000), “goods” includes all things that are movable, § 2-105(1), as well as timber, § 2-107(2), minerals or the like, § 2-107(1), and permanent-type buildings if the seller severs them from the land, § 2-107(1). Because seeds and crops are “goods,” sales and other transactions involving them result in the creation of warranties.

9. U.C.C. § 2-314 (2000). Implied warranties are imposed by law to assure a fair result and fulfill the buyer’s expectations that an acceptable product is being purchased. *Limestone Farms, Inc. v. Deere & Co.*, 29 P.3d 457, 461 (Kan. Ct. App. 2001). It is the buyer’s expectations that are key. *Id.* If the buyer is not the original purchaser of the goods, warranties (express and implied) are not likely to apply absent a separate contractual agreement. See, e.g., *id.*

10. U.C.C. § 2-313(1)(a) (2000). Under Article 2, an express warranty can be created if the seller makes “[a]ny affirmation of fact or promise” that “relates to the goods and becomes part of the basis of the bargain.” *Id.* The warranty is that the goods will conform to the affirmation or promise. *Id.*; see, e.g., *Smith v. Bearfield*, 950 S.W.2d 40, 40 (Tenn. Ct. App. 1997) (finding that when a tractor was sold under representation that it was “in good shape” but required extensive repair immediately after sale, the representation created an express warranty, and seller was liable for costs of repair). Similarly, if the seller provides “any description of the goods [that] becomes part of the basis of the bargain,” an express warranty may be created “that the goods [will] conform to the description.” See, e.g., *Smith v. Penbridge Assocs., Inc.*, 655 A.2d 1015, 1019 (Pa. Super. 1995) (determining that seller of two male emus breached the express warranty that emus were a “proven breeder pair”). Likewise, any sample or model, which is made part of the basis of the bargain, can create a warranty that the whole of the goods will conform to the sample or model. See, e.g., *Dakota Grain Co., Inc. v. Ehrmantrout*, 502 N.W.2d 234, 239 (N.D. 1993). The court found a breach of express warranty in an oral contract for sale of hard red spring wheat to be resold by buyer to other farmers for seeding when seed sold turned out to be winter wheat. *Id.* But, “puffing” talk (statements of value or mere opinions of the seller) generally does not create an express warranty. Express warranties, once created, are very difficult to disclaim.

1. Implied Warranty of Merchantability

Article 2 defines the terms "merchant"¹¹ and "between merchants"¹² solely for the purposes of Article 2. The provisions of Article 2 involving an implied warranty of merchantability require that a merchant be a seller of goods of the kind involved, or one who by occupation holds himself or herself out as having knowledge or skill peculiar to either the goods involved or the practice of buying and selling such goods.¹³ Courts are divided on the issue of whether a farmer or rancher is a merchant, with the outcome depending on the jurisdiction and the facts of the particular case.¹⁴ Unfortunately, in many instances, farmers and ranchers cannot know with certainty whether they are merchants without becoming involved in a legal action on the issue.¹⁵

The implied warranty of merchantability is present in every transaction involving the sale of goods. Thus, if a producer is asked by the first purchaser to promise that a delivered crop is non-GMO, the producer must be very careful concerning what is signed or what oral comments are made about the crop.¹⁶ Because low levels of GMO germplasm are not unusual in non-GMO loads of grain, even though the seed was represented as non-GMO, contamination could have occurred in the seed in planting, growing, harvesting, transporting, and storing the crop. Thus, a producer can state that no seed represented by the seed company as GMO was planted and can state that the seed represented by the seed company as non-GMO seed was planted. The

11. U.C.C. § 2-104(1) (2000).

12. § 2-104(3).

13. § 2-105(1) (definition of goods); § 2-104 cmt. 2.

14. For reasons of public policy, a slim majority of jurisdictions have held that a farmer in most circumstances is not a merchant. Courts also consider the intent of the drafters of Article 2. These jurisdictions, however, do not rule out the possibility for merchant status of a farmer if probative evidence warrants this conclusion. A majority of the jurisdictions that have considered the existence of merchant status when the attempt has been to base it on either of the knowledge and skill formulations, § 2-104(1), (3), have held that the ordinary farmer, as a matter of law, is not to be deemed a merchant for purposes of U.C.C. § 2-201(2) (2000), or otherwise. See, e.g., *Pierson v. Arnst*, 534 F. Supp. 360, 362 (D. Mont. 1982); *Sand Seed Serv., Inc. v. Poeckes*, 249 N.W.2d 663, 664-66 (Iowa 1977); *Terminal Grain Corp. v. Freeman*, 270 N.W.2d 806, 812-13 (S.D. 1978).

15. In the GMO context, contracts have been utilized, reciting that the producer warranted the crop would pass without objection anywhere in the world.

16. Firms buying crops at the original point of purchase (such as the local elevator) may not be equipped to test for the presence of GMO germplasm. As a result, initial purchasers are likely to attempt to impose warranty conditions on sellers, and the grain marketing system will likely attempt to push the problem back to or toward the producer. But, producers will be put in a difficult position of not knowing conclusively that non-GMO seed is free of GMOs (due to the potential for cross-pollination) and in being expected to warrant to the purchaser that the crop is GMO-free. Absent testing at the point of entry into the marketing system, it will likely be difficult to hold producers liable for selling GMO grain into a non-GMO marketing channel or selling non-GMO grain contaminated with GMO germplasm. As reliable testing becomes more widespread, the responsibility will move down the marketing channel. Relatedly, seed companies may encounter pricing pressures for seed of GMO hybrids, even though producers likely will bear the bulk of any economic problems.

producer can also state that care was taken in avoiding contamination in harvesting, storing, and transporting the crop to market. However, a producer must take care not to state that the crop in question has *no* GMO germplasm. Likewise, care must be exercised to ensure that a statement is not made that no contamination has occurred from mechanical handling and storage of the crop or from pollen drift.¹⁷ In any event, producers should maintain complete records and keep a sample for every lot delivered to buyers.

2. Implied Warranty of Fitness for a Particular Purpose

The implied warranty of fitness for a particular purpose is imposed if a seller (who is a merchant) "has reason to know [of] any particular purpose for which the goods are required and [if] the buyer is relying on the seller's skill [and] judgment" in providing such goods.¹⁸ In the biotech context, a statement that the purchaser anticipates that the crop will be exported to the European Union, for example, could invoke an implied warranty of fitness even if the seller makes no specific representations about the crop.

Growers not wanting the presence of GMOs in the crops that are to be marketed¹⁹ should always check labels and only utilize non-GMO hybrids. Because of the possibility that seeds containing GMO germplasm may appear in bags of non-GMO seed due to the possibility of cross-pollination, seed companies are not likely to be in a position to warrant that non-GMO seed is free of GMOs.²⁰ Because no tolerances have been set for GMO germplasm in non-GMO seed, producers requesting an express warranty from the seed company that seed is GMO free will likely be met with a counter offer requiring the producer to state that the seed was produced without using GMO germplasm.²¹

17. The degree of and potential for cross-pollination is dependent on the type of crop at issue. For soybeans, cross-pollination is unlikely. The soybean plant produces a perfect flower (each flower contains both male and female reproductive structures) and is self-pollinated. But, the corn plant produces separate flowers for the male and female reproductive structures, which increases considerably the chances for cross-pollination. Pollen generally travels within about a twenty-foot radius of the plant, but some may be carried much farther, perhaps up to a quarter mile or farther in response to environmental conditions. The seed industry uses a separation distance of 660 feet (forty rods).

18. U.C.C. § 2-315.

19. The marketing of conventional crops may be desired due to prior contractual marketing arrangements or identity preserved crop agreements designed for crops to be marketed to specific overseas markets that do not accept genetically modified crops.

20. Some seed companies concede that their seed purporting to be non-GMO contains low levels of GMO germplasm. Likewise, seed companies admit that contamination from pollination occurs (some say it is less than one-tenth of one percent). Similarly, with respect to Bt cotton, the government's request that farmers set aside twenty percent of their land in non-Bt cotton illustrates the government's recognition of the risks of genetic pollution (and resistance buildup). Thus, a significant question is who will take responsibility for fields that are contaminated with GMO crops when non-GMO crops were planted.

21. This warranty may not be an adequate defense if tolerances are set at low levels.

It is, however, possible to disclaim contract warranties. The implied warranty of merchantability may be excluded or modified by the seller if the disclaimer is oral or is a written disclaimer that mentions merchantability.²² The implied warranty of fitness for a particular purpose may be excluded or modified only by a conspicuous, written provision in the contract.²³ Likewise, disclaimer language stating that the goods are being sold "as is" or "with all faults" can be effective. Similarly, if the buyer refuses to examine the goods before signing the contract, the seller may be excused from implied warranties if an examination would have disclosed the defects.²⁴

B. Other Contract-Related Issues

1. Fraudulent Inducement, Negligent Misrepresentation, and Promissory Estoppel

Contracts involving genetically modified seeds and crops may give rise to fraudulent inducement to contract and promissory estoppel claims. For example, justifiable reliance upon representations of biotech companies concerning the performance of their biotech products may give rise to claims of fraudulent inducement and promissory estoppel if the representations were known to be false when made and the representations were made with the intent to induce a party to enter into a contract. Technically, such a case is not a contract case, but is a misrepresentation, fraud, or promissory estoppel cause of action.²⁵ Representations that genetically modified seed will produce greater producer income compared to conventional seed could form the basis of a fraudulent inducement claim.²⁶ Indeed, up to one mil-

22. U.C.C. § 2-316(2).

23. *Id.*

24. The key is to examine contracts carefully concerning any representations about the genetic make-up of the crop being marketed. Contract language should be examined very carefully.

25. Positioning the case in this manner allows the admission of evidence extrinsic to the contract. *See, e.g.*, *Tyson Foods, Inc. v. Davis*, 66 S.W.3d 568, 570-71 (Ark. 2002) (upholding fraud and promissory estoppel claims in relation to hog contract). *But see Crowell v. Campbell Soup Co.*, 264 F.3d 756, 759, 762 (8th Cir. 2001) (trying case as a production contract case with result that extrinsic evidence contrary to four corners of the document was inadmissible).

26. For example, University of Arkansas researchers have found net income from land in Arkansas planted with Bt cotton was often less than the net income from land planted with conventional cotton by an average of twenty-five dollars per acre. Pesticide Action Network of North America Update Service, *Disappointing Biotech Crops*, <http://www.panna.org/resources/pestis/PESTIS980424.1.html> (Apr. 24, 1998). Also, the University of Arkansas confirmed on May 19, 2003, that marestail is resistant to Roundup at three times the normal rate of Roundup application. Marestail is a major problem in northeast Arkansas where rice and cotton are the predominant crops. Robert Wisner, Iowa State University agricultural economist, has found a "high risk" that the U.S. wheat industry would lose thirty to fifty percent of its business with foreign markets for spring wheat if Monsanto Co. released genetically modified wheat over the next few years. *See Robert Wisner, GMO Spring Wheat: Its Potential Short-Term Impacts on U.S. Wheat Exports Markets and Prices*, Nov. 4, 2003, at *6, <http://www.econ.iastate.edu/faculty/wisner/gmowheatreportMarch200311.pdf>. Dr. Wisner notes that the biotech wheat issue is also a corn grower issue because biotech wheat rejected by certain foreign markets may end up as

lion acres of Bt cotton were attacked by bollworms in 1996, prompting lawsuits based on fraudulent inducement. In *Monsanto Co. v. Davis*,²⁷ a group of farmers sued Monsanto (a chemical company holding patent rights on biotech cotton) for fraud, violations of the Texas Deceptive Trade Practices Act, negligence, negligent misrepresentation, and usury. The plaintiffs sought class certification. While the trial court certified the class, the certification was overturned on appeal because the court found arguable defenses "peculiar to a subset of plaintiffs."²⁸ These defenses destroyed the typicality requirement necessary to achieve class status.²⁹

Likewise, according to a report published by the Institute for Agriculture and Trade Policy, from 1996 to 2001 U.S. farmers paid \$659 million extra in price premiums to plant genetically modified corn but realized only \$567 million for a net loss of \$1.31 per acre.³⁰ In Iowa, decreased farrowing rates in sows have been tied to the feeding of Bt corn.³¹ Similarly, the U.S. Government Accounting Office released a report in June of 2001 stating, in part,

We now have a fairly good handle on our loss of corn exports due, in large part, to the loss of international confidence in our corn supplies from our questionable experiment with genetically modified (GMO) corn. What we do not know is how much this experiment has cost the grain marketing sector and the U.S. taxpayer.³²

livestock feed and in ethanol plants, thereby reducing the demand for corn. *Id.* at 37-38. On May 10, 2004, Monsanto announced that it was dropping its efforts to introduce genetically modified wheat in the United States. See Andrew Pollack, *Monsanto Shelves Plan for Modified Wheat*, N.Y. TIMES, May 11, 2004, at C1. Similarly, research conducted by Iowa State University agricultural economist Michael Duffy has shown that Iowa farmers lost an additional \$8.85 per acre (in terms of return to labor and management) when using GMO soybeans compared to non-GMO soybeans. See Michael Duffy, *Who Benefits from Biotechnology?*, <http://www.pakistan.com/english/advisory/biotechnology/who.benefits.bio.tech.shtml> (Mar. 26, 2004). The same was found to be true for Bt corn, with added costs resulting in an additional loss of \$3.25 per acre (in terms of return to labor and management) compared to non-GMO corn. *Id.*

27. 97 S.W.3d 642 (Tex. Ct. App. 2002).

28. *Id.* at 645.

29. *Id.*

30. See Charles M. Benbrook, *When Does It Pay to Plant Bt Corn?: Farm Level Impacts of Bt Corn, 1996-2001*, http://www.biotech-info.net/bt_farmlevel_IATP2001.html (Nov. 2001). The report notes that most of the losses were attributable to 1998, and the best year was 2001 (due to large infestations of corn borers). *Id.* The author of the report is Charles Benbrook, former executive director of the National Academy of Sciences Board of Agriculture. *Id.*; see also Charles M. Benbrook, *Troubled Times Amid Commercial Success for Roundup Ready Soybeans: Glyphosate Efficacy Is Slipping and Unstable Transgene Expression Erodes Plant Defenses and Yields*, <http://www.biotech-info.net/troubledtimes.html> (May 3, 2001).

31. See, e.g., *Iowa Farm Bureau Spokesman*, Apr. 29, 2002 (on file with author).

32. U.S. GEN. ACCOUNTING OFFICE, PUB. NO. GAO-01-727, INTERNATIONAL TRADE: CONCERN OVER BIOTECHNOLOGY CHALLENGE U.S. AGRICULTURAL EXPORTS (June 2001). Dan McGuire, CEO of the American Corn Growers Foundation, has opined that the cumulative loss of corn exports to the European import market since the introduction of biotech corn has been between 500 million and 700 million bushels. If that amount were to be removed from current ending stocks in the United States, McGuire estimates that current corn prices would be at least one dollar per bushel higher. See David Bennett, *Liability Issue Bogs Down Energy Bill: Dan McGuire Discusses Energy Issues, GMOs and Farm Bill*, CROPCHOICE NEWS, Apr. 24, 2004, at <http://www.cropchoice.com/leadstry.asp?recid=2538>.

The head of Ethiopia's EPA, Tewolde Berhan Gebre Egziabher, has stated that “[t]o my knowledge there has not been one commercially grown transgenic crop that out-yields all other varieties of that crop. . . . What the transgenic crops have done so far is tie the farmer to specific chemicals and a specific company.”³³ Clearly, the use of genetically modified seed is of little to no economic advantage for producers. Thus, specific seed company statements to the contrary may give rise to fraudulent inducement and/or negligent misrepresentation claims.

2. Contract Purchase Agreements and Label Notices

Another tactic is to challenge contractual purchase agreements and label notices. Contracts with producers that grant the seed company better intellectual property right protection than can be achieved with a Plant Variety Protection Act (PVPA) certificate or a general utility patent could be invalidated by a court on the basis that the protection provided by a PVPA or a general utility patent cannot be exceeded by contract. If an agreement is upheld under contract law, federal intellectual property law could preempt state contract law.³⁴ With respect to label notices, seed companies often obtain a patent for the seed at issue and then affix a label notice containing all of the protective provisions to the seed bag in order to bind the purchaser and protect the company's intellectual property rights. Because the label notice protection is an extension of federal patent law, it is not subject to preemption.³⁵

33. *Against the Grain; Why Poor Nations Would Lose in a Biotech War on Hunger*, CROPCHOICE NEWS, June 20, 2003, at <http://www.cropchoice.com/leadstry.asp?recid=1764>. Indeed, Monsanto industry affairs manager Michael Doane is quoted as stating in 2001 that the company's business strategy is to use biotechnology to increase sales of Roundup such that the company can dominate both “the seed and herbicide market[s].” Robert Schubert, *Pushin' Roundup Via Roundup Ready Wheat*, CROPCHOICE News, June 17, 2002, at <http://www.cropchoice.com/leadstry.asp?recid=751>. Indeed, one study has indicated that farmers growing Monsanto's Roundup Ready soybean seed use “2 to 5 times more herbicide measured in pounds applied per acre, compared to the other . . . weed management systems used on . . . fields” planted to conventional seed varieties in 1998. CHARLES BENBROOK, EVIDENCE OF THE MAGNITUDE AND CONSEQUENCES OF THE ROUNDUP READY SOYBEAN YIELD DRAG FROM UNIVERSITY-BASED VARIETAL TRIALS IN 1998, at 2 (Ag BioTech InfoNet, Technical Paper No. 1, July 13, 1999), at http://www.biotech-info.net/RR_yield_drag_98.pdf.

34. See, e.g., *Vault Corp. v. Quaid Software Ltd.*, 847 F.2d 255 (5th Cir. 1988). The Federal Copyright Act allowing limited copying preempts computer software licenses designed to prevent purchasers from making copies of purchased programs. *Id.* at 263.

35. In *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), the court held that a patentee may restrict a purchaser's use of a patented item by affixing a “label notice” of the restriction to the item and that label notices are not a violation of antitrust law if the restrictions in the label notice are in accordance with the rule of reason. *Id.* at 710. Thus, as long as a patentee restriction on reuse is within the scope of its patent and does not have anticompetitive effects, it is enforceable against infringers. That is the case even if a court would not find an enforceable contract under state law. A question perhaps could be raised concerning a potential antitrust violation if a seed company with a dominant position in the market blocks competitors from developing competing technologies by imposing licensing or royalty terms that prevent or discourage licensees from adopting the new technologies. But, *Mallinckrodt* may not be followed by other courts. It is noted *Mallinckrodt* represents a departure from precedent that did

3. Adhesion Contracts

Producers may not be in a strong bargaining position with respect to GMO seed sale contracts. As a result, contracts may be offered on a “take it or leave it basis.” The vulnerability of producers is evidenced in that many producers may be unable, as a practical matter, to do more than rely on labels and seed company representations as to what is GMO and non-GMO seed. Thus, consideration may be given to challenging such contracts on the basis that they constitute contracts of adhesion.³⁶ For example, with respect to biotech seed contracts, the contract could be held to be unconscionable if the “agreement” consists merely of a label printed on a bag that does not require the purchaser’s signature. Also, if contract language attempts to limit the company’s liability to the cost of the seed purchased, the language may be challenged on the basis that it is unconscionable and unenforceable as an adhesion contract.³⁷

III. LAND USE RELATED LIABILITY ISSUES

A. *Trespass*

A “[t]respass is the unlawful or unauthorized entry upon another person’s land that interferes with that person’s exclusive possession or ownership of the land.”³⁸ A trespass claim could arise if a farmer plants genetically modified crops with knowledge that the genetic traits from the crops would likely enter a neighbor’s property, and genetic drift does in fact occur, causing harm to the neighbor’s crop.³⁹ Arguably, a trespass claim involving GMOs could be posited as either an intentional trespass or a negligent trespass. With an intentional trespass, the defendant can have the requisite intent even though not intending any harm to the plaintiff’s property interest.⁴⁰ If the plaintiff suffers no harm due to the defendant’s intentional trespass, the defendant is entitled to nominal damages.⁴¹

not allow companies to restrict use via label notices. For additional discussion of antitrust issues associated with GMOs, see *infra* Part IV.F.

36. An adhesion contract exists if a court determines that the seller is attempting to avoid the seller’s basic obligations of “good faith, diligence, reasonableness and care.” Okla. Op. Att’y Gen. No. 01-17 (Apr. 11, 2001). The production contracts were determined to be adhesion contracts. There was disparate bargaining power, and the terms were drafted unilaterally. *Id.*

37. See, e.g., *Mullis v. Speight Seed Farms, Inc.*, 505 S.E.2d 818 (Ga. Ct. App. 1998) (finding that the farmer was not in position to bargain for better contract terms or test tobacco seed before purchase).

38. See ROGER A. MC EWEN & NEIL E. HARL, PRINCIPLES OF AGRICULTURAL LAW § 11.02[2][a] (Jan. 2004).

39. Note should be taken that the legal action would be against the neighboring farmer that planted the genetically modified seed, not the biotech company that sold the seed.

40. See, e.g., *Cleveland Park Club v. Perry*, 165 A.2d 485, 488-89 (D.C. 1960). The legal question is whether the defendant “possessed the capability to perform the physical act intentionally without regard to knowledge of possible injurious consequences.” *Id.*

41. RESTATEMENT (SECOND) OF TORTS § 163 (1965).

A key question is whether an intentional tort claim can even be made in the context of pollen-drift from GMO crops. The answer seems to turn on the applicable duty that producers of GMO crops owe to owners of adjacent fields containing non-GMO crops.⁴² Clearly, the pollen-drift potential of GMO crops is understood by seed companies and growers alike.⁴³ Whether mere knowledge alone is sufficient to establish an intentional trespass claim is a question that the legal system has not yet addressed.

While the liability of farmers and ranchers for the spread of weeds and other noxious vegetation onto adjoining land is governed by statute in almost all jurisdictions,⁴⁴ state legislatures and courts have yet to address the legal duty associated with GMO crops and pollen drift. Noxious weed laws create a duty on the part of owners, tenants, and other possessors of land to destroy noxious weeds or otherwise prevent their spread.⁴⁵ An open question at the present time is whether the legal system will treat GMOs similarly to noxious weeds. While that outcome seems unlikely, it is entirely possible that the planting of GMO crops with malicious intent to harm a neighbor's non-GMO crops could give rise to liability.⁴⁶

Another significant question is whether a seed dealer or seed manufacturer would accept responsibility for non-GMO fields becoming contaminated with GMOs or whether a court would hold either the dealer or manufacturer liable to the non-GMO farmer on a trespass claim.⁴⁷ The issue is of primary importance for farmers because

42. It is important to note that a trespass claim arising from pollen drift could also be made by a farmer raising GMO crops against organic and conventional farmers if the plaintiff can establish the elements of a common law tort claim—duty, breach, causation, and damages. Again, the key elements of such a claim would appear to be the applicable duty owed to the farmer raising GMO crops and whether damages can be established.

43. The potential for pollen drift varies, depending on the type of crop at issue. See *supra* note 17.

44. Only Alaska, Maryland, and New Hampshire do not have noxious weed statutes.

45. A landowner's duty to control the spread of weeds (absent malicious intent to injure an adjoining landowner) only extends to weeds specifically listed in the applicable state noxious weed law. In *Krug v. Koriel*, the court held that there is no common law duty in Kansas "to control volunteer wheat" so as to prevent the spread of wheat streak mosaic (volunteer wheat not listed as noxious weed under Kansas noxious weed law). 935 P.2d 1063, 1067 (Kan. Ct. App. 1997). Also, offended landowners may be able to recover damages for the spread of weeds onto their land from an adjoining landowner's premises by showing that the noxious weeds were destroyed negligently. See *Kukowski v. Simonson Farm, Inc.*, 507 N.W.2d 68, 71 (N.D. 1993) (holding that a farmer has a duty to exercise ordinary care when attempting to control or remove noxious weeds).

46. Cf. *Krug*, 935 P.2d at 1065-66. This outcome may be particularly true if the farmer planting GMO crops has knowledge that the adjacent owner is an organic farmer or is planting conventional crops for specific markets that do not accept GMO crops.

47. Bayer Cropscience has indicated that it has no intention of accepting costs and liabilities for the control of genetically modified canola and has noted its belief that liability issues can be addressed through the law of contracts and common law remedies. Relatedly, it is entirely possible that crop destruction caused by pesticide drift (and the inability to insure against that loss) has increased the pressure for farmers raising conventional crops to use GMOs. Non-GMO farmers adjacent to GMO fields may find it more economical to switch to GMOs than to initiate litigation on a trespass claim. This may explain, at least in part, the rapid adoption of GMO

insurance is generally unavailable for farmers raising genetically modified crops (as well as farmers raising conventional crops) to protect the business from trespass liability due to pollen drift.⁴⁸ The United States Government recognizes the potential problems associated with pollen drift. In 2003, the United States Department of Agriculture (USDA) established a new enforcement unit to ensure that the biotech companies are properly managing field trials of GMOs.⁴⁹

Presently, there has not been a case of pollen drift involving GMOs litigated to an appellate-level court on a trespass claim. However, cases involving comparable situations have been litigated.⁵⁰ A significant question exists concerning whether all farmers would be potentially exposed to legal liability for trespass via cross-pollination.⁵¹ In the United States, conventional seed crops and organic crops may contain a minimal level of genetically modified germplasm without losing certification under government-established standards.⁵² However, that may not be the case if certification is through a private

crops in the United States (along with the fact that planting GMOs makes farming much easier from the farmer's standpoint than raising conventional crops).

48. See Kristen Philipkoski, *GE Crops Are Uninsurable*, http://www.organicconsumers.org/ge/ge_insurance.cfm (Dec. 1, 2003). The article quotes Robert Hartwig, chief economist for the Insurance Information Institute in New York, as stating, "Genetically modified foods are among the riskiest of all possible insurance exposures that we have today." *Id.* Relatedly, the top five insurers in the United Kingdom refuse to insure farmers growing GMOs and non-GMO farmers seeking protection from GMO contamination. See U.K. Organization Finds No Insurance for Biotech Crops, CROPCHOICE NEWS, Oct. 7, 2003, at <http://www.cropchoice.com/leadstry.asp?recid=2112>.

49. See Philip Brasher, *U.S. Team to Monitor Biotech Field Trials*, DES MOINES REGISTER, Oct. 18, 2003, <http://www.gene.ch/genet/2003/Oct/msg00077.html>. The unit has a staff of thirty-three persons charged with inspecting fields of pharmaceutical and industrial crops seven times over two years. *Id.*

50. See, e.g., Hall v. DeWeld Mica Corp., 93 S.E.2d 56, 57 (N.C. 1956) (finding trespass for invasion onto plaintiff's land by cloud of silicon dust that had the potential to cause injury); Martin v. Reynolds Metal Co., 342 P.2d 790, 797 (Or. 1959) (holding a defendant liable for trespass onto plaintiff's property for emission of microscopic fluoride particles from defendant's plant that rendered plaintiff's land and drinking water unfit for livestock grazing).

51. The answer seems to turn on whether actual damage occurred.

52. The Association of Official Seed Certifying Agencies (AOSCA) establishes the minimum standards for genetic purity and identity and recommends minimum standards for seed quality for the classes of certified seed. See Association of Official Seed Certifying Agencies, at <http://www.aosca.org/aoscaflash.html> (last visited May 13, 2004). The AOSCA works through numerous affiliated state entities. *See id.* Under most of the established standards, seed producers must comply with land use requirements (including separation distances and buffer rows) and agronomic practices (including weed control and detasseling) and must produce a seed crop satisfying tolerance levels for genetic purity. See, e.g., NEB. CROP IMPROVEMENT ASSOC., GENERAL SEED CERTIFICATION STANDARDS 2-44, <http://www.unl.edu/ncia> (Jan. 2003). For organic crops, the USDA's National Organic Program (NOP) establishes the applicable standards. Section 205.2 of the NOP, while stating that methods used to genetically modify organisms is an excluded method of production, notes that "[t]he presence of detectable residue of a product of excluded methods . . . does not necessarily constitute a violation." National Organic Program, 65 Fed. Reg. 80,548, 80,556 (Dec. 21, 2000) (to be codified at 7 C.F.R. pt. 205). The regulation provides that

as long as an organic operation has not used excluded methods and takes responsible steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

Id. As a result, compliance with required production standards is the key to maintaining certification under the government standards.

entity or a contract that specifies that the presence of GMO germplasm is unacceptable. In that event, damages may be easier to prove by a disaffected party. Related to the trespass issue, a conventional crop farmer whose fields become contaminated by drift from a GMO farmer's crops could be sued by the company that owns the rights to the technology for misappropriation of intellectual property rights.⁵³

B. Negligence

Negligence is a fault-based tort system involving a legal duty to act in a certain manner with respect to a particular activity.⁵⁴ If a legal duty to act as a reasonable and prudent person exists and is breached, and the breach of duty causes damages to others or their property, liability results.⁵⁵ With respect to GMOs, a negligence claim could be brought by a person claiming personal damage from GMOs or damage to non-GMO crops. A personal injury claim could be based on an allergic response to food products containing GMOs that caused injury to the individual.⁵⁶ It is more likely, however, that a personal injury claim for damages could arise from actions associated with pharmaceutical crops. As a result, in almost all instances, pharmaceutical crops must be kept out of the human food chain.⁵⁷

In order to prove that contamination by the GMOs was a result of negligence, a disaffected neighbor would have to show a reasonably foreseeable likelihood of injury arising from the GMO crop farmer's failure to exercise reasonable care to avoid causing injury or harm to the neighbor's crops. Such evidence could take the form of increased weeds, significant cross-pollination, or the presence of volunteer plants.⁵⁸ Additional problems may be associated with pharmaceutical crops. If a court finds that a GMO crop farmer has a duty to prevent contamination to neighboring fields, a breach of that duty causing injury to the neighbor could give rise to liability.⁵⁹ Failure to select seed

53. See *infra* Part IV.E.

54. RESTATEMENT, *supra* note 41, § 282 defines negligence as conduct "which falls below the standard established by law for the protection of others against unreasonable risk of harm."

55. See, e.g., *Palsgraf v. Long Island R.R.*, 162 N.E. 99 (N.Y. 1928).

56. To the extent food products are not labeled to notify the consumer as to the presence of GMOs, the potential for an injury claim based on an allergic reaction is heightened.

57. The USDA's Animal and Plant Health Inspection Service (APHIS) has proposed new guidelines for the segregation of pharmaceutical crops from crops intended for human and livestock consumption. See ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEPT' OF AGRIC., DRUGS, BIOLOGICS, AND MEDICAL DEVICES DERIVED FROM BIOENGINEERED PLANTS FOR USE IN HUMANS AND ANIMALS, at <http://www.aphis.usda.gov/vs/cvb/notices/bioplantguidancedoc.pdf> (last visited June 1, 2004).

58. If such evidence is present, biotech companies and GMO crop farmers may have an obligation to take additional reasonable precautions to prevent problems to adjacent crops associated with pollen drift. Similarly, if a biotech company has the capability of engineering GMO seeds in a manner that would minimize or eliminate pollen drift, the failure to utilize such technology could lead to a product liability claim against the company.

59. Again, proof of injury would appear to be the most difficult element of the plaintiff's case to establish.

properly, failure to adhere to specified buffer zones, or failure to follow specified growing and harvesting procedures could constitute a breach of duty.⁶⁰

Several negligence-based lawsuits have been filed against biotech companies by non-GMO crop farmers.⁶¹ In the suits, the farmers claim damage in the form of contamination of their conventional corn, increased production and equipment costs, and depressed market prices.⁶² While recovery in tort is allowed for physical injuries to persons or property, solely economic injuries are not compensable in tort.⁶³

It would be helpful if the legal system, perhaps via congressional legislation, would establish an acceptable standard of behavior for farmers growing genetically modified crops and identify the duty owed to neighbors growing non-GMO crops. Establishing a standard should provide greater certainty in determining whether crop contamination, in a particular case, was due to negligence.⁶⁴ Likewise, con-

60. Clearly, the utilization of best management practices to minimize or prevent cross-pollination of non-GMO crops is critical to reducing exposure to a negligence-based lawsuit. Likewise, a colorable argument can be made that biotech companies have a duty to advise farmers using their biotech products concerning such best management practices. That duty, perhaps, could be extended to require biotech companies to establish a use protocol for biotech products with compliance monitored by the companies.

61. See, e.g., *In re StarLink Corn Prods. Liab. Litig.*, 211 F. Supp. 2d 1060 (N.D. Ill. 2002). The maker of biotech corn seed (Aventis) failed to notify or instruct farmers of the use restrictions, "segregation methods and buffer zone requirements, and did not require [some] farmers to sign . . . contracts." *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 835 (N.D. Ill. 2002). The plaintiff class stated a compensable claim for resulting damage to conventional corn by cross-pollination or commingling. *Id.* at 842-43. Aventis had a duty to ensure that biotech corn did not enter human food supply (where Environmental Protection Agency (EPA) had granted limited and conditional registration for biotech corn seed at issue to be used solely for animal feed), and the breach of duty caused contamination of conventional corn. *Id.* at 843; see also *In re StarLink Corn Prods.*, 211 F. Supp. 2d at 1062. However, the court noted that Aventis' role in contaminating the corn supply did not constitute a conversion of the plaintiffs' property. *In re StarLink Corn Prods.*, 212 F. Supp. 2d at 844. The court noted that a mere negligent failure to prevent cross-pollination and commingling would not give rise to a conversion claim. *Id.* For a complete history of the legal developments of the StarLink debacle, see Neil E. Harl et al., *The StarLink™ Situation*, at <http://www.exnet.iastate.edu/Pages/grain/publications/buspub/0010star.pdf> (Nov. 18, 2003).

62. See, e.g., *Sample v. Monsanto Co.*, 283 F. Supp. 2d 1088 (E.D. Mo. 2003); *McNair v. Monsanto Co.*, 279 F. Supp. 2d 1290, 1293 (M.D. Ga. 2003) (claiming crop failure and/or yield reduction from use of GMOs); *In re StarLink Corn Prods.*, 211 F. Supp. 2d 1060; *Blades v. Monsanto Co.*, No. 00-CV-4034-DRH, 2001 WL 775980 (S.D. Ill. Jan. 3, 2001).

63. This is known as the "economic loss doctrine." See, e.g., *Sample*, 283 F. Supp. 2d at 1092; *In re StarLink Corn Prods.*, 212 F. Supp. 2d at 838. However, some jurisdictions permit recovery solely of special damages, such as loss of income, in public nuisance actions. For further discussion of the economic loss doctrine, see *infra* notes 86-91 and accompanying text.

64. In its 2001 legislative session, the South Dakota legislature passed a resolution urging the Congress to create legislation placing all liability for damages caused by GMO seed on the companies that develop and manufacture the seeds. At the federal level, the Genetically Engineered Crop and Animal Farmer Protection Act of 2002, H.R. 4812, 107th Cong. (2002), was introduced into the U.S. House on May 22, 2002. The legislation requires a biotech company that sells any genetically engineered animal, plant, or seed that will be used in the United States to: (1) provide the purchaser with written notice of possible legal and environmental risks of such use; and (2) disclose any technology fees to the Secretary of Agriculture and not charge fees that are higher than those outside the U.S. *Id.* The bill also directs the Secretary to: (1) identify which plants are outcrossed pollinators and make such information available to affected sellers

sideration may need to be given to the establishment of an indemnity fund to reimburse losses caused by genetic contamination of non-GM and organic crops by GMOs.⁶⁵ Presently, many comprehensive insurance policies for farmers do not cover pollution-related damages, and insurers are likely to claim that pollen drift is a type of pollution.⁶⁶ Perhaps federal crop insurance programs should be modified to provide cross-pollination coverage. The issue is one of particular importance because producers are not likely to be in a strong enough bargaining position with a well-heeled seed company to request that the company indemnify them against liability in the event of a lawsuit brought by a disaffected neighbor.

C. Private Nuisance

A private nuisance is an invasion of an individual's interest in the reasonable use and enjoyment of his or her land rather than an interference with the exclusive possession or ownership of the land.⁶⁷ The interference must be both "substantial" and "unreasonable."⁶⁸ For

and purchasers; and (2) issue rules to require mitigation strategies for predominantly outcrossed crops. *Id.* The legislation also would amend Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to direct the EPA administrator to: (1) establish the best achievable resistance plan for plant-incorporated pesticides engineered to include toxins derived from Bt; (2) revoke Bt registrations not in plan compliance; and (3) reduce a pesticide's use if it is determined to be facilitating Bt-toxin resistance in pests. *Id.* The bill prohibits: (1) the labeling of seeds as non-genetically engineered if the Secretary determines such seeds contain genetically engineered material; (2) the manufacture, sale, or planting of genetically engineered or chemically induced nonfertile seeds; and (3) loan discrimination against a producer who refused to use genetically engineered plants or animals. *Id.* On July 24, 2002, the bill was referred to the House Subcommittee on Farm Commodities and Risk Management. Thomas Legislative Information, <http://thomas.loc.gov/cgi-bin/bdquery/D?d107:1:/temp/~bddm6x:@@L&summ2=M&—/bss/d107query.html—1> (last visited May 13, 2004).

65. Standards set for organic crops are processed-based. National Organic Program, 65 Fed. Reg. 80,548, 80,549 (Dec. 21, 2000) (to be codified at 7 C.F.R. pt. 205). Under USDA regulations, the presence of detectable residue from GMO crops "does not necessarily constitute a violation of" organic standards. *Id.* at 80,556. As a result, the unintentional presence of GMOs in organic crops "should not affect the status of an organic product or operation." See *id.* But, some private, nongovernmental organic organizations may impose stricter requirements.

66. See Philipkoski, *supra* note 48.

67. RESTATEMENT (SECOND) OF TORTS § 822 (1979). A private nuisance should be contrasted with a public nuisance which is an "interference with a right common to the general public." *Id.* § 821B(1). In *In re StarLink Corn Products*, the plaintiffs brought a class action lawsuit on behalf of growers of conventional corn against the maker of GM corn (StarLink) on the basis of private and public nuisance (among other claims), for the contamination of the U.S. corn supply. 212 F. Supp. 2d at 833. The GM corn at issue had not been approved for human consumption and, through cross-pollination and commingling, had entered the human food supply. *Id.* at 834. On the plaintiff's private nuisance claim, the court framed the issue as whether the biotech company was responsible for the contamination caused by StarLink "beyond the point of sale." *Id.* at 845. The court cited case law from various jurisdictions holding a manufacturer liable for nuisance beyond the point of sale. *Id.* at 845-48. As such, the plaintiffs had stated a valid claim for private nuisance sufficient to withstand a motion to dismiss. *Id.* at 848, 852. On the public nuisance claim (contamination of the general food supply), the court held that a sufficient claim had been stated inasmuch as "[c]ommercial corn farmers, as a group, are affected differently than the general public." *Id.* at 850.

68. If the plaintiff is injured personally or the plaintiff's personal property is damaged physically, the interference will always be "substantial." However, if the plaintiff is merely inconvenienced, the interference is not substantial unless a person of normal sensitivity in the community would be injured seriously.

producers utilizing GMOs, the potential for cross-pollination could affect which crops a neighboring farmer can grow, and a court could find the existence of a nuisance for substantial interference with the neighboring farmer's use and enjoyment of the land.⁶⁹ A significant issue may be the role that state right-to-farm laws have on the outcome of such cases.⁷⁰ Also a major factor limiting the efficacy of a nuisance claim, however, is the widespread planting of GMO crops.⁷¹ Accordingly, persons bringing a nuisance claim may have a difficult time establishing that the planting of GMO seed and the harvesting of GMO crops constitutes an unreasonable agricultural practice unless a court were to adopt a zero tolerance standard for cross-pollination.⁷²

D. Strict Liability

Under a strict liability approach, persons are liable for injuries caused by their actions, even if they were not negligent or did not intend to injure or damage.⁷³ Strict liability is generally reserved for highly (or abnormally) dangerous activities.⁷⁴ Theoretically, farmers planting GMO seed with knowledge that the resulting crop is likely to cross-pollinate a neighbor's conventional crop could be held strictly

69. Several organic farmers in Saskatchewan, Canada, have filed a statement of claim in the Court of Queen's Bench, seeking class action status against Monsanto and Aventis for damages for the contamination from genetically modified canola that has made it impossible for them to grow organic canola. According to the complaint, genetically modified canola had been found growing on land for which it was not intended, and few, if any, seed suppliers will certify their seeds as organic. The complaint alleges that the defendants are responsible for genetic contamination on the grounds of negligence, nuisance, trespass, pollution under the Saskatchewan Environmental Management Protection Act, and failure to conduct an environmental assessment. Present estimates peg damages in the millions of dollars for the loss of canola as an organic crop in Saskatchewan. The trial court required the companies to file statements of defense. The case is presently on appeal.

70. In *re StarLink Corn Products*, involved, in part, a private nuisance claim arising from cross-pollination. 212 F. Supp. 2d at 828. On the private nuisance claim, the court framed the issue as whether Aventis (the maker of the biotech corn seed at issue) was "responsible for contamination caused by [the biotech corn] beyond the point of sale." *Id.* at 845. The court noted case law from various jurisdictions that held manufacturers liable for nuisance beyond the point of sale. *Id.* at 845-48. As such, the court determined, the plaintiff class had stated a valid claim for private nuisance sufficient to withstand a motion to dismiss. *Id.* at 848, 852.

71. For a discussion of state right-to-farm laws, see McEOWEN & HARL, *supra* note 38, at § 11.07[2][c][ii].

72. As the planting of GMO crops becomes more common, the argument that GMO crops constitute an unreasonable use of land becomes less viable.

73. That outcome seems unlikely inasmuch as the courts generally attempt to balance the interests of all of the parties when determining whether a private nuisance exists. See RESTATEMENT, *supra* note 67, §§ 826-828.

74. See McEOWEN & HARL, *supra* note 38, § 11.06.

75. Thus, whether a strict liability approach applies with respect to GMOs hinges on whether the use of GMOs is an abnormally dangerous activity. A strict liability approach for "non-natural" land use activities was first applied in *Rylands v. Fletcher*, L.R. 3 H.L. (1868), an English case involving the escape of impounded water that flooded a neighbor's adjacent abandoned mine shafts. The court held the defendant strictly liable because the defendant's land had been put to a "non-natural use for the purpose of introducing [onto it] that which in its natural condition was not in or upon it." McEOWEN & HARL, *supra* note 38, § 11.06 (quoting *Rylands*, L.R. 3 H.L.). However, the court noted that had the water entered the plaintiff's land due to a "natural use" of the defendant's land, there would have been no liability.

liable for damages.⁷⁵ While there are currently no appellate-level court opinions on the matter, cases involving similar facts exist.⁷⁶ The determination of whether an activity is abnormally dangerous involves an examination of several factors: (1) existence of a high degree of risk of some harm to the person, land, or property of another; (2) likelihood that the resulting harm will be great; (3) inability to eliminate the risk by exercise of reasonable care; (4) extent to which the activity is not common; (5) inappropriateness of the activity to the location where it is conducted; and (6) extent to which the value to the community is outweighed by dangerous attributes.⁷⁷ As such, an equitable outcome would seemingly require responsibility for the unwanted spread of the technology be placed on the company introducing the technology and make the company bear the burden of controlling the spread.⁷⁸ In reality, parties alleging a strict liability claim may have difficulty establishing the existence and likelihood of the first two factors. Also, given the level of GMO crops planted in the United States, uncommonness and inappropriateness of the activity may be difficult to establish.

Damages, under a strict liability approach, could include (for organic farmers) loss of organic certification,⁷⁹ inability to meet contract obligations or obtain higher premiums, and costs relating to violation of identity-preserved crop contracts. Neighboring farmers could also be sued by companies for “theft” of genetic technology that was actually present in their fields due to cross-pollination.⁸⁰

E. Product Liability

An injured party must establish five elements in order to recover from a manufacturer on a product liability claim:⁸¹ (1) that the defendant sold the product and was engaged in the business of selling the

75. RESTATEMENT (SECOND) OF TORTS §§ 519-524 (1977) sets forth the common law principles for strict liability.

76. See, e.g., *Langan v. Valicopters, Inc.*, 567 P.2d 218, 223-24 (Wash. 1977) (holding an aerial crop-duster strictly liable for spray drift onto neighboring organic farmer’s crop).

77. RESTATEMENT, *supra* note 75, § 520.

78. However, the basic policy in the United States is that agricultural biotechnology is the same as other breeding technologies.

79. While RESTATEMENT (SECOND) OF TORTS § 524A, states that a defendant is not to be held liable on a strict liability theory for harm caused by an abnormally dangerous activity if the harm would not have resulted but for the abnormally sensitive character of the plaintiff’s activity, some courts have not limited the strict liability rule in such situations. See, e.g., *Langan*, 567 P.2d at 223-24 (holding an aerial crop applicator strictly liable for damages caused by spray drift of pesticide to neighboring organic crops).

80. See *infra* Part IV.E. In its 2001 session, the Massachusetts legislature considered a bill (Mass. 1789) that would hold any person or business that genetically engineers an organism for use as food strictly liable for resulting damages if the user followed reasonable safety precautions in using the product. Damages were specified as including the loss of price due to crop contamination. The bill was heard in the Senate Committee on Science and Technology on December 13, 2001.

81. See McEOWEN & HARL, *supra* note 38, § 11.05[3][d].

product; (2) that the product was in a defective condition; (3) that the defective condition was unreasonably dangerous to an ordinary user during normal use;⁸² (4) that the product was expected to reach the user without substantial change in condition and, in fact, did so; and (5) that the product was the proximate cause of the plaintiff's injury or damage.

Some limitations exist, however, on the ability to sue a manufacturer on a product liability claim. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),⁸³ applies in situations involving damage to persons or realty arising from the use of registered pesticides. Under FIFRA, it is unlawful to use any registered pesticide in a manner inconsistent with its labeling. While this label use provision gives the EPA authority to assess civil penalties against producers that use pesticides improperly or damage the environment, it also limits the ability of injured parties to sue pesticide manufacturers on either an inadequate labeling or wrongful death theory.⁸⁴ However, one court previously held that a pesticide manufacturer's compliance with FIFRA's labeling requirements does not bar a damage suit under state law stemming from a failure to warn the purchaser of specific dangers.⁸⁵

Under the "economic loss doctrine,"⁸⁶ product defects that damage only the product itself, or make the product useless, are not within

82. See, e.g., *Ellis v. Weasler Eng'g, Inc.*, 258 F.3d 326, 331-32 (5th Cir. 2001). In *Ellis* the plaintiff's method of inspection and type of clothing worn were within reasonably anticipated actions for users of pecan harvesters. *Id.* at 342. A product may be deemed to be unreasonably dangerous if the manufacturer fails to warn of dangers inherent in the product's normal use that is not obvious to an ordinary user. RESTATEMENT, *supra* note 75, § 822 cmt. j. If the product bears an adequate warning, the product is deemed not to be in defective condition in those states whose product liability act follows comment j of the RESTATEMENT (SECOND) OF TORTS § 402A. Some states follow RESTATEMENT (THIRD) OF TORTS § 822 cmt. i (2003), which provides that an adequate warning does not foreclose a finding that a product is defectively designed. See, e.g., *Delaney v. Deere & Co.*, 999 P.2d 930, 934-35 (Kan. 2000), *rev'd*, 219 F.3d 1195, 1195 (10th Cir. 2000).

83. 7 U.S.C. §§ 136-136y (2000).

84. See, e.g., *Hopkins v. Am. Cyanamid Co.*, 666 So. 2d 615, 623 (La. 1996) (holding that FIFRA preempts an action based on failure to warn but not an action based on defective product). In one case involving biotech corn, the court held that the claim that the biotech corn was a defective product because it could not be used safely for its intended non-food purpose due to its inevitable commingling with and cross-pollination of crops intended for the human food supply was, in essence, a label-based claim that challenged the label warning and was, therefore, preempted by FIFRA. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 838 (N.D. Ill. 2002). But, statements of company representatives that the biotech corn seed was safe for consumption and that EPA would issue a tolerance for the presence of the gene at issue in food products were not preempted by FIFRA because they directly contradicted the EPA-approved label. *Id.* at 835-38.

85. *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366, 368 (Cal. 2000), *rev'd* 65 Cal. App. 4th 467 (1998); see also *McAlpine v. Rhone-Poulenc Ag. Co.*, 16 P.3d 1054, 1060 (Mont. 2000); *Pfeifer v. E.I. DuPont de Nemours & Co.*, 606 N.W.2d 773 (Neb. 2000) (holding that FIFRA does not preempt state common law damage actions, thus evidence of the herbicide's product label was admissible in further proceedings).

86. See RESTATEMENT (THIRD) OF TORTS § 21 cmt. d (1998).

the domain of product liability law.⁸⁷ Instead, these types of cases are decided under contract law, with contract-based damages. The question is for what the purchaser contracted. If what was purchased was insured, the insurance company is liable for the loss.⁸⁸ The doctrine also applies to "other property" that is damaged if the damage was or should have been reasonably contemplated by the contracting parties.⁸⁹ Thus, if a GMO crop causes physical harm to a non-GMO crop (through cross-pollination or commingling), a tort claim may lie.⁹⁰ If no physical harm occurs, the economic loss doctrine may bar the claim.⁹¹

IV. ISSUES RELATED TO THE LEGAL PROTECTION OF BIOTECHNOLOGY PRODUCTS

Seed companies that develop GMOs have invested tremendous sums in the technology and, as a result, seek to protect their investment in the developed technology through various legal means. Agricultural producers must take care not to violate the intellectual property rights of seed companies. Thus, a review of the available means of intellectual property right protection of GMOs is in order.

87. *Id.* The doctrine applies when the losses occur to property acquired in transactions bargained for by commercial parties. Most courts hold that the doctrine applies equally to consumer purchasers as well as business purchasers. Thus, mere economic loss without physical injury to other property does not suffice for a product liability claim. *See, e.g., Russell v. Deere & Co.*, 61 P.3d 955 (Or. Ct. App. 2003). In this case involving a defective combine, the plaintiff alleged and presented evidence only of economic loss; the economic loss doctrine barred the product liability claim. *Id.* at 959.

88. *See, e.g., Jordan v. Case Corp.*, 993 P.2d 650, 651-52 (Kan. Ct. App. 1999). In *Jordan*, the farmer bought a self-propelled combine and insured it against fire loss; the combine engine triggered a fire, destroying the combine; the insurance company (Kansas Farm Bureau) sued the manufacturer in a subrogation action to recover on the claim amount paid to the farmer on the basis that the engine was not a component part of combine. The engine was held to be a component part, and the insurer was liable on claim. *Id.*; *see also Hofstee v. Dow*, 36 P.3d 1073, 1076-78 (Wash. Ct. App. 2001) (determining that in a case where purchased dairy cows were quarantined after testing for brucellosis, negligence and strict liability claims were dismissed because testing was part of the commercial transaction).

89. *See, e.g., Purvis v. Consol. Energy Prods. Co.*, 674 F.2d 217, 223 (4th Cir. 1982) (finding that tort claim for loss of tobacco caused by defect in tobacco barns was barred because the loss resulted from "ordinary commercial risk of product ineffectiveness"); *Theuerkauf v. United Vaccines Div. of Harlen Sprague Dawley, Inc.*, 821 F. Supp. 1238, 1242 (W.D. Mich. 1993) (holding that tort claim of death of rancher's mink caused by defective vaccine was barred because loss was the natural, foreseeable result of product defect); *Neibarger v. Universal Coops., Inc.*, 486 N.W.2d 612, 614 (Mich. 1992) (opining that tort claim for damage to cattle caused by defective milking machine was barred because loss within contemplation of parties).

90. In *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 838 (N.D. Ill. 2002), the court ruled that the economic loss doctrine did not apply to bar a claim against the maker of GMO corn that cross-pollinated and commingled with conventional corn, which could then not be marketed into human food supply channels. The GMO corn at issue in the case had not been approved for human consumption. *Id.* at 834.

91. *Id.* at 838. Cases have been filed against biotech companies, alleging (in part) that cross-pollination of their conventional crop by GMO crops (or commingling after harvest) has increased their production costs and depressed market prices for their crops. *See id.* To overcome the application of the economic loss doctrine barring their tort claims, the plaintiffs will have to establish physical harm to their conventional crops. *Id.* at 842-43. Recovery for merely economic loss will be barred by the economic loss doctrine. *See, e.g., Sample v. Monsanto Co.*, 283 F. Supp. 2d 1088 (E.D. Mo. 2003).

A. Plant Patent Act (PPA) of 1930

Before 1930, it was commonly believed that plants and other living organisms, even those bred by man, were not patentable because they were products of nature. Indeed, the Commissioner of Patents, in *Ex Parte Latimer*,⁹² held that the fiber from the needle of an evergreen tree was not patentable because it was a product of nature. Similarly, plants were considered not amenable to the patent law's "written description" requirement.⁹³

In response to these concerns, Congress passed the Townsend-Purnell Plant Patent Act (PPA) in 1930.⁹⁴ Advocates of the legislation noted the contributions to society of plant breeders and their contributions to agriculture and horticulture. Indeed, one rationale for the legislation was to "remove the existing discrimination between plant developers and industrial inventors."⁹⁵ Because the PPA provisions were included as amendments to general patent law,⁹⁶ the application of the written description requirement to plant patent claims needed to be examined. Congress addressed the written description requirement by explaining that the work of the plant breeder in "aid of nature" should be subject to patent protection and that the written description requirement for plant patent applications should consist of a description "as complete as is reasonably possible."⁹⁷ Thus, to reflect the concerns of plant breeders with respect to protecting germplasm, the PPA exempted plant patent applications from the written description requirement of general utility patent law.⁹⁸

The PPA also amended utility patent law to read, "any person who has invented or discovered any new and useful art, [or] machine . . . or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant

92. 1889 Dec. Comm'r. 123 (1889).

93. See 35 U.S.C. § 33, 46 Stat. 376 (1930), the predecessor of 35 U.S.C. § 112. Indeed, the Commissioner of Patents cited this factor in arguing against granting a patent for living things such as genetically engineered microorganisms in *Diamond v. Chakrabarty*, 447 U.S. 303, 306-07, 312 (1980). Under the written description requirement, a patent application must contain a written description of the invention and must describe the manner and process of making and using the invention. 35 U.S.C. § 112 (2000).

94. 35 U.S.C. §§ 161-164.

95. S. REP. NO. 315 (1930).

96. 35 U.S.C. § 162. "The specification [of a plant patent application] must contain as full and complete a disclosure as possible of the plant and the characteristics thereof that distinguish [it from] related known varieties . . . and must particularly point out where and in what manner the [plant] variety . . . has been asexually reproduced." 37 C.F.R. § 1.163(a) (2004). Only a single claim is permitted. 35 U.S.C. § 164; see also U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 1605 (8th ed. 2003) (granting plant patent on entire plant) [hereinafter MPEP].

97. Section 4884 of the revised statutes was amended to read, "every patent shall contain . . . a grant to the patentee . . . of the exclusive right to make, use, and vend the invention or discovery (including in the case of a plant patent [for] the exclusive right to asexually reproduce the plant)." Patents for Plants, ch. 312, § 1, 46 Stat. 376, 376 (1930) (current version at 35 U.S.C. § 163).

98. *Id.*

. . . may . . . obtain a patent therefor.”⁹⁹ This amendment addressed the concerns of plant breeders by statutorily recognizing that they created products (i.e., germplasm) that were more than mere products of nature and specifically exempting plant patent applications from the written description requirement of general utility patent law.¹⁰⁰

Patentable subject matter under the PPA is defined as: “[any] asexually reproduce[d] . . . distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state.”¹⁰¹ Therefore, the PPA extends patent protection not only to inventors but also “discoverers” of eligible subject matter. However, the act limits protection specifically to plants and plant varieties which have already reproduced asexually.¹⁰² Tuber-propagated plants and plants found in an uncultivated state were expressly excluded from coverage under the PPA.¹⁰³ PPA protection is limited to a single plant and its asexually reproduced progeny.¹⁰⁴ As a result, the PPA’s narrow scope limited patent protection for plant breeders by failing to cover those plant species comprising the majority of commercial agriculture in the United States.¹⁰⁵

B. *Plant Variety Protection Act (PVPA) of 1970*

1. In General

Plant breeding technology advanced sufficiently after the PPA’s passage in 1930 such that there was a generalized perception by 1970 that new sexually reproduced varieties could be replicated true-to-

99. *Id.* (codified as amended at 35 U.S.C. §§ 101, 161 (2000)).

100. See 35 U.S.C. § 112. The Plant Patent Act is now contained in 35 U.S.C. §§ 161-164.

101. 35 U.S.C. § 161.

102. The limitation of patent protection to plants and plant varieties which have already reproduced asexually was apparently premised on the belief that plants produced other than asexually could not be reproduced reliably true-to-type. MPEP, *supra* note 96, § 1601. The exclusion of tuber-propagated plants (Irish potatoes and Jerusalem artichokes) appears to have been a political rather than technical distinction based on the notion that, with tuber-propagated plants, the propagating and edible portions of the plant are identical. *Id.* The 1954 amendments to the PPA broadened the statute to include (based on statutory interpretation) those plants found in a cultivated state that subsequently were reproduced asexually. Patents for Plants, Pub. L. No. 83-775, 68 Stat. 1190 (codified as amended at 35 U.S.C. § 161 (2000)). By judicial interpretation, the term “plant” as used in the PPA is defined in its lay, rather than scientific, meaning, and thus bacteria are excluded from the Act. See *In re Arzberger*, 112 F.2d 834, 837-38 (C.C.P.A 1940).

103. See 35 U.S.C. § 161.

104. *Id.* The patent application under the PPA is limited to asexually reproducing plants that are produced from cuttings or grafts and are not grown from seed. See *Imazio Nursery, Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1568 (Fed. Cir. 1995). The court construed the term “variety” in PPA to limit PPA protection to a single plant and its asexually reproduced progeny. *Id.*

105. As such, infringement requires proof of asexual reproduction of the actual plant patented, and evidence of independent creation is a valid affirmative defense to a plant patent infringement claim.

type.¹⁰⁶ Therefore, Congress passed the PVPA in 1970 to provide patent-like protection to novel varieties of sexually reproduced plants (i.e., plants grown from seed) parallel to that afforded asexually reproduced plant varieties (varieties reproduced by propagation or grafting) under the PPA.¹⁰⁷ The intent was to grant patent protection to plant species comprising most of commercial agriculture that was generally unavailable to plant breeders at the time. Thus, the primary focus of the PVPA was to add additional legal protection for plant breeders' intellectual property rights in germplasm and to ensure that plant breeding technology would not result in the germplasm of sexually reproduced varieties becoming part of the public domain.¹⁰⁸

2. Scope of Protection

The PVPA, as originally enacted, provided a system of protection independent of federal patent law under which the USDA issued certificates of plant variety protection to the breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first-generation hybrids) who had reproduced the variety.¹⁰⁹ The plant variety certificate protection extends to both the plant and its seeds.¹¹⁰ Under the PVPA, it is unlawful to sell or grow a protected plant variety without permission of the holder of the plant variety protection certificate.

Novel plant varieties are protectable subject matter under the PVPA if the variety possesses "distinctiveness," "uniformity," and "stability."¹¹¹ The "distinctiveness" requirement is the most critical and requires a variety to clearly differ by one or more identifiable morphological, physiological, or other characteristics.¹¹² Similar to

106. Sexually reproduced varieties are non-hybrid varieties or cultivars of plants that, for practical purposes, breed true-to-form when self-pollinated.

107. Plant Variety Protection Act, 7 U.S.C. §§ 2321-2582 (2000).

108. Also, much of the impetus behind the PVPA's enactment in 1970 was attributable to the creation of the International Union for the Protection of New Varieties of Plants (UPOV) in 1961 by several European countries to provide protection for seed plant varieties. At the time the U.S. signed the UPOV Convention, the PVPA was in full accordance with the UPOV Convention. A 1991 amendment to the UPOV Convention significantly broadened the scope of protection. As a result, the United States amended the PVPA in 1994 to conform to the 1991 revision of the UPOV Convention. See H.R. REP. NO. 103-699, at 2425 (1994). The PVPA changes required by the UPOV amendments (and accomplished by the 1994 PVPA amendments) include: (1) extending protection to first-generation hybrids; (2) lengthening the term of protection to twenty years; and (3) extending protection to harvested plant parts.

109. 7 U.S.C. § 2402(a). First-generation hybrid plants are produced by mass-breeding to different inbred (breeding true-to-type) varieties. First-generation hybrids do not reproduce true-to-type.

110. *Id.* § 163. By contrast, a plant variety patent granted under the PPA extends only to the plant and gives the patentee "the right to exclude others from asexually reproducing the plant," or selling or using the plant reproduced. *Id.*

111. *Id.* § 2402(a)(1)-(4). Thus, the PVPA's requirements are more restrictive than the PPA's. While the PPA requires only that a variety be new and distinct, the PVPA also requires that the variety be uniform and stable. See *id.* § 2402(a)(3)-(4). Therefore, plants which through breeding fail to exhibit the same traits when grown out over several generations (e.g., hybrid varieties that do not breed true-to-form) are not eligible for PVPA protection.

112. *Id.* § 2402(a)(2).

protection under the PPA, the right afforded by the certificate is limited to the specific variety.¹¹³

The PVPA, while providing protection independent of federal patent law, is procedurally similar to the utility patent system. Included is a series of statutory bars, requirements for the content of the application,¹¹⁴ and a requirement for a seed deposit to be made with the Plant Variety Protection Office.¹¹⁵ Infringement activities under the PVPA include selling the novel variety, importing the novel variety, sexually multiplying the novel variety, using the novel variety in producing (rather than developing) a hybrid or different variety, using seed that has been prohibited from propagation, or distributing the protected variety to another without proper notice.¹¹⁶

However, there are certain aspects of the PVPA that are unlike utility patent law or the PPA. These include a mandatory license requirement,¹¹⁷ a series of statutory exemptions for saved seed (known as the "farmer's exemption"),¹¹⁸ an exemption for sales by persons whose primary occupation is farming,¹¹⁹ and a research exemption.¹²⁰ Under the exemptions, it is not an infringement when sexual reproduction occurs in the context of developing a new inbred line and when asexual reproduction occurs in pursuance of a valid U.S. plant patent.

The major disadvantage of the PVPA to plant breeders is the so-called "saved seed" or "farmer exemption" that originally permitted farmers to sell the protected variety to other farmers who would use it as seed, thereby eliminating their need to buy the protected variety

113. In the absence of a judicial doctrine of equivalents, a variety protected under one certificate cannot logically infringe the right granted under any other.

114. *Id.* § 2422.

115. *Id.* § 2422(4). The Plant Variety Protection Office is a branch of the USDA. Also, unlike the deposit requirement in patent law, the seed deposit with the Plant Variety Protection Office is not available publicly.

116. *Id.* § 2541(a)(1)-(6).

117. *Id.* § 2404.

118. *Id.* § 2543. The farmer's exemption has led to the most litigation under the PVPA. *See, e.g.*, Asgrow Seed Co. v. Kunkle Seed Co., 845 F.2d 1034 (Fed. Cir. 1988); Delta & Pine Land Co. v. Peoples Gin Co., 694 F.2d 1012 (5th Cir. 1983).

119. *See* 7 U.S.C. § 2543.

120. *Id.* § 2544. However, the research exemption does not allow a breeder to use a protected variety to produce (as distinguished from develop) a hybrid or different variety therefrom. The difference between "producing" and "developing" a hybrid variety has not been litigated. Thus, breeders may try to justify infringement of a protected variety by calling their attempt to copy the variety "development" rather than "production." Congressional intent, however, seems to disallow breeders from free-riding on others' research investments. Instead, the intent of the Congress appears to be to allow breeders to use each others' discoveries to advance biotechnology developments. The 1994 amendments to the PVPA specify that varieties that are "essentially derived" from protected varieties constitute an infringement. *See id.* § 2541(c)(1). Unfortunately, "essentially derived" is not precisely defined and leaves room for litigation. It appears that the Congress intended an infringement to occur whenever a new variety incorporates a significant trait from a protected variety and is the same as the protected variety but for slight cosmetic changes. Because of the vague definition, and the potential for litigation concerning it, a significant question exists as to whether the 1994 amendments will limit abuse of the research exemption. Presently, no court has interpreted the meaning of the phrase.

directly from the seed company. As enacted, the PVPA statutory exemption for saved seed contained no limits on the amount of seed that could be sold under the exemption.¹²¹ However, in 1983, the Fifth Circuit Court of Appeals limited the use of the exemption by holding that farmers may sell saved seed directly to other farmers but may not sell through intermediaries such as farm cooperatives and grain elevators.¹²²

The scope of the saved seed exemption was clarified further in *Asgrow Seed Co. v. Winterboer*.¹²³ The Winterboers, through their corporation, purchased soybean seed from Asgrow Seed Co. The farmers planted the seed, harvested the crop, cleaned it, and placed the seed in bags for sale. Asgrow sought an injunction under the PVPA to prohibit the Winterboers from selling the seed. The court granted an injunction for the 1991 season. Asgrow then brought a patent infringement action and a request for a permanent injunction. The Winterboers defended on the ground that the sales were within the saved seed exception to the PVPA. The federal district court found evidence that "Congress intended to create a narrow exemption" for "saved seed," and held that saved seed was to be "limited to the amount of the protected seed reasonably needed by the farmer who grew it to plant the number of acres of the protected variety, or its progeny, [needed] in the upcoming crop year."¹²⁴

On appeal, the district court's decision was reversed.¹²⁵ The appellate court noted that the statute did not limit the amount of seed a farmer can save under the "saved seed" exception but acknowledged that the statute imposed several limitations on such sales. In essence, the court held that the "saved seed" exception permitted up to fifty percent of a farmer's crop produced from a protected novel plant variety to be sold as seed in competition with the owner of the novel variety. As such, the court held that the district court had erred in the reading of the limitation into the statute and vacated the permanent injunction against the farmers. On review, the United States Supreme Court held that the "saved seed" exception of the PVPA did not permit up to fifty percent of a farmer's crop produced from a protected novel plant variety to be sold as seed in competition with the owner of the novel variety.¹²⁶

121. The exception is of no consequence for corn because any saved seed from the first generation of production after the crossbreeding to produce a commercial variety lacks the performance of the original seed. However, the exception is of great importance for soybeans and other crops where saved seed performs almost as well as the parent seed.

122. *Peoples Gin Co.*, 694 F.2d at 1016-17.

123. 513 U.S. 179, 181-91 (1995).

124. *Asgrow Seed Co. v. Winterboer*, 795 F. Supp. 915, 918, 920 (N.D. Iowa 1991).

125. *Asgrow Seed Co. v. Winterboer*, 982 F.2d 486, 492 (Fed. Cir. 1992).

126. *Asgrow Seed Co.*, 513 U.S. at 191-93. As such, the Court limited the right to save seed to the seed needed to plant the farmer's next crop. *Id.*

Under amendments to the PVPA in 1994, the sales provision was removed from the crop exemption.¹²⁷ Farmers may now only sell seed "for other than reproductive purposes"—for food or feed, and not for planting. Thus, the activity involved in *Winterboer* would now constitute infringement. However, farmers are still permitted to save seed for replanting, to save seed for planting the following season on owned and rented acreage, or to sell seed for other than reproductive purposes.¹²⁸ So, from a seed company's perspective, the PVPA has significant limitations as to the ability of the seed company to protect its intellectual property rights in seed technology—farmers have the ability to replant saved seed, and competitors are able to appropriate a plant breeder's invention in slightly altered form.

It is unclear whether a claim of independent development can be successfully made as a defense to an infringement action under the PVPA. However, the PVPA does include a provision for an interference proceeding,¹²⁹ which leads to the inference that independent development is contemplated. Indeed, the PVPA's legislative history recognizes that independent invention, while infrequent, may occur.¹³⁰ Thus, independent development is not likely to avoid infringement liability. However, an improved variety is presumably not dominated by a certificate on its parental variety.¹³¹

Protection under the PVPA runs for twenty years,¹³² and any violator of the rights provided by a PVPA certificate can be sued for infringement.¹³³ Unlike the utility patent statute, however, which allows the patentee to exclude anyone from making, using, or selling an invention, the PVPA allows a breeder's competitors to use a protected

127. The 1994 PVPA amendments attempted to narrow the scope of the two exemptions and allowed the United States to become the first country to comply with the 1991 amendments to the UPOV. The UPOV, created in 1960, provides uniform plant variety protection for its signatory nations. Sixteen nations had signed the UPOV by 1991. Presently, the following nations are signatories to the UPOV: Argentina, Australia, Austria, Belarus, Belgium, Bolivia, Brazil, Bulgaria, Canada, Chile, China, Columbia, Croatia, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Kenya, Kyrgyzstan, Latvia, Lithuania, Mexico, Netherlands, New Zealand, Nicaragua, Norway, Panama, Paraguay, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Trinidad and Tobago, Tunisia, Ukraine, United Kingdom, United States of America, and Uruguay. See Press Release, UPOV, Lithuania Accedes to the UPOV Convention (Nov. 10, 2003), <http://www.upov.int/en/news/pressroom/pdf/pr58.pdf>.

128. The ability of farmers to replant with saved seed is an important issue to seed companies. Every time a farmer replants with saved seed, the seed companies lose a potential sale. With certain varieties, a farmer may have to purchase seed only once to be able to plant, harvest, save, and replant the seed indefinitely.

129. 7 U.S.C. § 2504 (2000).

130. S. REP. NO. 91-1138, at 1 (1970), reprinted in 1978 U.S.C.C.A.N. 5082.

131. 7 U.S.C. § 2504(a)(1).

132. *Id.* § 2453(b). The length of protection had been eighteen years before being changed by a 1994 amendment, effective April 16, 1995.

133. This section, 7 U.S.C. § 2541, specifies those activities that constitute infringement under the PVPA.

variety to create new varieties without permission.¹³⁴ The other exemptions provided for under the PVPA also limit the PVPA's strength.

C. General Utility Patents

"[W]hoever 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 therefore subject to the conditions and requirements of this title."¹³⁵ Utility patents provide a plant breeder with strong protection, allowing the breeder to exclude others from making, using, or selling the patented item (or practicing the patented process) without the breeder's permission.¹³⁶ The length of protection is twenty years.¹³⁷ The scope of protection is wide. In addition, under the "doctrine of equivalents,"¹³⁸ patentees are protected from inventors who independently come up with the same invention. Independent discovery is not a defense in an infringement suit.

While the PVPA, as enacted, protects sexually reproducible plants, the United States Supreme Court, in *Diamond v. Chakrabarty*,¹³⁹ determined that bacterial microorganisms were patentable so long as they satisfied the statutory criteria. The Court's language was sufficiently broad to suggest that even plants that could be protected under the PPA or the PVPA could be the objects of a general utility patent.¹⁴⁰ The Board of Patent Appeals and Interferences confirmed this suspicion in 1985 when it ruled that maize plants were patentable.¹⁴¹ Sixteen years later, the United States Supreme

134. *Id.* § 2544.

135. 35 U.S.C. §101 (2000). The text of 35 U.S.C. § 101 has generally been construed liberally to include the diverse range of imaginable and unforeseen technological developments. For example, the court, in *In re Bergy*, stated,

[T]he founding fathers and the Congresses of the past century could not have foreseen the technologies that have allowed man to walk on the moon, switch travel from the railroads to heavier-than-air craft, fill our houses with color TV, cure normally fatal diseases with antibiotics produced by cultures of molds (microorganisms), and give to school children at small cost pocket calculators with which they can produce square roots in microseconds through complex electronic circuitry on an 'IC' (integrated circuit) so small the circuits are not visible to the naked eye.

596 F.2d 952, 974 (C.C.P.A. 1979). Consequently, the subject matter provisions of general utility patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting "the progress of science and the useful arts" with all the means for the social and economic benefits envisioned by the framers. *Id.* at 973 (quoting *Kendall v. Winsor*, 21 How. 322, 62 U.S. 322, 328 (1859)).

136. 35 U.S.C. § 271(a).

137. *Id.* § 154(a)(2).

138. The test provided by the doctrine of equivalents is that if the product accomplishes the same things as the patent claims, and in substantially the same way, it infringes on the patent.

139. 447 U.S. 303, 309-10 (1980).

140. Indeed, the Court's opinion ultimately resulted in the issuance of over 1800 utility patents for plants.

141. *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Interferences 1985). The Board of Patent Appeals and Interferences reasoned that the PPA and the PVPA were enacted

Court agreed in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*¹⁴² The Court held specifically that “[n]ewly developed plant breeds fall within the terms” and scope of general utility patent law “and that neither the PPA nor the PVPA limits the scope of” coverage of general utility patent law.¹⁴³ The Court noted that the Congress had not given any indication of narrowing the scope of the general utility patent law’s application to plants since the Court’s 1980 *Chakrabarty*¹⁴⁴ decision. The Court also determined that the United States Patent and Trademark Office had issued over 1800 utility patents for plants, plant parts, and seeds since 1985.¹⁴⁵ The Court held that something that can be protected under the PVPA may also qualify for patent protection as a utility patent under general utility patent law and that general utility patent law protected all seeds, offspring, and hybrids containing the patented technology.¹⁴⁶ Accordingly, there is considerable concern that with the development of techniques for genetic engineering, many other new varieties of agricultural plants may also be patented rather than simply being protected by the PVPA.¹⁴⁷ A patent would essentially give the developers an exclusive monopoly over their varieties for a period of twenty years without the problem of the “farmer exemption.”¹⁴⁸

Seed companies are serious about enforcing their intellectual property rights in seed technology.¹⁴⁹ This has led to consideration, at

out of a concern that plants would not qualify for general utility patent protection rather than because the Congress thought plants were inherently unpatentable. While the patent examiner in *Hibberd* argued that the PPA and the PVPA were “plant specific” statutes, thereby evidencing a congressional intent to exclude plants from eligibility for utility patents, the Board of Patent Appeals ruled otherwise. The Board found no express congressional intent indicating that the PPA and PVPA should supersede utility patents for plants. The Board held that when the Congress enacted the PVPA in 1970, it believed that “it did not alter protection currently available within the patent system.” *Id.* at *8. Thus, the Board held that the Congress enacted the PPA and the PVPA out of concern that plants would not qualify for patent protection because of the way the enablement and written description provisions of utility patent law were written, not because the Congress thought plants were inherently unpatentable.

142. 534 U.S. 124 (2001).

143. *Id.* at 145.

144. 447 U.S. 303 (1980).

145. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 140 n.12.

146. *Id.* at 152 (Breyer, J., dissenting). The dissent, however, argued that protection only existed under the PPA for GMO crops. *Id.* at 147-56 (Breyer, J., dissenting). Under the dissent’s approach, the hybrids, pollen and second-generation seeds that invade non-GMO farmland and are derived from purchased, patented GMO seeds, would not be subject to patent protection. *Id.* (Breyer, J., dissenting).

147. In addition, unlike the utility patent statute, which allows the patentee to exclude anyone from making, using, or selling the patent holder’s invention, the PVPA allows a breeder’s competitors to use a protected variety to create new varieties without the certificate holder’s permission. 7 U.S.C. § 2544 (2000).

148. The American Seed Trade Association has proposed limiting patentees’ rights by establishing a compulsory licensing scheme whereby breeders could gain access to patented germplasm for a fee. Also, an important point is that patenting is not limited to GMO varieties. Conventional varieties may also be patented.

149. Monsanto has created an entire department to enforce its seed patents and binding agreements. The department has seventy-five employees and an annual budget of \$10 million. As of May 12, 2003, Monsanto had seventy-three lawsuits pending against farmers for alleged

the state level, of legislation that would allow farmers to save patented genetically modified seeds¹⁵⁰ or legislation that would provide property right protection to farmers.¹⁵¹

D. *Other Methods of Intellectual Property Right Protection*

1. Trade Secret

a. *In General*

For crops that are sold primarily as hybrid seeds, it is possible to protect the inbred parent lines as trade secrets.¹⁵² The practice of protecting inbred parent seed under trade secret law has been adopted as a strategy by several breeders of proprietary lines of inbred lines. Trade secret protection is based on state tort law¹⁵³ and is designed to protect commercially valuable trade secrets from misappropriation. The trade secret itself is sometimes referred to as a type of property,¹⁵⁴ but it is different than other commercial intangibles that can be subjected to misappropriation. For example, a trade secret is not in the public domain unless the defendant's tort places it there.¹⁵⁵ This is a critical point for plant breeders attempting to use trade secret law to protect germplasm against piracy activities. Germplasm protected as a trade secret is not deemed to be a part of the public domain and can only become part of the public domain through the tortious conduct of another party attempting to appropriate the protected germplasm.¹⁵⁶

violation of Monsanto's intellectual property rights. Thirty of these cases were filed in the Federal District Court for the Eastern District of Missouri. The other cases are spread over nineteen states, ranging from Nebraska to New Jersey and Michigan to Louisiana.

150. In its 2003 session, the Missouri legislature defeated an amendment to S.B. 668 that would have allowed farmers to save patented genetically modified seeds by allowing them to pay a seven-dollar fee as opposed to buying seeds annually. The amendment would have created the Genetically Engineered Seed Fund that would have paid six dollars to the patent holder on seeds, with the remaining dollar split between administering the fund and further research at the University of Missouri.

151. The South Dakota legislature, in its 2002 session, enacted legislation covering patent infringement claims brought against farmers by holders of patents on transgenic seeds. Under S.B. 179, a patent holder may not enter farmland to obtain crop samples to determine whether patent infringement has occurred, unless the farmer is notified in writing of the claim of patent infringement and grants written permission for entry within seven days of receiving a request to enter the land. If permission is denied, the patent holder may petition the circuit court for an order granting permission to enter the land. Either party has the right to request the State Secretary of Agriculture to provide for the collection of samples from a standing crop, representative standing plants in the field, or from crops remaining in the field after harvest. The law directs the Secretary to promulgate rules to set sampling protocols. S.D. CODIFIED LAWS §§ 38-1-45, 38-1-49 (Michie Supp. 2003).

152. See *Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds*, 35 F.3d 1226 (8th Cir. 1994). The inbred parent lines are necessary to make the hybrid.

153. See, e.g., KAN. STAT. ANN. § 60-3320 to -3330 (1994).

154. See, e.g., E.I. DuPont de Nemours Powder Co. v. Masland, 244 U.S. 100, 102 (1917).

155. See RESTATEMENT, *supra* note 41, § 757 cmt. b.

156. Under the Kansas version of the Uniform Trade Secrets Act, "misappropriation" is defined as "acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means." KAN. STAT. ANN. § 60-3320(2)(i). The

b. Scope of Trade Secret Protection

A trade secret may consist of any “formula, pattern, compilation [of information], program, device, method, technique, or process” that is used in one’s business and which gives the business owner an opportunity to obtain an advantage over competitors who do not know of, or use, the trade secret.¹⁵⁷ While the list of subject matter eligible for trade secret protection under either the Uniform Trade Secret Act or the *Restatement of Torts* does not include “genetic material,” the district court in *Pioneer Hi-Bred International, Inc. v. Holden Foundation Seeds*¹⁵⁸ held that the genetic messages of Pioneer’s hybrid parent seeds were “trade secrets” because they were “akin to a secret formula . . . [which] did not exist outside of Pioneer’s field[] . . . and could only be duplicated with a great deal of effort and some luck.”¹⁵⁹ The Eighth Circuit Court of Appeals affirmed the district court’s holding that Holden had misappropriated Pioneer’s trade secrets.¹⁶⁰ Thus, based on the *Holden*¹⁶¹ decision, plant breeders can sue others for misappropriation of the “secret” genetic messages of varieties they create. However, the court noted that the owner of a trade secret does not enjoy an absolute property right in the trade secret that may be used to exclude the world from using the secret because the federal patent laws place a ceiling on the strength of intellectual property protection that states may offer.¹⁶² While patent protection grants the patentee the right to exclude others from making, using, or selling the invention, trade-secret law merely aims to protect against misappropriation of a reasonably protected commercial secret.¹⁶³

statute provides additional definitions of “misappropriation,” with the act turning on the acquisition, disclosure, or use of a trade secret by “improper means.” KAN. STAT. ANN. § 60-3320(2)(ii). The statute defines “improper means” as including “theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through electronic or other means.” KAN. STAT. ANN. § 60-3320(1).

157. See, e.g., KAN. STAT. ANN. § 60-3320(4). Under RESTATEMENT OF TORTS § 757 cmt. b, a trade secret may be a formula or a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

158. No. 81-60-E, 1987 U.S. Dist. LEXIS 18286, at *101 (S.D. Iowa Oct. 30, 1987).

159. *Id.*

160. *Pioneer Hi-Bred Int’l, Inc. v. Holden Found. Seeds*, 35 F.3d 1226, 1228 (8th Cir. 1994).

161. *Id.*

162. *Id.* at 1238. The court’s reasoning on the property right issue is also of particular concern if contractual language purports to grant a seed company greater protection than that possible under federal law. A court could hold that the Congress enacted the PPA, PVPA, and patent law for the express purpose of placing a ceiling on intellectual property rights for plant breeders. With few reported appellate-level decisions concerning this matter, it is difficult to determine in advance of litigation on the issue whether a seed company’s contractual restrictions on the use of parent seed run afoul of federal preemption. This uncertainty imposes an element of legal risk whenever a breeder attempts to protect intellectual property rights in germplasm via a trade secret.

163. It is important to note that an action based on misappropriation of a trade secret involves the plaintiff establishing that the subject plant material is derived from the plant material subject to a trade secret. Proof of derivation of plant material is not required in a general utility patent infringement case. Presumably, phenotypic claims to plant varieties are enforceable

The tort of conversion may indeed apply to the misuse of germplasm. A subsidiary holding of the federal district court in *Holden* was that Holden had converted the genetic quality or genetic message of Pioneer's inbred line.¹⁶⁴ The district court did not have to specifically address the conversion issue because of the way the court held on the trade-secret allegations. However, the district court did state that if trade-secret law did not provide effective relief, Pioneer's interest in the "genetic message" of its proprietary inbred line was independently protected by the common law of conversion, and its taking would establish a common law cause of action against Holden. Standing by itself, this dicta of the district court in *Holden* could probably be ignored. However, in *Moore v. Regents of the University of California*,¹⁶⁵ the court ruled that an individual's genotype and DNA are attributes of the person, subject to a sufficient property right to establish a cause of action for tortious conversion if taken without permission. Taken together, the dicta of the district court in *Holden* and the holding of the *Moore* court on the conversion issue indicate rather strongly that the common law of conversion may be applied to certain forms of appropriation of genetic information including germplasm. Presently, the boundaries of any such common law cause of action for conversion of genetic information are uncertain. Courts will more clearly define the boundaries in future litigation.

c. Requirements for Trade-Secret Protection

To preserve the right to sue competitors for misappropriation of trade-secret-protected germplasm, a seed company must take "reasonable precautions" to ensure that their innovations are kept secret.¹⁶⁶ In a typical trade secret case, the courts require security measures to be taken to establish and maintain trade secret status.¹⁶⁷ That requirement could pose extreme difficulty for plant breeders whose parental plant lines are planted outdoors over a wide area, and the resulting crops are grown in open fields and sold to a broad market with no requirement of confidentiality.¹⁶⁸

against any variety satisfying the phenotypic characteristics, regardless of origin or method of creation.

164. 1987 U.S. Dist. LEXIS 18286, at *116-17.

165. 249 Cal. Rptr. 494 (Cal. Ct. App. 1988).

166. UNIF. TRADE SECRETS ACT § 1(4)(c), 14 U.L.A. 437, 438 (1990). See, e.g., E.I. DuPont de Nemours & Co. v. Christopher, 431 F.2d 1012, 1015 (5th Cir. 1970).

167. For example, KAN. STAT. ANN. § 60-3320(4)(ii) (1994), states that a trade secret must be "the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

168. Hybrid seed varieties may be the easiest to keep secret because the seed company, rather than pursuing PVPA or utility patent protection, will typically keep its parental lines secured and will sell only the seed that results from crossing the two lines. Because of the difficulty (but not impossibility) in determining the exact characteristics of the two parents from the resulting seed, this method would presumably constitute a "reasonable precaution" as required by trade secret law. See, e.g., *id*; see also *Holden Found. Seeds*, 35 F.3d at 1336-37 (holding that

A trade secret is not obtained merely by copying a product that is available publicly, but by breach of confidence¹⁶⁹ or breach of contract.¹⁷⁰ The focus is on the defendant's behavior in terms of improperly acquiring the trade secret of another. This indicates that contract remedies are available to a seed company whose germplasm protected as a trade secret has been misappropriated. Indeed, under the Kansas version of the Uniform Trade Secrets Act, a plaintiff may recover damages for the actual loss caused by the misappropriation in addition to or in lieu of injunctive relief.¹⁷¹ The statute also provides that a plaintiff may recover for the unjust enrichment caused by the misappropriation that is not accounted for in computing damages for actual loss.¹⁷² Exemplary damages may be awarded in an amount granted under any of the other contract remedies if the appropriation of the trade secret was willful and malicious.¹⁷³

d. Contract Language and Trade Secret Law

Restrictive language on a seed bag, while not necessary to maintain a trade secret, is another method to bolster trade secret protection. These "confidentiality" provisions in purchase agreements may provide a further buffer against trade secret misappropriation. Contract language can be worded such that it puts the purchaser on notice that the seed company's hybrid parent lines are trade secrets.¹⁷⁴ If the purchaser comes across any parental seed in the bag sold under such a contract (whether contained in a purchase agreement or in a seed bag label), the purchaser cannot use it without incurring liability for misappropriation.¹⁷⁵ This language should place the purchaser on notice that the purchaser has "reason to know" that such acquisition of the

hybrid parent seeds could be the subject of a trade secret and could be duplicated only with much effort).

169. See, e.g., *Hyman & Co. v. Velsicol Corp.*, 233 P.2d 977, 1000 (Colo. 1951).

170. *Lear Siegler, Inc. v. Ark-Ell Springs, Inc.*, 569 F.2d 286, 287 (5th Cir. 1978).

171. KAN. STAT. ANN. § 60-3322(a).

172. *Id.*

173. KAN. STAT. ANN. § 60-3322(b).

174. A purchaser can also be put on notice by a label on a bag for hybrid seed notifying the purchaser that any parental line found in the bag is the exclusive property of the seller and that the purchaser does not obtain any right to use any parental line found in the bag for breeding, research, or seed production purposes, or for any purpose other than production of forage or grain for feed or processing. Examples of seed bag label language used by Pioneer Hi-Bred International, Inc. can be found in *Pioneer Hi-Bred Int'l, Inc. v. Ottawa Plant Food, Inc.*, 283 F. Supp. 2d 1018, 1045-46 (N.D. Iowa 2003).

175. In late 1998, Pioneer Hi-Bred International, Inc. sued Cargill, Inc. and Monsanto Co. for violation of Pioneer's intellectual property rights. The defendants were alleged to have utilized a "chasing-the-selfs" practice (identifying self-pollinated inbred plants from seeds in purchased bags of commercially available hybrid seed) on purchased bags of Pioneer brand seed. The seed bags contained language specifically prohibiting the use of any inbred seed found in the bag for research or breeding purposes. In May 2000, Cargill executed a settlement agreement with Pioneer pursuant to which Pioneer released all claims against Cargill in exchange for a payment of \$100 million. Prior to filing the lawsuit, Cargill sold its international seed business to Monsanto. Cargill resolved Pioneer's claim against Monsanto "by compensating Monsanto for lost genetic materials" and costs associated with Cargill's misappropriation of Pioneer's intellec-

seed company's parental line could only be accomplished through misappropriation.¹⁷⁶

2. Private License

Another possible technique for protecting intellectual property rights in patented germplasm is to license its use. The license allows the licensor to impose license fees on other companies for using the seeds in research and development efforts and impose royalties on farmers who bring the licensor's products to market. For example, if a farmer purchases seed, grows a crop, and collects some of the seeds from the crop to replant, the seed company's intellectual property rights will have attached with the genetic code on the second-generation seeds. Thus, the licensor who holds a patent on the seeds may condition sale or replanting upon payment of royalties.

Pursuant to a license, a grower enters into a contractual arrangement with a seed company that allows the grower to use the protected seed in accordance with the license. The license does not constitute a sale of the seed subject to the agreement but merely amounts to a limited use of the seed.¹⁷⁷ Typically, seed protected under a general utility patent is licensed such that the grower (licensee) can use the patented technology for the planting of a single crop. The licensee is prohibited from reselling or supplying any seed used under the license to any other person or entity for breeding, research, seed production, reverse engineering, or analysis of the genetic makeup of the seed.¹⁷⁸

tual property rights. See Dave Price, *Cargill Reaps Bitter Harvest in Pioneer Dispute*, FIN. & COM., May 17, 2000, http://www.finance-commerce.com/recent_articles/051700b.htm.

176. See UNIF. TRADE SECRETS ACT § 1(2)(I), 14 U.L.A. 438 (1990). "Misappropriation" of a trade secret is defined, in part, as "acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means." See, e.g., KAN. STAT. ANN. § 60-3320(2)(i) (1994).

177. Traditionally, restrictions on the use of patented material have been viewed with suspicion. Restrictions found in license agreements have been held invalid as adhesion contracts and because of federal preemption. See *Vault Corp. v. Quaid Software, Ltd.*, 847 F.2d 255 (5th Cir. 1988). Thus, if a licensing agreement granted a seed company greater protection than what could be obtained under the PPA, PVPA, or general utility patent law, a court might conclude that the Congress enacted the PPA, PVPA, and patent law for the express purpose of placing a ceiling on intellectual property rights for plant breeders.

178. Rights arising under patent licensing contracts are purely contractual rights governed by state law with the question of assignability of a patent license determined from an examination of the purposes and provisions of the particular license. See, e.g., *Farmland Irrigation Co. v. Dopplmaier*, 308 P.2d 732, 737-38 (Cal. 1957). A number of courts have held that a patent licensing contract is personal to the licensee and may not be assigned unless it contains words of assignability such as heirs, executors, administrators, and assigns. See, e.g., *Oliver v. Rumford Chem. Works*, 109 U.S. 75 (1883); *Bowers v. Lake Superior Contracting & Dredging Co.*, 149 F. 983, 984 (8th Cir. 1906). Other courts have held that the language of particular patent licensing contracts rendered the licenses assignable. See, e.g., *Paul E. Hawkins Co. v. Carnell*, 112 F.2d 396, 398-99 (3d Cir. 1940); *Moors v. Gilbert*, 198 S.W. 903 (Ky. Ct. App. 1917).

Another question may arise similar to assignability if the licensee is bought out by another company. For example, in *Mycogen Corp. v. Monsanto Co.*, 51 P.3d 297 (Cal. 2002), Monsanto and Lubrizol Genetics, Inc. entered into an agreement in 1989, which included a licensing option for Monsanto's re-engineered genes in cotton, canola, and corn. In 1992, Mycogen bought Lubrizol and its subsidiaries and attempted to exercise the licensing option with Monsanto.

The licensee is also typically prohibited from saving any of the seed produced from the licensed seed for the purpose of using it for planting seed and is required to return any unused seed to an authorized seed dealer upon completion of planting. However, under the 1994 amendments to the PVPA, a farmer is allowed to save seed for replanting, to save seed for planting the following season on owned and rented acreage, or to sell the seed for other than reproductive purposes. As such, a question can be raised as to whether the PVPA crop exemption takes precedence over patent law and makes a patent-license restriction that prohibits the saving of seed unenforceable. The answer would appear to be in the negative. When the Congress amended the PVPA's crop exemption in 1994, the Congress knew that the provisions of general utility patent law were already in place and presumably knew that general utility patent law does not contain a crop exemption similar or comparable to that found in the PVPA. Accordingly, seeds protected with utility patents that are coupled with post-sale licensing restrictions should not be subject to the PVPA crop exemption.¹⁷⁹

If the licensee violates any of the license conditions, the license is terminated, and the licensee forfeits any right to obtain a license in the future. Most licenses contain a liquidated damages clause setting damages at the average ratio of seed produced from planted seed times the licensee fee times the number of acres that could be planted with the seed transferred in violation of the license. Seed licenses usually specify that state law controls any legal issue arising from the license arrangement.

It appears that the remedies available to a seed company upon a licensee's breach of a license agreement are limited to contract remedies. The licensee's breach of the license would not, under most circumstances, involve patent infringement. The procedural aspects of bringing a patent infringement suit would, therefore, be avoided.¹⁸⁰

Monsanto refused, arguing that the license agreement entered into with Lubrizol Genetics, Inc. was not transferable. Mycogen sued for specific performance. The trial court granted Monsanto's motion for summary judgment, but the appellate court reversed and ordered Monsanto to "specifically perform the relevant terms of the agreement." *Id.* at 300. The parties could not agree on the precise technology subject to the terms of the license (Mycogen argued it was entitled to germplasm; Monsanto maintained that the agreement covered only genes), and Mycogen brought a second suit for damages. The jury returned a verdict for Mycogen of \$174.9 million. *Id.* at 301. The jury award was reversed on appeal, with the appellate court ruling that Mycogen's lawsuit for damages was barred by the doctrine of res judicata. *Id.* In 2002, the California Supreme Court affirmed. *Id.*

179. But, licensing restrictions on seeds not protected with a utility patent may be subject to the federal PVPA crop exemption.

180. A party injured by another's actions infringing a patent does not have to sue for patent infringement in a federal court but may bring an action in state court founded upon state-recognized wrongs arising from the holder's rights under the patent. Such an action is not one "arising under" the patent laws, and exclusive jurisdiction is not vested in the federal district courts. Jurisdiction of the federal district courts in patent cases is established in 28 U.S.C. § 1338(a) (2000). While state courts do not have jurisdiction over cases arising under the patent laws, a

3. Contractual Language in Purchase Agreements and Label Notices

Seed companies have also attempted to utilize language in purchase contracts to gain protection exceeding that offered by the PVPA. Typical agreements allow breach of contract remedies if the farmer/purchaser uses harvested seed for replanting the farmer's own fields, sells seed to another farmer, or allows seed to fall into the hands of a plant breeder who uses it to develop a new variety. The purchase agreements may offer stronger protection than the PVPA offers (no crop and research exemptions) and may grant stronger protection than general utility patents (no disclosure of variety to the public required). Accordingly, the enforceability of such agreements remains unclear inasmuch as they could be construed as an adhesion contract if a court determines that the seller is attempting to avoid the seller's basic obligations of "good faith, diligence, reasonableness and care."¹⁸¹ The agreements could also be determined to be unconscionable if the "agreement" consists merely of a label printed on a bag and does not require the purchaser's signature.¹⁸² Upon breach of the contract provisions in purchase agreements, a seed company will be limited to contract remedies. Likewise, upon the sale by a farmer of seed to a rival company, the disaffected seed company could only sue the farmer for contract damages and would not be able to sue in tort or enjoin the rival company from using the variety.¹⁸³

A seed company that holds a patent on seed technology may also restrict a purchaser's use of a patented item by affixing to the item a label notice of the restriction to the item. In *Mallinckrodt, Inc. v. Medipart, Inc.*,¹⁸⁴ the court held that a restriction on reuse was within the scope of a patent, did not have anticompetitive effects, and was enforceable against infringers. Thus, *Mallinckrodt*¹⁸⁵ indicates that a seed company may be able to affix a label notice containing all its

case involving patent rights does not necessarily "arise under the patent law," and a state court has jurisdiction to determine questions relating to patent rights whenever the questions arise incidentally or collaterally to a main cause of action over which a state court has jurisdiction. Thus, when an act constitutes a patent infringement and is also a breach of a contract, the plaintiff may waive the statutory right to recover for infringement and bring an action for damages proximately resulting from the breach. In that case, federal courts do not have exclusive jurisdiction.

181. See, e.g., Op. Att'y Gen. No. 2001-17 (Okla. Apr. 11, 2001). The production contracts were determined to be adhesion contracts. There was disparate bargaining power, and the terms were drafted unilaterally. *Id.*

182. A seed company pursuing contractual protection may need to make significant expenditures throughout all phases of marketing so as to put potential and actual purchasers on notice of the company's intellectual property rights.

183. Consequently, contract remedies might cover only a fraction of the overall losses suffered by the offending seed company.

184. 976 F.2d 700, 701 (Fed. Cir. 1992).

185. *Id.*

protective provisions to the seed bag and thereby bind the purchaser.¹⁸⁶

E. Intellectual Property Right Misappropriation Lawsuits

The ability to obtain a general utility patent on seed technology has led to cases in which farmers have been sued for misappropriation of the technology. Because seed is reproducible, any farmer that saves seed is a natural competitor of a company that sells seed.¹⁸⁷ But, for seed that is patented, the saved-seed exemption of the PVPA¹⁸⁸ is avoided, and the saving of seed can be prohibited. For example, Monsanto's patent for the gene inserted to make Roundup Ready seeds mandates that every purchaser of the seed sign a Grower's Agreement and a Technology Use Agreement. Under the agreements, a farmer can use the seed for one-time planting, may not supply the seed to anyone else for planting, may not save any crop produced from the seed for replanting (or supply saved seed to anyone else for replanting), and must not use the seed or provide it to anyone for crop breeding, research, generation of herbicide registration data, or seed production.¹⁸⁹ Clearly, a farmer signing a technology agreement is prohibited from saving seed subject to the agreement. But, what if the patented traits are present in the crops and/or resulting seed of a farmer that did not purchase or plant the patented seed?¹⁹⁰ Has that farmer illegally infringed Monsanto's patent even though having no intent to acquire the protected seed or infringe the patent?

In *Monsanto v. Trantham*,¹⁹¹ Trantham allegedly saved and replanted Roundup Ready soybeans and Roundup Ready cottonseed. Trantham had purchased and planted the seeds in 1999 but did not sign Monsanto's technology agreement. Trantham harvested the crop, saved seed from the harvest, and used the seeds to plant next year's crop. Monsanto sued for patent infringement, and Trantham counter-sued for monopolization, conspiracy to monopolize, and unreasonable

186. To take advantage of this approach, a seed company would first need to obtain a patent for its seed, which may present a significant obstacle. But, for plant breeders with utility patents, this approach seems to present an effective means of protecting intellectual property.

187. See, e.g., JACK RALPH KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 1492-2000, at 280 (1988).

188. 7 U.S.C. § 2543 (2000).

189. See *Monsanto Co. v. McFarling*, 363 F.3d 1336 (Fed. Cir. 2004) (referring to 1998 version of "Monsanto Technology Agreement").

190. The widespread contamination of existing conventional seed stock presents a significant problem on this issue. See, e.g., MARGARET MELLON & JANE RISSLER, UNION OF CONCERNED SCIENTISTS, GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY, http://www.ucsusa.org/documents/seedreport_fullreport.pdf (last visited June 24, 2004); see also Philip Brasher & Anne Fitzgerald, *Biotech Taint Found Common in Crop Seed*, DES MOINES REG., Feb. 24, 2004, <http://desmoinesregister.com/business/stories/c4789013/23617073.html> (referencing the Union of Concerned Scientists report).

191. 156 F. Supp. 2d 855 (W.D. Tenn. 2001).

restraint of trade. The court ruled for Monsanto, noting that crop sample tests revealed that Monsanto's patented technology was present in all of the samples from eleven of Trantham's fields.¹⁹² In a later bankruptcy proceeding involving Trantham, the court held that the judgment against Trantham was nondischargeable on the basis that Trantham's actions were willful and malicious and that patent infringement is an intentional tort.¹⁹³

In *Monsanto v. McFarling*,¹⁹⁴ McFarling purchased and planted Roundup Ready soybeans in 1997 and 1998. McFarling signed Monsanto's technology agreement that limited the use of the seeds to "planting a commercial crop only in a single season" and specified that the seeds could not be saved.¹⁹⁵ McFarling saved and replanted some of the seeds and Monsanto sued for patent infringement. The jury found that McFarling willfully infringed Monsanto's patented seed technology and rejected his claim that the technology agreement amounted to an illegal restraint of trade.¹⁹⁶ Also, while the trial court upheld the liquidated damages clause contained in the technology agreement requiring McFarling to pay 120 times the applicable technology fee per bag of seed (amounting to a total of \$780,000 based on a per bag technology fee of \$6.50/bag), the appellate court invalidated the provision on the basis that it constituted an unenforceable and invalid penalty clause.¹⁹⁷

The opinions indicate that the process by which the patented seed arrives on a farmer's land is irrelevant.¹⁹⁸ Thus, a landowner has an

192. It should be noted that Monsanto's patent for the gene inserted to make Roundup Ready seeds mandates that every purchaser of the seed sign a Grower's Agreement and a Technology Use Agreement. Under the agreements, a farmer can use the seed for one-time planting and may only sell it to a commercial purchaser authorized by Monsanto for consumption. The farmer may not sell or give the seed for replanting the following year. The Technology Use Agreement also authorizes Monsanto to enter the contracting farmer's land to verify compliance with the agreement. Thus, it is a violation of Monsanto's patent if any person knowingly uses a plant containing the patented gene without having paid for the seed or having signed the requisite agreements. No determinative inquiry into how the person came into possession of the patented seed is required. See 2004 Monsanto Technology/Stewardship Agreement (on file with author). For a more in-depth discussion of the antitrust aspects of cases like *Trantham*, see *infra* Part IV.F.

193. *In re Trantham*, 304 B.R. 298 (B.A.P. 6th Cir. 2004).

194. 302 F.3d 1291 (Fed. Cir. 2002); *see also In re Wood*, No. 02-25981-WHB, 2004 Bankr. LEXIS 656 (Bankr. W.D. Tenn. Apr. 12, 2004).

195. *McFarling*, 302 F.3d at 1293.

196. *Id.* at 1299-1300; *see also Monsanto Co. v. Swann*, 308 F. Supp. 2d 937 (E.D. Mo. 2003) (finding that a farmer signed a single-year technology agreement but was found, in a later year, to be planting protected seed; patent infringement found and technology agreement did not constitute patent misuse because technology agreement did not obligate the purchase of the plaintiff's seed). It should be noted that the antitrust arguments made by the farmers in *Trantham* and *McFarling* were not fully developed. Thus, a question is raised as to the weight of the cases as authority on the antitrust issues involved. For a further discussion of the antitrust issues implicated in agricultural biotechnology cases, see *infra* Part IV.F.

197. *Monsanto Co. v. McFarling*, 363 F.3d 1336 (Fed. Cir. 2004) (construing Missouri law).

198. *See also Monsanto Co. v. Dawson*, No. 4:98CV2004, 2000 WL 33953542, at *2 (E.D. Mo. Nov. 24, 2000). The court held that inadvertent presence of the technology on the defendant's land did not protect the defendant as an innocent possessor from liability for infringement. *Id.*

affirmative duty (if the landowner either knows or has reason to know of the patented gene's presence) to notify the patent holder of the intrusion.¹⁹⁹ It is probably not an adequate solution to have the seed company, upon receiving notice of the presence of the unwanted technology on the land, remove the patented plants—the farmer would still be prohibited from saving seeds despite the fact that the farmer has done nothing differently from years in the past (has taken no deliberate steps to acquire the patented material).²⁰⁰ The problems are magnified when an organic farmer is located adjacent to a GMO crop.²⁰¹ Because of market resistance to GMO crops, the inadvertent transformation of conventional crops into GMO crops may significantly limit the available market outlets for a farmer's crops.

In *Monsanto Canada Inc. v. Schmeiser*,²⁰² the Canadian Court of Appeal held that Schmeiser, a Canadian farmer, had infringed Monsanto's patent on Roundup Ready canola by saving and replanting protected seed without a license.²⁰³ Schmeiser had not paid a license fee to use the technology and claimed that pollen drift from a neighbor's fields or passing grain trucks had contaminated his fields.²⁰⁴ Schmeiser claimed that he did not knowingly acquire the technology or segregate the contaminated seeds nor did he spray his crop with Roundup.²⁰⁵ Indeed, Schmeiser had a long-standing farming practice

199. However, it is important to note that the general utility patent law of the United States does not provide expressly for the right of the patent holder to contaminate the property of persons not wanting the patented technology. Thus, an appropriate resolution of the competing property interests involved in such cases would be to require intent to infringe as an element to a patent infringement case involving patented plants. *See, e.g., Hughes Tool Co. v. G.W. Murphy Indus., Inc.*, 491 F.2d 923, 927 (5th Cir. 1973) (suggesting situations when "literal infringement should be overlooked," particularly when the "infringing device only occasionally strays across the patent boundary"); *L.A. Gear, Inc. v. E.S. Originals, Inc.*, 859 F. Supp. 1294, 1298 (C.D. Cal. 1994) (noting that mere possession of a patented item "does not constitute infringement absent a 'threatened or contemplated use' or sale"); *Beidler v. Photostat Corp.*, 10 F. Supp. 628, 630 (W.D.N.Y. 1935) (stating that in the "absence of proof that [patented] machine is held for purposes of profit," mere possession does not constitute infringement).

200. Remember, the problem is complicated by the inability of a farmer to distinguish GMO crops from conventional crops. The way to identify the GMO crops is to spray all crops with Roundup, but that will destroy the conventional crops (and any resulting profit from sale of the crop). Also, what if the GMO volunteer crops return in subsequent years? How can a farm be guaranteed to be free of GMO crops? Consequently, some farmers may view the only remedy to avoid further problems is to enter a contractual relationship with the patent holder to grow GMO crops.

201. The upholding of patent rights over the right to be free of unwanted genetic contamination could have a particularly detrimental effect for organic farmers that might be in danger of losing their customer base as well as organic certification due to genetic contamination.

202. [2001] F.C. 256 (Fed. Ct.), *aff'd*, [2003] 2 F.C. 165 (Fed. Ct.).

203. *Id.* Schmeiser historically saved his own canola seed for replanting. Thus, the contamination carried into his next year's crop for which patent infringement was alleged. Importantly, the initial sources of contamination were an inadvertent but unavoidable result of normal farming practices.

204. University of Manitoba tests confirmed that the presence of Roundup Ready canola ranged from nearly zero percent to sixty-eight percent. Monsanto claimed that the degree of contamination in Schmeiser's 1998 crop ranged from ninety-five percent to ninety-eight percent.

205. The origin of the genetically altered plants on Schmeiser's land was unclear. Schmeiser claimed that the plants resulted from genetically modified canola seed that blew onto his land or as a result of cross pollination of his conventional canola. During the 1997 growing season,

of saving his own canola seed and replanting that saved seed the following year. Thus, the initial sources of contamination were an inadvertent, but nonetheless unavoidable, result of a normal farming practice. However, the appellate court held that Schmeiser either knew or should have known that the subject seeds were glyphosate resistant.²⁰⁶ Schmeiser was fined \$15,450 in license fees, \$105,000 for the value of the crop, and \$25,000 for punitive and exemplary damages.²⁰⁷ In essence, the appellate court held that crop farmers growing and harvesting conventional seed and harvesting conventional crops have an affirmative duty to ensure that unwanted and patented genetic traits do not enter their premises. That would seem to present non-GMO farmers with a legal duty that is next to impossible to comply with, short of adopting the technology, for their own crops (and, of course, paying associated technology fees).²⁰⁸

After the appellate court's opinion in *Schmeiser*,²⁰⁹ the Canadian Supreme Court rendered an opinion concerning the patentability of the so-called "Harvard Mouse."²¹⁰ In the case, the court held that a mouse, as a higher life form, was not patentable under the specific wording of the Canadian Patent Act.²¹¹ The court noted that the Ca-

Schmeiser sprayed Roundup near a canola field, and some of the canola plants were unaffected. Schmeiser then sprayed a three-acre field, and most of the canola did not die. After harvesting the 1997 canola crop, Schmeiser stored some of the seed from the acreage and used it to plant part of his 1998 crop. During the trial, a local Roundup Ready canola farmer testified that while hauling his grain to market past Schmeiser's fields in 1997, a tarp came loose and "acted like a cyclone," releasing considerable seed into Schmeiser's adjoining fields. AR Vol. VI. at 1132-35. The trial court judge also acknowledged wind-blown swaths from adjoining Roundup Ready canola fields landing on Schmeiser's land. *Id.*

206. A problem with Monsanto's argument is that the type of patent held by Monsanto Canada, Inc. involved in the case, Patent 830 (entitled "Glyphosate-Resistant Plants") consists of fifty-two claims encompassing various aspects of the Roundup Ready gene itself and the Roundup Ready cells that result from inserting the gene. Thus, although its actual patent ends at the cell level, Monsanto argued that its patent rights applied not only to the genetic material in the seeds purchased but also the next generation seeds and any plants resulting from a hybrid of genetically engineered plants and non-GMO plants. [2003] 2 F.C. 165.

207. [2001] F.C. 256 (Fed. Ct.), *aff'd*, [2003] 2 F.C. 165 (Fed. Ct.). The Canadian Supreme Court granted Schmeiser's request to hear the case.

208. At a minimum, non-GMO farmers will be obliged to adjust their crop rotation, herbicide schedules, and field design in an attempt to protect their own crops from contamination and avoid an intellectual property right misappropriation lawsuit. But, even taking these steps may be futile given the widespread contamination of existing conventional seed stock. See, e.g., MELLON & RISSLER, *supra* note 190; see also Brasher & Fitzgerald, *supra* note 190. In any event, however, the court left unanswered the question of the nature and extent of the property right involved. The appellate court, in essence, took the approach that a conventional crop farmer's right to be free from the presence of unwanted genetic traits is subordinate to the patent-holder's right to enforce patents in genetic technology that self-reproduce and cannot be contained.

209. [2001] F.C. 256 (Fed. Ct.), *aff'd*, [2003] 2 F.C. 165 (Fed. Ct.).

210. Comm'r of Patents v. President & Fellows of Harvard Coll., [2002] S.C.C. 76 (holding that a transgenic mouse with cells genetically altered by a cancer-promoting gene (oncogene) is not patentable subject matter).

211. *Id.* The Canadian Federal Court of Appeal had previously ruled that higher plant life forms did not fall within the definition of an invention in the Patent Act. Pioneer Hi-Bred Ltd. v. Comm'r of Patents, [1987] 14 C.P.R. (3d) 491 (Fed. Ct.) (finding that soybean variety resulting from cross-breeding was not patentable). The Canadian Supreme Court dismissed Pioneer's

nadian Patent Act provides for protection of intellectual property rights in the “making, constructing, and using [of an] invention and selling it to others to be used.”²¹² Thus, under the Act, infringement involves the making, constructing, or using of a patented invention (in the *Schmeiser* case, the Roundup Ready gene or cells) for sale with the patent owner’s permission. Clearly, Schmeiser did not make or construct the patented invention.²¹³ Under Canadian law, intellectual property rights in seeds and plants are protectable under the Plant Breeder’s Rights Act.²¹⁴ Upon review by the Canadian Supreme Court, the key questions were whether the genes and cells of seeds and plants were intended to be covered by the Patent Act in spite of the wording of the statute, and whether plants and seeds are patentable in light of the court’s earlier opinion in *Harvard Mouse*.²¹⁵

On May 21, 2004, the Canadian Supreme Court rendered its opinion in *Schmeiser*.²¹⁶ While the court ruled that plants, as a higher life form, are not patentable subject matter, the court stated that the Monsanto patent at issue applied to the gene and was valid.²¹⁷ Schmeiser was found to have infringed the patent because his “use” of the patented invention deprived Monsanto of the full enjoyment of the monopoly conferred by the patent. The court noted that mere possession of a patented invention creates a rebuttable presumption of “use” and that the intent of the alleged infringer may be relevant to rebutting the presumption. The court reasoned that Schmeiser failed to provide sufficient evidence to rebut the presumption of “use” and had infringed Monsanto’s patent.

On the issue of damages, however, the court noted that the Patent Act only entitles the patentee whose patent has been infringed to the portion of the infringer’s profit which is causally attributable to the patented invention. Because Schmeiser earned no profit from in-

appeal of the case in 1989 on the grounds that the patent for the new soybean variety was invalid as comprising insufficient disclosure to support its claims.

212. Patent Act, R.S.C. 1985, c. P-4, § 42 [rep. & subs. c. 33 (3d Supp.)].

213. A question remained as to whether Schmeiser “used” the patented genes in violation of the Patent Act.

214. The Plant Breeders’ Right Act provides protection for propagating material (the seed and the cuttings) pertaining to new plant varieties. The Act does not provide protection for the actual plant, nor does the Act prevent the development of different plant varieties from protected plants or the use of seeds from protected varieties.

215. *Harvard Coll.*, [2002] S.C.C. 76. The patent application was for the process for preparing the affected mouse as well as the product of the process (the mouse itself).

216. *Schmeiser v. Monsanto Canada Inc.*, [2004] S.C.C. 34.

217. *Id.* The dissent (the decision was five to four) held that the cultivation of plants containing the patented gene and cell did not constitute infringement and that to conclude otherwise would confer patent protection on the resulting plants. The dissent pointed out that the patent at issue made no claim for a glyphosate-resistant plant and all of its offspring. Thus, the dissent reasoned, the saving, planting, or selling of seed from glyphosate-resistant plants does not constitute an infringement. Such restrictions, the dissent noted, can be handled through Monsanto’s licensing of seeds produced from the patented gene and contractual obligations that prohibit the saving of the licensed seed.

fringing Monsanto's patent,²¹⁸ Monsanto was not entitled to damages. Thus, Schmeiser was not required to pay Monsanto any damages, penalties, court costs, or the technology use fee of fifteen dollars per acre. Schmeiser, however, will be barred from using Roundup Ready canola unless he pays a license fee and must turn over any Roundup Ready seeds remaining in his possession.

While Canadian legal opinions have no direct bearing on American courts, the *Schmeiser*²¹⁹ opinion could have an impact on patent infringement claims by patentees of genetic seed traits against farmers in the United States. To the extent courts in the United States hold that patentees are not entitled to damages in situations where the alleged infringer has not profited from the misappropriated technology, it will reduce the economic incentive for patentees to pursue infringement claims against innocent infringers.

Similar to the issues addressed by the Canadian Supreme Court in *Schmeiser*,²²⁰ the question of whether products that reproduce naturally are even patentable has arisen recently in the United States with the outcome of the debate having the potential to influence significantly future patent infringement lawsuits brought against farmers for alleged "theft" of genetic technology. In *Smithkline Beecham Corp. v. Apotex Corp.*,²²¹ the United States Court of Appeals for the Federal Circuit invalidated a patent on a self-reproducing antidepressant drug because previous clinical trials constituted a prior use.²²² In the 1970s, a British company invented and patented paroxetine, disclosing its antidepressant properties. Eventually, the company developed a process to produce the crystalline hydrochloride salt of paroxetine, paroxetine hydrochloride (PHC). In 1980, Smithkline Beecham received a license for the technology and began manufacturing it. In the mid-1980s, a Smithkline Beecham chemist created a new crystalline form of PHC known as PHC hemihydrate.²²³ Later it was discovered that three months earlier a different Smithkline Beecham laboratory had made PHC hemihydrate. PHC hemihydrate ultimately proved more stable and easier to package and preserve. Smithkline

218. No finding was made that Schmeiser sprayed his crops with Roundup herbicide to reduce weeds. *Id.*

219. *Id.*

220. *Id.*

221. 365 F.3d 1306 (Fed. Cir. 2004).

222. Under 35 U.S.C. § 102(b) (2000), a patent claim is not valid if "the invention was . . . in the public use . . . in this country, more than one year prior to the date of the application for patent in the United States." "Public use includes 'any use of the claimed invention by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor.'" *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002) (quoting *Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 1425 (Fed. Cir. 1996)).

223. The original patented form of PHC was anhydrous PHC (PHC anhydrate) that is made up of PHC without bound water molecules, whereas PHC hemihydrate contains PHC crystals with one bound water molecule for every two PHC molecules.

Beecham was awarded a patent for PHC hemihydrate in 1988 and began marketing it as Paxil in 1993. In 1998, Apotex sought approval from the Food and Drug Administration to market its own PHC antidepressant drug with PHC anhydrate as the active ingredient. Smithkline Beecham brought an infringement action against Apotex in 1998, claiming that Apotex was infringing its PHC hemihydrate patent by manufacturing PHC anhydrate tablets that necessarily contain, by processes of nature, trace amounts of PHC hemihydrate.

The trial court found that the hemihydrate that Smithkline Beecham created in 1984 had spread (i.e., seeded itself) to numerous manufacturing environments, including those of Apotex.²²⁴ As a result, under normal conditions in a seeded environment, some of the original anhydrate converted spontaneously into the patented hemihydrate crystals. The court upheld the patent's validity but ruled that Apotex had not infringed the patent because its production processes had resulted in small, commercially insignificant amounts of hemihydrate.²²⁵ The court specifically noted that failing to limit the scope of the patent would lead to inevitable infringement.

Of particular interest was the trial judge's opinion that it is a defense to a charge of patent infringement that the patentee caused the infringement.²²⁶ In the agricultural setting, that could mean that the judge would not hold a conventional (or organic) crop farmer liable for patent infringement when the reason for the presence of the patented traits in growing or harvested crops is cross-pollination, contamination from passing grain trucks or machinery, or simply because trace amounts of the patented genes and cells appear in conventional seed stocks.²²⁷ However, by establishing a patent infringement test of commercial significance, the judge apparently would require any commercially significant amounts of the patented technology to be given back to the patentee.²²⁸

On appeal, the Federal Circuit Court of Appeals disagreed with the trial court by noting that any amount of hemihydrated PHC pro-

224. Smithkline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011 (N.D. Ill. 2003).

225. *Id.* at 1030. The court, instead of invalidating the patent, interpreted the patent claim as "excluding hemihydrate produced by involuntary conversion of a proportion of an anhydrous mixture so small as to lack any commercial significance." *Id.* at 1029-30.

226. The trial judge opinion was written by Richard A. Posner. Posner, a judge on the United States Court of Appeals for the Seventh Circuit, was designated by the chief circuit judge to conduct the trial in the case. Posner analogized the situation to breach of contract cases and noted that it is a defense to a breach of contract claim that the plaintiff prevented the defendant from performing the defendant's required contractual duty. *Id.* at 1043.

227. Clearly, the judge is recognizing the value of the conventional (or organic) crop farmer's right to be free from unwanted genetic technology.

228. A question can be raised as to whether the judge would require the patentee to pay damages to the disaffected party for any costs incurred by reason of the unwanted patented genetic traits.

duced (whether commercially viable or not) infringed the patent.²²⁹ However, the court agreed that Apotex had not infringed the patent because Smithkline Beecham's clinical trials constituted a prior use. As a result, the compound was already in the public domain, and the patent was invalid.

A concurring opinion reasoned that the patent was invalid not because of prior use of the subject matter, but because the subject matter was not patentable. The concurrence noted that man-made products or processes are patentable, but products that result from natural processes are not patentable.²³⁰ Thus, PHC would qualify for a patent because it is a man-made product, but because the original paroxetine anhydrate could naturally convert itself into the hemihydrate, the resulting PHC is not patentable. The judge compared the seeding and conversion process of PHC to the spread of patented, biotech seed traits via cross-pollination and concluded that "the implication—that the patent owner would be entitled to collect royalties from every farmer whose cornfields contained even a few patented . . . stalks—cannot possibly be correct."²³¹ The judge went on to state, "In short, patent claims drawn broadly enough to encompass products that spread, appear, and 'reproduce' through natural processes cover subject matter unpatentable under Section 101—and are therefore invalid."²³²

While the concurring judge's opinion can be read as invalidating existing patents on genetically modified seeds (genes and cells),²³³ a more likely interpretation is that the judge would find such patents valid but would carve out exemptions for unintentional infringement. In any event, Judge Posner's comments in *Smithkline Beecham*,²³⁴ the Federal Circuit's opinion in the same case,²³⁵ and, to a lesser extent, the Canadian Supreme Court's opinion (particularly the dissent) in *Schmeiser*²³⁶ provide a framework for the development of future cases and legislation supporting an equitable enforcement of patent laws respecting both the rights of patentees and the rights of innocent infringers.

229. *Smithkline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004).

230. *Id.* at 1321-22 (Gajarsa, J., concurring); see *J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l*, 534 U.S. 124, 130 (2001); *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

231. *Smithkline Beecham Corp.*, 365 F.3d at 1331 (Gajarsa, J., concurring).

232. *Id.* (Gajarsa, J., concurring).

233. The analogy to the development of PHC at issue in the *Smithkline Beecham* case would be that crop fields are synonymous with factories and laboratories that become seeded unintentionally with patented traits.

234. *Smithkline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003).

235. 365 F.3d at 1306.

236. *Schmeiser v. Monsanto Canada Inc.*, [2004] S.C.C. 34.

F. Antitrust Concerns

Patent law does not trump federal or state antitrust claims.²³⁷ Thus, a traditional antitrust analysis applies in determining whether a biotech firm violates antitrust law when it protects its intellectual property rights in germplasm by virtue of a general utility patent that bars the saving of seed.²³⁸ Anticompetitive concerns are heightened when the intellectual property right protection is coupled with label notices and licenses restricting the use of the patented germplasm.

1. Sherman Act, 15 U.S.C. § 1

Section 1 of the Sherman Act of 1890 states that “[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is . . . illegal.”²³⁹ Several types of violations of § 1 of the Sherman Act are per se offenses. Under a per se rule, it is only necessary that the plaintiff prove that certain conduct occurred that is within the class of practices subject to the per se prohibition.²⁴⁰ Thus, explicit (albeit secret) collusion to fix prices, allocate territories, or otherwise rig the market is illegal regardless of the reasonableness or unreasonableness of the economic consequences. The only proof required is proof that conspiracy actually occurred. Indeed, mere *attempts* to fix prices are punishable.

Section 1 is also broad enough to apply to a price-fixing agreement that does not involve any actual communication among the parties to the agreement. In *In re High Fructose Corn Syrup Antitrust Litigation*,²⁴¹ the court noted that, without explicit evidence of an agreement to fix prices, clear and convincing circumstantial evidence must be present from which a price-fixing agreement can be inferred.²⁴² The required evidence, according to the court, may be established by showing a market structure that would be conducive to price fixing and by producing evidence that the market behaved in a noncompetitive manner. Even if some of the transactions occurred at a lower price than that set by the alleged price-fixing activity, that is

237. *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) (rejecting Microsoft's claim that the lawful acquisition and subsequent exercise of intellectual property rights cannot give rise to antitrust liability).

238. The matter is complicated by the notion that a plaintiff, in a patent infringement case, need not establish intent to infringe on the defendant's part. *See, e.g., Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Savs. Bank*, 527 U.S. 627, 645 (1999) (stating that patent infringement actions “do not require any showing of intent to infringe”); *Dawson*, 2000 WL 33953542, at *2. The inadvertent presence of the technology on the defendant's land did not protect the defendant, as an innocent possessor, from liability for infringement. *Id.* For cases requiring intent to infringe, see *supra* note 199.

239. 15 U.S.C. § 1 (2000).

240. *See, e.g., Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679 (1978).

241. 295 F.3d 651 (7th Cir. 2002), *cert. denied*, 123 S. Ct. 1254 (2003).

242. Such circumstantial evidence may be found in communications between industry executives, parallel pricing decisions, and incidents of deliberately reduced competition.

not a sufficient defense because, the court noted, the price could later become unreasonable due to market conditions. The court agreed with the plaintiffs that the structure of the high fructose corn syrup market was conducive to price fixing and that the defendants limited price competition. Thus, the court reversed the trial court's grant of summary judgment and remanded the case for trial on the issue of whether a price fixing antitrust violation occurred. On remand, the court held that the plaintiffs' evidence of price fixing was "marginally sufficient" to show concerted action to fix the price.²⁴³

A seed company occupying a dominant market position that holds a patent for germplasm and enforces a no-replant policy through restrictive licensing agreements that ban the use of saved seeds, could be found to have engaged in a horizontal conspiracy to control the particular seed market in violation of § 1.²⁴⁴ Anticompetitive concerns are heightened if the licensing agreements operate as a substantial barrier to potential competition in trait and transgenic seed markets²⁴⁵ or have the effect of increasing the price of seed while simultaneously concentrating the seed market amongst fewer firms.²⁴⁶ Similar concerns are raised if the seed company utilizes a license that restricts the price at which the resulting seeds can be sold or the geographic territory in which the seeds can be utilized.²⁴⁷

Sherman § 1 also prohibits tying arrangements whereby a firm possessing an appreciable degree of market power concerning a prod-

243. *In re High Fructose Corn Syrup Antitrust Litig.*, 261 F. Supp. 2d 1017, 1026 (C.D. Ill. 2003). In March of 2004, two of the defendants filed a no-fault settlement offer in the case proposing to pay twenty-four million dollars to settle the lawsuit that alleged the defendants were part of a conspiracy to fix the price of high fructose corn syrup.

244. The key legal question is whether such a seed company has a less restrictive alternative means of exploiting its patent monopoly. Clearly, an antitrust violation is less likely if farmers are allowed to save seed upon payment of a technology fee. While Monsanto does not allow farmers in the United States to save patented seed, the company utilizes a saved seed royalty system in Argentina that permits soybean farmers to save and replant patented varieties upon payment of an annual fee. See David Dechant, *Monsanto Wants Extended Seed Royalties*, <http://www.mindfully.org/GE/2003/Monsanto-Seed-Royalties22may03.htm> (May 22, 2003). Likewise, Monsanto Co. presently employs a similar strategy when licensing its intellectual property rights in the United Kingdom. On its United Kingdom website, Monsanto accepts the practice of saving seed as an ordinary business practice. See Monsanto in the UK, www.monsanto.co.uk/asp/agriculture/pbic/news/news1.asp?highlight=1&subnav=5 (noting that "Farm Saved Seed should . . . only be used where seed hygiene and cleaning is of a particularly high standard and testing shows first class germination rates") (last visited May 20, 2004).

245. See U.S. DEP'T OF JUSTICE, FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 4.1.1 (1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132 (noting the dangers of foreclosure and market concentration).

246. JTC Petroleum Co. v. Piasa Motor Fuels, Inc., 190 F.3d 775, 779 (7th Cir. 1999) (stating that summary judgment is improper where evidence is present that cartelists' conduct increases the profits of cartel members in the form of higher product prices or services of cartel members).

247. It is noted that Monsanto charges differing prices for cottonseed based on the extent to which users in different parts of the country will benefit from the insect-resistance qualities of the product. Price discrimination is generally viewed as "evidence of the presence of monopoly power." *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 603 (7th Cir. 1997). Indeed, in an antitrust case filed against Monsanto, class certification was denied because of the lack of uniform claims across the class (individual issues predominated over class issues). *Sample v. Monsanto Co.*, 283 F. Supp. 2d 1088 (E.D. Mo. 2003).

uct ties the purchase of that product to another product, and the tie effects more than a de minimis amount of commerce.²⁴⁸ Beginning in 1996, Monsanto Co. tied the sale of Roundup herbicide to the sale of Roundup Ready seeds.²⁴⁹ Monsanto also ties the sale of the Bollgard cotton trait to Roundup Ready cottonseed, a practice known as trait-stacking. While a cotton farmer may prefer Roundup Ready cotton without the Bollgard trait because the threat of bollworms or bugworms is not anticipated, such option is not available, and Monsanto is able to avoid competition on the merits for the Bollgard trait.²⁵⁰ Given Monsanto's market dominance in seed and glyphosate, such tying practices raise serious anticompetitive concerns.²⁵¹ Indeed, the Federal Circuit Court of Appeals has held that price fixing and tying arrangements accompanying the sale of a patented good is per se illegal.²⁵² However, if the license restriction leads to anticompetitive effects extending beyond the patentee's statutory right to exclude but does not involve price-fixing or tying, a rule of reason analysis will be used to determine whether the license is enforceable.²⁵³

2. Sherman Act, 15 U.S.C. § 2

Section 2 of the Sherman Act declares that “[e]very 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 . . .”²⁵⁴ While § 2 covers those who “combine or conspire” to monopolize, it is primarily concerned with

248. See, e.g., *Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451, 461-62 (1992). The general view of the courts is that tying arrangements have the sole purpose and effect of extending the seller's power in the market for the tying product into that for the tied product. Tying arrangements are per se unlawful under § 1 of the Sherman Act, § 3 of the Clayton Act, or both. See, e.g., *Int'l Salt Co. v. United States*, 332 U.S. 392, 398 (1947).

249. The 1996 Monsanto Grower License Agreement required growers to use only Roundup herbicide “if a herbicide containing glyphosate or any other herbicide containing glyphosate or any other EPSP synthase inhibitor is used over the top of Roundup Ready soybeans.” (Agreement on file with author.)

250. The anticompetitive effects are made even more pernicious because farmers are required to purchase new cottonseed each year as a condition of using the Roundup Ready traits in subsequent years.

251. Monsanto presently controls over eighty percent of the U.S. soybean seed market and almost as much of the cottonseed market, while maintaining almost exclusive control of the U.S. supply of glyphosate molecules.

252. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 701 (Fed. Cir. 1992). *But see Monsanto Co. v. Swann*, 308 F. Supp. 2d 937 (E.D. Mo. 2003) (stating that the plaintiff “did not engage in tying arrangement that would have been a per se patent misuse”). The technology agreement involved “did not obligate purchase of” plaintiff's seed. *Id.*

253. *Id.*; see also *Pioneer Hi-Bred Int'l, Inc. v. Ottawa Plant Food, Inc.*, 283 F. Supp. 2d 1018, 1045-46 (N.D. Iowa 2003). Pioneer's “limited label license” did not tie purchase or sale of Pioneer seed corn to purchase or sale of any other product. The effect of license should be considered under rule of reason. *Id.*

254. 15 U.S.C. § 2 (2000).

single firm activities and structural conditions. A “rule of reason” is applied to determine if § 2 has been violated.²⁵⁵

Illegal monopolization under § 2 of the Sherman Act requires substantial market power and intent.²⁵⁶ A firm has monopolized in violation of § 2 if it has deliberately followed a course of market conduct through which it has obtained or maintained power to control price or exclude competition in some part of trade or commerce that the act covers.²⁵⁷ Indeed, “the offense of monopoly” has been held to require the “possession of monopoly power in the relevant market and . . . the willful acquisition or maintenance of that power. . . .”²⁵⁸ Reason is exercised to establish both elements. In appraising monopoly power, the courts have considered barriers to entry of various kinds, including patents. However, the one index of monopoly power consistently receiving greatest attention is the market share of the accused in the relevant market.²⁵⁹

Historically, the cases involving § 2 of the Sherman Act indicate that a market share of fourteen percent does not amount to illegal monopoly, but an eighty-seven percent market share does.²⁶⁰ In two major cases, the United States Supreme Court ruled that sixty-four percent of the farm machinery industry²⁶¹ and fifty percent of the steel industry did not amount to monopoly.²⁶² Judge Learned Hand, in one opinion, stated that while any percentage over ninety “is enough to constitute a monopoly; it is doubtful whether 60 percent or 64 percent would be enough; and certainly 33 percent is not.”²⁶³ However, a more recent case indicates that an antitrust violation may be present with significantly far less market share than previously believed. In

255. Under a rule of reason, the plaintiff must show that the restraint is likely to have an adverse effect on competition. *See, e.g.*, *Bhan v. NME Hosps., Inc.*, 929 F.2d 1404, 1410 (9th Cir. 1991). The adverse competitive effect can be shown by proof of an obvious effect on price or output, “proof of an actual adverse effect on competition, or . . . proof that the defendant has power in a properly defined relevant market.” *Carter v. Variflex, Inc.*, 101 F. Supp. 2d 1261, 1266 (C.D. Cal. 2000).

256. A claim of attempted monopolization does not require a showing of market power to the extent required when the claim is that the defendant has created a monopoly. *See, e.g.*, *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447 (1993) (holding that the dangerous probability of success, not dominance, is sufficient to show attempted monopolization). Indeed, more than a fifty percent share of the relevant market is presumptively sufficient. *M & M Med. Supplies & Servs., Inc. v. Pleasant Valley Hosp., Inc.*, 981 F.2d 160, 168 (4th Cir. 1992).

257. *See Standard Oil Co. v. United States*, 221 U.S. 1 (1911).

258. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

259. The relevant market is influenced by many factors such as the physical characteristics of the products involved, the end uses of the products, the cross-elasticity of demand between products, the absolute level of various sellers’ costs, the absolute level of product prices, apart from consideration of cross-elasticities, and the geographic extent of the market.

260. *See, e.g.*, *United States v. E.I. DuPont de Nemours & Co.*, 351 U.S. 377 (1956).

261. *United States v. Int’l Harvester Co.*, 274 U.S. 693, 710 (1927).

262. *United States v. United States Steel Corp.*, 251 U.S. 417, 439 (1920).

263. *United States v. Aluminum Co. of Am.*, 148 F.2d 416 (2d Cir. 1945). For these reasons, the consensus seems to be that market shares below 60% lie beneath the courts’ reach and that shares of even 70-75% may manage to avoid violating § 2 of the Sherman Act.

Toys "R" Us, Inc. v. Federal Trade Commission,²⁶⁴ the plaintiff coordinated a horizontal agreement between the plaintiff and manufacturers to restrict the distribution of the manufacturers' products. The court held that the plaintiff violated antitrust law even though the company only controlled a twenty-percent market share.

On the issue of intent, the United States Supreme Court indicated that the requisite intent that must be shown to warrant a finding of attempt to monopolize under § 2 is not simply an intent to do acts that can be objectively viewed as tending toward monopoly.²⁶⁵ Instead, it must be proved that the defendant had the specific intent to destroy competition or achieve monopoly.²⁶⁶ However, it appears that courts tend to engage in a trade-off between the market share and the degree of intent the prosecuting attorneys must prove to win a guilty verdict. For example, a clear-cut case of ninety-five percent market share would probably run afoul of the law with relatively little proof of intent. Conversely, intent gains importance when a market share of less than sixty percent is involved.²⁶⁷ Traditionally, proof of an attempt to monopolize requires specific intent and a dangerous probability of success.

The legal analysis of § 2 remains unchanged when it is commingled with patent law. To establish a violation, a plaintiff must establish monopoly power plus exclusionary conduct or specific intent to monopolize plus exclusionary conduct.²⁶⁸ The existence of a patent is only marginally relevant to the power issue. A patent, although creating a legal monopoly of the patented item and serving to an extent as a barrier to entry, does not eliminate the plaintiff's need to show possession or intent to acquire the degree of market power sufficient to constitute a monopoly.²⁶⁹ The existence of monopoly power cannot be inferred merely from the possession of one or more patents.²⁷⁰ Indeed, the protected invention or process may be so narrow that by excluding others from it, the patentee may attain very little market power because of numerous other products or processes not covered by the patent that are commercially feasible substitutes.²⁷¹ On the other hand, a single patent may convey sufficient power to constitute

264. 221 F.3d 928 (7th Cir. 2000).

265. *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594 (1953).

266. *Id.*

267. Other factors in addition to a single firm's concentration ratio may also be important. For instance, one important factor may be the manner in which the shares of the nondominant firms are distributed. A firm having 60% of a market could have greater single firm power if the remaining 40% is held by twenty firms, each with about 2%, than if it is held by two firms each with about 20%.

268. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965).

269. *Id.*

270. The fact that a firm has acquired a patent does not, by itself, constitute monopolization. That is the case even when the patent conveys monopoly power in the economic sense.

271. *See, e.g., United States v. E.I. DuPont de Nemours & Co.*, 351 U.S. 377 (1956).

a monopoly. For example, if a patent covers a product for which there is no close substitute, the patent would comprehend a whole “product market” and the patentee could, through the patent, exclude all others. Likewise, if a patent covers a process that is the only commercially feasible one for making products constituting a product market, such as the genetic manipulation needed to produce transgenic hybrids, it could convey monopoly power. Thus, proof that a patent exists does not prove monopoly power.²⁷² The relevant market and the power of the defendant must be proved independently, just as in cases where the defendant’s power is predicated on other market entry barriers. Therefore, in analyzing a Sherman § 2 case involving a patent-owning firm, the focus is on whether the firm’s practices associated with the acquisition and use of the patent have exclusionary effects.

Exclusionary conduct reasonably capable of contributing to the maintenance of a firm’s dominance through unjustified means has long been recognized as giving rise to serious competitive concerns.²⁷³ If a biotech firm with a dominant market position has a no-replant policy with respect to patented seed, anticompetitive conduct may be present.²⁷⁴ Likewise, an unjustified change in established business practices can constitute an antitrust violation.²⁷⁵ Thus, a no-replant policy of a seed company in a monopoly position could be an exclusionary practice in violation of § 2.²⁷⁶ That would particularly seem to be the case if the firm also utilizes contract provisions and licenses that exclude competition.

272. While the existence of a patent does not necessarily prove market power, existence of one or more patents may well be relevant to establishing the conduct element in an antitrust case involving § 2, whether the charge be monopolizing or attempting to monopolize.

273. See *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

274. A single-use policy is patent misuse if the policy is imposed in a manner that harms competition by a firm that possesses substantial market power. Resale restrictions are not always within the patent grant. The question is whether the no-replant policy violates the rule of reason. See, e.g., *Mallinckrodt v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992). While patent holder may restrict purchaser’s use of patented item, such restrictions must not have anticompetitive effects. *Id.* at 701. A firm possessing intellectual property rights must engage in competition on the merits. See *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981). A patent holder is entitled to exact the full value of the patented item but cannot endanger competition in other areas by manipulating the patent monopoly. *Id.*

275. See, e.g., *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610-11 (1985). There was an antitrust violation present where firm in dominant market position changed pattern of distribution that had existed for several years. *Id.* Arguably, a biotech firm’s no-replant policy that eliminates saved seed, a long-standing practice of farmers, may constitute an antitrust violation as an exclusionary practice if the firm enjoys a dominant position in the seed market. Indeed, such an allegation has been raised against Monsanto in *Monsanto Co. v. Scruggs*, 249 F. Supp. 2d 746, 748 (N.D. Miss. 2001).

276. Monsanto’s introduction of Roundup Ready soybeans introduced unprecedeted restrictions on the freedom of farmers to use the new technology.

3. 1995 Antitrust Guidelines for the Licensing of Intellectual Property

Intellectual property licensing practices are the subject of extensive guidelines that were issued jointly by the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission.²⁷⁷ The guidelines were finalized in 1995. The issuance of the guidelines and several recent government antitrust investigations and enforcement actions (particularly those involving Microsoft and Intel) suggest that the antitrust enforcement agencies are paying particular attention to issues of technology and innovation, and the intersection of antitrust law and intellectual property. The intersection of antitrust law and intellectual property appears to be a major agenda item for the Antitrust Division of the Department of Justice. Thus, it may be appropriate to expect greater attention and activity from the antitrust community on issues of intellectual property law and policy.²⁷⁸

Under section 1.0 of the guidelines, "the intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare."²⁷⁹ Antitrust law has long focused on targeting practices that tend to block or discourage innovation, while simultaneously recognizing and accommodating the critical role of the intellectual property laws in promoting the development of new technologies. Perhaps the most difficult issue with respect to antitrust law's application to intellectual property arises when the focus of antitrust law on avoiding the abuse of monopoly power and unreasonable restraints of trade appears to conflict with the purported freedom of an intellectual property owner to use (or not use) its property as it sees fit. This appears to be the critical legal issue involved in determining whether a contract restriction limiting the use of parent seed would be enforceable or unenforceable under antitrust law. Patent licensing issues are the subject of the 1995 guidelines, and the guidelines identify specific licensing practices that are likely to raise antitrust issues and trigger enforcement actions.

Section 1.0 of the 1995 guidelines emphasizes that the same general antitrust principles should apply to conduct involving intellectual property as are applied to conduct involving other forms of property. Consequently, intellectual property does not *necessarily* confer monopoly power on its owner. Instead, intellectual property merely provides a right to exclude others from copying a particular process, product, or idea. This right should not be treated as different from

277. See ANTITRUST GUIDELINES, *supra* note 245.

278. Keep in mind, however, that the pendulum of antitrust enforcement has swung wildly over the past eighteen years. Antitrust was in a state of near eclipse from 1981-1987.

279. ANTITRUST GUIDELINES, *supra* note 245.

any other property right.²⁸⁰ The 1995 guidelines point this out in section 2.1 and state that the differences are to be handled by standard antitrust analysis without applying fundamentally different principles.²⁸¹

A question can be raised as to whether a seed company can refuse to license or use a patented product. The patent laws create a property right in the patented invention and contain an express provision that a patent holder may not be deemed guilty of misuse based upon a refusal to license or use a patent.²⁸² A rather persuasive argument can be made that this provision evidences a congressional intent to insulate intellectual property owners from attack for failing to fully exploit their property through refusal to license or by placing significant contractual restrictions on the post-sale use of the intellectual property involved. In addition, the law on this point appears to be reasonably clear. A firm, even one possessing monopoly power, may *unilaterally* decide not to utilize intellectual property that it has developed internally.²⁸³ The only limitation on this protection is a limited obligation to deal (in accordance with § 2 of the Sherman Act) derived from the general antitrust principle that a monopolist may not refuse to deal with competitors absent a valid business purpose.²⁸⁴ But, in a recent decision of the Federal District Court for the District of Kansas, the court held that Xerox was free to refuse to license lawfully acquired, patented technology or copyrighted matters to competing independent service operators.²⁸⁵ Other than this potential split of authority among the circuit courts, it appears that it would take an act of the Congress to result in significant post-sale restrictions on the use of intellectual property.

An argument could be made that Sherman § 2 does not apply because the intellectual property at issue does not confer (or even create the risk of) monopoly power in a relevant market.²⁸⁶ Similarly, section 2.2 of the 1995 guidelines states that enforcement agencies

280. The claim is not that intellectual property rights are identical to other types of property. Intellectual property may, indeed, be more readily appropriated than other types of property. This is especially true with seeds.

281. See ANTITRUST GUIDELINES, *supra* note 245.

282. 35 U.S.C. § 271(d)(4) (2000).

283. See, e.g., *Hartford-Empire Co. v. United States*, 323 U.S. 386 (1945).

284. See, e.g., *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997). The court upheld the jury's finding of a § 2 violation based, in part, on Kodak's refusal to sell certain patented products relating to its copying machines to organizations that competed with Kodak in servicing those machines. *Id.* at 1227. The court held that refusal to license or sell patented products was presumed lawful, but the presumption was rebuttable by evidence that the company's refusal to sell was "pretextual." *Id.* at 1212; see also *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1184-85 (1st Cir. 1994). The court declined to hold refusal to license copyright per se lawful, holding instead that there is a rebuttable presumption that such refusal is lawful. *Id.*

285. *In re Indep. Serv. Orgs. Antitrust Litig.*, 989 F. Supp. 1131, 1144 (D. Kan. 1997).

286. See, e.g., *Abbott Labs. v. Brennen*, 952 F.2d 1346, 1354-55 (Fed. Cir. 1991).

"will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner."²⁸⁷

A question can be raised concerning a potential antitrust violation if a seed company with a dominant position in the market blocks competitors from developing competing technologies by imposing licensing or royalty terms that prevent or discourage licensees from adopting the new technologies. Perhaps such an arrangement could be challenged as either a form of monopolization (under a Sherman § 2 analysis) or as an unreasonable restraint of trade (under Sherman § 1). Section 5.4 of the 1995 guidelines recognizes this possibility. Nevertheless, section 5.4 of the guidelines also points out that this practice may have the legitimate, procompetitive business purpose of encouraging the licensee to develop and market the licensed technology or specialized applications of the technology. High market share in the relevant market, coupled with specific intent to destroy competition or achieve monopoly, may be key factors to establishing a Sherman § 2 violation.

Therefore, absent collusion, neither antitrust law nor the 1995 guidelines expressly prohibit a patent owner from refusing to commercialize an invention or refusing to license it to others who would commercialize it. Nonuse is not misuse. Similarly, contractually restricted use does not constitute misuse.²⁸⁸

None of this represents the last word. If the Congress becomes convinced that the exercise or nonexercise of intellectual property rights becomes anticompetitive, this could change the U.S. approach in this area.

287. ANTITRUST GUIDELINES, *supra* note 245.

288. However, in contrast to U.S. patent and antitrust law, the law of the European Union obligates patent owners to commercialize their inventions at the peril of being compelled to license others to do so. Indeed, Article 86 of the Treaty of Rome specifically forbids technology suppression. The Treaty provides that "abuse" of a dominant market position consists of "limiting production, markets or technical development to the prejudice of consumers." Treaty of Rome, Mar. 25, 1957, art. 86, <http://www.hri.org/docs/Rome57/Part3Title05.html#Art86> (last visited May 20, 2004).