

## SELF-REPLICATING TECHNOLOGIES AND THE CHALLENGE FOR THE PATENT AND ANTITRUST LAWS<sup>•</sup>

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### *Abstract*

Few patented inventions challenge the traditional boundaries of the patent and antitrust laws like those that are capable of multiplying as they are used. These self-replicating technologies are embedded in our food, fortify our vaccines, and form the computer code upon which the information age is based. These inventions create an inherent conflict between patentees and their customers. The conflict arises because every customer could become competitors as the product replicates, potentially making every first sale the patentee's last. They also challenge how we think about fundamental issues of ownership as well as innovation and market competition, and make it necessary to identify what downstream uses are or should be permissible.

This struggle culminated recently in the Supreme Court case of *Bowman v. Monsanto*. There, the Court had to determine what rights a farmer had over the genetically modified seeds he had bought. At the

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core of *Bowman v. Monsanto* was the scope of patent exhaustion, a judge-made doctrine designed to end the patent owner's control over downstream commerce once its patented goods or methods were sold. Monsanto had also been accused of monopolizing the market, leading to upward spiraling prices and a drought of seed varieties. The Article examines the patent and antitrust issues arising in agro-biotechnology, and analyzes their impact on other self-replicating technologies.

In looking at patent issues, this Article first explains how courts can apply a technology neutral three-step test to distinguish between permissible "uses" and impermissible "making" of patented articles. Second, it explores the benefits of five alternatives to patent infringement as a means of appropriating returns to innovation, and explains why their limitations vindicate the Court's conclusion in *Bowman v. Monsanto*. Third, it discusses thorny matters left unresolved: inadvertent and "incidental" infringement, as well as the "conditional sale" doctrine.

In looking at the antitrust issues, the Article first explains why the controversial essential facilities doctrine could prove to be a useful tool for courts to ensure adequate access to standard essential patents over traits like Roundup Ready. Second, it explains why Monsanto's win over *Bowman* may hold an unexpected promise of a better future for farmers as its customers. Third, it argues that legislation similar to Paragraph IV challenges under the Hatch-Waxman Act can serve to incentivize greater competition in agro-biotechnology and other fields of technology.

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## INTRODUCTION

Few patented inventions challenge the traditional boundaries of the patent and antitrust laws like those that are capable of multiplying as they are used. These self-replicating technologies (“SRTs”) are embedded in our food, fortify our vaccines, and form the computer code upon which the information age is based.<sup>1</sup> These inventions create an inherent conflict between patentees and their customers. The conflict arises because every customer could become competitors as the product replicates, potentially making every first sale the patentee’s last.<sup>2</sup> They also challenge how we think about fundamental issues of ownership as well as innovation and market competition, and make it necessary to identify what downstream uses are or should be permissible.

The recent Supreme Court case of *Bowman v. Monsanto* became the arena for this conflict. Monsanto, an agricultural biotechnology company headquartered in St. Louis, Missouri, has won more than \$23 million from hundreds of farmers accused of replanting seeds bearing

<sup>1</sup> Brief for Respondents at 2–3, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 179941; *id.* at 31–32 (“Other inventions and technologies with similar characteristics would also be at risk: a software product that is replicated by a machine, a 3-D printer that can be used to print components for more 3-D printers, or a synthetic molecule that can be used to produce copies of itself.”); Brief for the United States as Amicus Curiae Supporting Affirmance at 16–17, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 137188; *id.* at 16 (“Like soybeans, computer software can be reproduced in materially identical form with limited human intervention. It is often impossible, moreover, to use computer software for its intended purpose without making another copy.”); *id.* at 18 (“The Court’s decision could also affect the enforcement of patents for man-made cell lines, DNA molecules, some nanotechnologies, and other technologies that involve self-replicating features.”).

<sup>2</sup> Brief of Intellectual Prop. Owners Ass’n in Support of Respondents at 11, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 267019; *see also id.* at 13 (“If the doctrine of patent exhaustion were improperly extended to the routine growth of recombinant host cells, this could have a devastating effect on investment in the production of new biologic drugs made from recombinant cells. If patents on recombinant cells used to make new drugs could be easily circumvented by reliance on the exhaustion doctrine, the deleterious effects on the pharmaceutical industry could be even greater than in the agricultural arena.”).

its modified germplasm.<sup>3</sup> In 2007, Monsanto accused Vernon H. Bowman, a seventy-five year old farmer from Knox County, Indiana, of patent infringement.<sup>4</sup> First as a pro se, then as a pro bono defendant, Bowman tried to convince the courts that he should be allowed to plant and harvest crops grown from seeds he had bought from a local grain elevator.<sup>5</sup> The Supreme Court, in affirming both the Court of Appeals for the Federal Circuit and the district court below, found that every one of the eight generations of his crop grown without Monsanto's permission was infringing.<sup>6</sup>

The narrative of Monsanto's patent litigation would be incomplete without also discussing its antitrust dimension. In 2007, state attorneys general reportedly launched an investigation against Monsanto for anticompetitive seed trait licensing practices that locked out competitor genetic trait providers.<sup>7</sup> When DuPont sought to offer a stacked gene containing Monsanto's herbicide resistant gene, it was sued by Monsanto.<sup>8</sup> DuPont responded with a private antitrust suit, accusing Monsanto of using its monopoly in the provision of genetic traits both to exclude rivals and to gain advantage in the market for the breeding and retail of seeds.<sup>9</sup> Other allegations include tie-in restrictions requiring farmers to apply only herbicide containing expired patents on

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<sup>3</sup> CENTER FOR FOOD SAFETY & SAVE OUR SEEDS, SEED GIANTS VS. U.S. FARMERS 1 (2013), available at [www.centerforfoodsafety.org/files/seed-giants\\_final\\_04424.pdf](http://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf); Alessandro Garofalo, *Monsanto Takes Home \$23mln from Small Farmers, Seeks to Maintain 'Seed Oligarchy'*, REUTERS (Feb. 14, 2013), <http://rt.com/usa/monsanto-seeds-trial-bowman-123/>.

<sup>4</sup> *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1345–46 (Fed. Cir. 2011); Heidi Ledford, *Seed-patent case in Supreme Court*, NATURE (Feb. 19, 2013), <http://www.nature.com/news/seed-patent-case-in-supreme-court-1.12445>.

<sup>5</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1765 (2013).

<sup>6</sup> *Id.* at 1769.

<sup>7</sup> Geoffrey Manne, *The Seeds of an Antitrust Disaster in Iowa*, FORBES, (Mar. 11, 2010), <http://www.forbes.com/sites/streettalk/2010/03/11/the-seeds-of-an-antitrust-disaster-in-iowa/>; see also Lina Khan, *How Monsanto Outfoxed the Obama Administration*, SALON (Mar. 15, 2013, 9:37 AM), [http://www.salon.com/2013/03/15/how\\_did\\_monsanto\\_outfox\\_the\\_obama\\_administration/](http://www.salon.com/2013/03/15/how_did_monsanto_outfox_the_obama_administration/) (“State officials uncovered agreements that, in one form or another, required seed breeders and retailers to favor Monsanto over its competitors. One provision, for example, prohibited seed companies from combining Monsanto's genetic traits with the traits controlled by its rivals, unless given explicit written permission from Monsanto. Since the vast majority of U.S. corn and soybean crops contain Monsanto's genes, the company could effectively lock out competitors.”).

<sup>8</sup> *Monsanto Co. v. E. I. du Pont de Nemours & Co.*, No. 4:09CV00686(ERW), 2009 WL 3012584 (E.D. Mo. Sept. 16, 2009).

<sup>9</sup> *Id.*; see also *Monsanto Co. v. E.I. DuPont de Nemours & Co.*, No. 4:09CV00686(ERW), 2012 WL 5397601, at \*1 n.4 (E.D. Mo. Nov. 2, 2012) (“Pioneer also asserted a number of antitrust counterclaims, alleging that Monsanto has abused its patent monopolies, has inserted anticompetitive restrictions into its license agreements with seed producers, and is attempting to employ an anticompetitive ‘switching strategy’ by using new licensing agreements to shift independent seed companies from the current RR trait seed lines to Roundup Ready 2 Yield®, in order to prevent generic entry into the market and extend Monsanto’ [sic] patent protection through 2020. On September 16, 2009, this Court entered its Order concluding that a separate trial of Pioneer’s antitrust counterclaims was warranted.”).

its Roundup technology to Roundup Ready crops containing its patented genes, and loyalty rebates for stocking up on Monsanto's inventory.<sup>10</sup>

The Department of Justice ("DOJ") followed up with its own investigations in 2010, and released a report in May 2012 highlighting the fact that farmers faced high prices and increasingly limited options for seeds as a result of companies' merger activities.<sup>11</sup> It warned that firm dominance in the agro-biotechnology industry promotes a "high degree of concentration, high and rising prices, limited choice, stagnant innovation."<sup>12</sup> In a decade, Monsanto had acquired thirty companies at the cost of \$12 billion.<sup>13</sup> Those companies that remain compete with the company they depend upon—Monsanto—for their supply for genetic traits, limiting their product offerings.<sup>14</sup>

By November 2012, however, the DOJ decided to close its investigations without explanation.<sup>15</sup> In a terse response to inquiries on the reasons for this closure, it stated that its investigation into "possible anticompetitive activity" in the seed industry was superseded by "marketplace developments that occurred during the pendency of the investigation."<sup>16</sup> The state attorneys general followed suit in discontinuing their own investigations.<sup>17</sup>

While not explicitly acknowledged, two events were responsible for keeping Monsanto out of further trouble with the antitrust enforcers. The first was Monsanto's participation in a remarkable private sector initiative led by the Biotechnology Industry Organization ("BIO") and the American Seed Trade Association ("ASTA"), a voluntary framework called the Accord, created to facilitate better and cheaper access to seed varieties and manage the potential trade disruption from patent expiration.<sup>18</sup> The Accord went into effect on November 15, 2012.<sup>19</sup> The second was Monsanto's billion-dollar settlement with

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<sup>10</sup> *Monsanto Co. v. E.I. DuPont de Nemours & Co.*, No. 4:09CV00686(ERW), 2012 WL 5397601, at \*1 n.4 (E.D. Mo. Nov. 2, 2012).

<sup>11</sup> DEP'T OF JUSTICE, COMPETITION AND AGRICULTURE: VOICES FROM THE WORKSHOPS ON AGRICULTURE AND ANTITRUST ENFORCEMENT IN OUR 21ST CENTURY ECONOMY AND THOUGHTS ON THE WAY FORWARD 13 (2012), 2012 WL 1828869.

<sup>12</sup> Tom Philpott, *DOJ Mysteriously Quits Monsanto Antitrust Investigation*, MOTHER JONES, (Dec. 1, 2012), <http://www.motherjones.com/tom-philpott/2012/11/dojs-monsantoseed-industry-investigation-ends-thud>.

<sup>13</sup> Khan, *supra* note 7.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* ("The DOJ released no written public statement.")

<sup>16</sup> See Philpott, *supra* note 12.

<sup>17</sup> Khan, *supra* note 7 ("The state attorneys general who initiated the probe five years ago also closed their inquiry and have chosen not to comment.")

<sup>18</sup> *Factsheet*, AM. SEED TRADE ASS'N & BIOTECHNOLOGY INDUS. ORG. (Oct. 31, 2012), <http://www.agaccord.org/include/facts.pdf>; see also Khan, *supra* note 7 ("Months after the Justice Department followed suit in 2009, Monsanto announced it would allow farmers to continue using its leading soybeans, Roundup Ready 1, even after its patent expired in 2014.")

<sup>19</sup> *The Accord: Generic Event Marketability and Access Agreement Is Now Effective*, BIO (Nov.

DuPont, which was publicly announced in March 2013.<sup>20</sup> As part of that settlement, Monsanto agreed to license DuPont's subsidiary Pioneer the rights to stack its next-generation herbicide resistant gene, Roundup Ready 2 Yield, in its seed offerings for \$1.75 billion.<sup>21</sup> In return, Monsanto will gain access to DuPont technology related to crop disease resistance.<sup>22</sup> These developments are a promising start to ensuring better access to seed varieties as well as cheaper seeds. More, however, can and should be done to promote competition in the industry for seeds and other SRTs.

This Article discusses the key patent and antitrust controversies relating to SRTs. Part I describes Monsanto's path to the Supreme Court. The last century witnessed a dramatic transformation in the relationship between farmers and the crops they tend. It is a transformation closely linked to a shift in using patents to protect agrobiotechnology. While farmers can now tap into the unlocked secrets of genes, they can no longer freely replant seeds, even from their own harvest. Instead they must return to biotech companies each season for new seeds at ever-higher prices or risk being sued for patent infringement, as *Bowman* was.

The Court's decision in *Bowman v. Monsanto* affirms that the law favors giving companies like Monsanto broad rights to control the use of SRTs. However, its brief ten-page judgment<sup>23</sup> serves more as a data point than a roadmap for those seeking guidance in this important area upon which our subsistence and sustenance depends.

Part II fills that gap by examining the traditional doctrinal and policy underpinnings of patent exhaustion, and the extent to which they may be applied to SRTs. First, it explains how courts can apply a technology neutral three-step test to distinguish between permissible "uses" and impermissible "makings" of patent articles. Second, it explores the benefits and limitations of five alternatives to patent infringement: contract law, technology "locks," natural inducements to

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15, 2012), <http://www.bio.org/media/press-release/accord-generic-event-marketability-and-access-agreement-now-effective>. As of June 2013, the ten signatories are the American Farm Bureau Federation, the American Seed Trade Association, the American Soybean Association, BASF Plant Science LP, Bayer CropScience, Dow AgroSciences L.L.C., Dupont Pioneer, Gro Alliance, L.L.C., Monsanto Company and National Corn Growers Association. *Generic Event Marketability and Access Agreement (GEMAA)*, AGACCORD.ORG, <http://www.agaccord.org/?p=GEMAA> (last visited Oct. 22, 2013).

<sup>20</sup> Carey Gillam, *Monsanto, DuPont strike \$1.75 billion licensing deal, end lawsuits*, REUTERS (Mar. 26, 2013), <http://www.reuters.com/article/2013/03/26/us-monsanto-dupont-gmo-idUSBRE92P0IK20130326>.

<sup>21</sup> Andrew Pollack, *Monsanto and DuPont Settle Fight Over Patent Licensing*, NYTIMES.COM (Mar. 26, 2013), <http://www.nytimes.com/2013/03/27/business/monsanto-and-dupont-settle-fight-over-roundup-ready-technology.html>.

<sup>22</sup> Gillam, *supra* note 20.

<sup>23</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 420 (2013).

innovation as new herbicide-resistant weeds evolve, compulsory licensing, and protection under patent-specific legislation. Third, it examines the Court's concern with "innocent" infringement. It discusses unintentional infringement by organic farmers and the limitations of disclaimers against litigation, labeling and state laws in protecting unintentional infringers. It then discusses incidental infringement and the impact of *Bowman v. Monsanto* on other forms of SRTs such as stem cells, genetically modified microorganisms, eukaryotic cells and plasmids. Finally, it looks at the third group of infringers who may remain vulnerable to patent infringement suits through post-sale licensing restrictions. It argues that patent owners should not be allowed an end-run around exhaustion using such restrictions, and that only contractual remedies should be allowed subject to the restrictions not falling afoul of federal preemption, patent misuse and the antitrust laws.

Part III examines the debate through an antitrust lens. First, it explains why the controversial essential facilities doctrine ("EFD") could prove to be a useful tool for courts to ensure adequate access to standard essential patents over the Roundup Ready soybean trait and SRTs. Second, it discusses the Accord's relationship with antitrust law and why Monsanto's win over Bowman may hold an unexpected promise of a better future for farmers. Third, it argues that the drug industry holds important lessons for making the agro-biotechnology more competitive. In particular, steps should be taken to prevent protection of undeserving patents through "product-hopping." In addition, Congress should consider enacting legislation similar to the Hatch-Waxman Act to incentivize challenges of poor quality patents.

#### I. BOWMAN V. MONSANTO

Agriculture in the United States is largely a private sector enterprise, with innovation fueled by a variety of plant-related intellectual property rights, each decidedly more robust than the last. Bowman was an archetypal Midwestern soybean farmer. His decision to replant seeds saved from an earlier harvest, however, caused him to become ensnared in Monsanto's web of patent rights over those seed. The question of how far Monsanto's control could reach was argued to a Supreme Court whose decision left unresolved questions that future courts will have to grapple with.

##### A. *The Privatization of Agriculture*

Soybeans are the second-most planted field crop in the United States, covering seventy-seven million<sup>24</sup> acres over 280,000 farms in

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<sup>24</sup> *Background*, USDA (Oct. 10, 2012), <http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/>

thirty-one states.<sup>25</sup> They account for a tenth of agricultural production and generate \$43 billion in sales revenue.<sup>26</sup> Soybeans can be consumed by humans as edamame, or processed into a variety of food products, including soymilk, tofu, and soy sauce.<sup>27</sup> Soybeans are also used to feed livestock.<sup>28</sup> Central to the discussion, soybean seeds can be planted and cultivated into new soybean plants.<sup>29</sup>

Monsanto is the largest seed company in the world.<sup>30</sup> Ninety-three percent of soybean farmers in the United States use Monsanto's flagship glyphosate-resistant technology, "Roundup Ready," which compliments Monsanto's glyphosate herbicide, Roundup.<sup>31</sup> Roundup kills competing vegetation by inhibiting the metabolic activity of 5-enolpyruvylshikimate-3-phosphate synthase ("EPSPS"), an enzyme necessary for plant growth.<sup>32</sup> Roundup Ready technology was claimed under the asserted "U.S. Patent Nos. 5,352,605 ('605 patent') and RE39, 247E ('247 patent')." <sup>33</sup> Roundup Ready is "by far the most

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background.aspx#Um7d9PmsiM4.

<sup>25</sup> Kevin E. Noonan, *It Ain't Necessarily So Down on the Farm: Not All Farmers Agree with Farmer Bowman in Bowman v. Monsanto*, PATENT DOCS (Jan. 31, 2013), <http://www.patentdocs.org/2013/02/it-aint-necessarily-so-down-on-the-farm-not-all-farmers-agree-with-farmer-bowman-in-bowman-v-monsant.html>; National Agricultural Statistics Service et al., Acreage 15 (2012), available at <http://www.usda.gov/nass/PUBS/TODAYRPT/acrg0612.pdf>; Ted Covey & Kevin Patrick, Cash Receipts By Commodity Group, USDA Economic Research Service (USDA ERS), available at <http://www.ers.usda.gov/topics/crops/.aspx#UeiugY21GSp> ("Corn is the most widely produced feed grain in the United States, with most of the crop providing the main energy ingredient in livestock feed.")

<sup>26</sup> *Soystats: 2012 Highlights*, THE AMERICAN SOYBEAN ASSOCIATION, <http://soystats.com/2012-soybean-highlights/> (last visited Nov. 2, 2013).

<sup>27</sup> See Brief of CropLife Am. as Amicus Curiae Supporting Affirmance at 2–3, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 314456.

<sup>28</sup> *Id.* at 2.

<sup>29</sup> *Id.* at 3.

<sup>30</sup> Greg Stohr, *Monsanto Seed Patent Case Gets U.S. Supreme Court Review*, BLOOMBERG BUSINESSWEEK (Oct. 5, 2012), <http://www.businessweek.com/news/2012-10-05/monsanto-seed-patent-case-gets-u-dot-s-dot-supreme-court-review>.

<sup>31</sup> Brief of Am. Soybean Ass'n et al. as Amici Curiae in Support of Respondents at 7, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 315223.

<sup>32</sup> *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1343 (Fed. Cir. 2011).

<sup>33</sup> See *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1343–44 (Fed. Cir. 2011) ("The '605 and '247E Patents cover different aspects of the Roundup Ready® technology . . . . The invention of the '605 Patent relates to the use of viral nucleic acid from the cauliflower mosaic virus ('CaMV'), a virus capable of infecting plant cells, as a vector for incorporating new genetic material into plant cells (a 'transformation' of the plant cells). To accomplish this transformation, the CaMV promoter region is isolated from the CaMV genome and combined with a heterologous protein-encoding DNA sequence, forming a chimeric gene to be expressed in the plant cell . . . . The invention of the '247E Patent involves the transformation of plant cells—using, for example, the CaMV promoters disclosed in the '605 Patent—to transform plant cells with novel protein-encoding gene sequences that encode for EPSPS, a glyphosate-tolerant enzyme. These genetically modified plants express EPSPS and exhibit glyphosate resistance. '247E Patent, col.1 ll.15–46. The advantage of this technology, which can be incorporated into a variety of crops, is that farmers can treat their fields with glyphosate-based herbicide to control weed growth without damaging their crops.").



widely used” genetic trait in American agriculture making up more than \$11.7 billion or 75% of Monsanto’s net annual income.<sup>34</sup>

Roundup Ready has benefited farmers in a number of ways. It has allowed for aerial spraying for weeds, instead of manual scouring, and it has matched specific herbicides to the weeds, thus reducing labor costs by \$6.50 per acre and herbicide costs by \$8.68 per acre.<sup>35</sup> This technology allowed farmers to reduce soil tillage compared with conventional methods.<sup>36</sup> The reduced soil tillage has enabled farmers to plant in narrower rows and has increased the number of plants grown per acre.<sup>37</sup> Many amici briefs supporting Monsanto assert a positive correlation between progressively stronger patent protection and innovation.<sup>38</sup>

Others are more skeptical. For instance, the Center for Food Safety and Save Our Seeds argued that the “vast majority” of plant innovation was accomplished without inducement by the patent system.<sup>39</sup> Indeed, according to the Center, “[f]or the first two centuries of this country’s history, Congress consistently refused to authorize patents on staple food crops.”<sup>40</sup> The Center also stated that the current regime was formed “under increasing pressure and marketing from agrichemical companies, seed patent and intellectual property law,” and that this pressure had resulted in “policies [which] have enshrined corporate interests instead of safeguarding farmers and small, independent businesses.”<sup>41</sup>

The impetus for advancing agro-technology was evident early in the nation’s history. In 1800, Thomas Jefferson declared that “[t]he greatest service which can be rendered any country is, to add an [sic]

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<sup>34</sup> *Monsanto: The Parable of the Sower*, THE ECONOMIST (Nov. 19, 2009), <http://www.economist.com/node/14904184>; Joseph M. Purcell, Jr., Note, *The “Essential Facilities” Doctrine in the Sunlight: Stacking Patented Genetic Traits in Agriculture*, 85 ST. JOHN’S L. REV. 1251, 1252 (2011).

<sup>35</sup> Brief for Respondents, *supra* note 1, at 2–3.

<sup>36</sup> Wade A. Givens et al., Roundup Ready® Crops Have Major Positive Impact on Tillage Practices (2009), available at <http://www.monsanto.com/weedmanagement/Documents/Benchmark-TillageSummaryRept2.pdf>.

<sup>37</sup> Janet Carpenter & Leonard Gianessi, *Herbicide Tolerant Soybeans: Why Growers are Adopting Roundup Ready Varieties*, 2 AGBIOFORUM 65, 65–72 (1999), available at <http://agbioforum.org/v2n2/v2n2a02-carpenter.pdf>.

<sup>38</sup> Brief of Am. Soybean Ass’n et al. as Amici Curiae in Support of Respondents, *supra* note 31, at 5 (“During the past few decades, enormous progress has been made in improving new seed varieties based upon the protections initially afforded by the Plant Variety Protection Act of 1970. Genetic innovation in soybeans grew exponentially, like Jack’s magical beanstalk, after this Court’s 1980 decision in *Diamond v. Chakrabarty*, 447 U.S. 303, which confirmed the applicability of utility patent protection to qualifying organisms.”).

<sup>39</sup> CENTER FOR FOOD SAFETY & SAVE OUR SEEDS, *supra* note 3, at 4.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

useful plant to its culture.”<sup>42</sup> During colonial times, wealthy merchants brought seeds from Europe to America.<sup>43</sup> Successful crops were shared among the select few who belonged to agricultural societies.<sup>44</sup> Given the yoke of patent lawsuits that farmers have borne in more recent years, it is perhaps ironic that it was the then Commissioner of Patents, Henry Ellsworth, who in 1839 obtained federal funds to collect and distribute new plant varieties to farmers for free.<sup>45</sup> The Department of Agriculture was later established to carry on this task, among others.<sup>46</sup> Farmers who benefited from the system in turn donated their seed to a seed bank that freely distributed approximately a billion seed packets a year to other farmers.<sup>47</sup>

A small private seed industry existed even then, but it was limited to vegetables and flowers grown by home gardeners.<sup>48</sup> Early breeders lacked the incentive to invest in developing more productive plants.<sup>49</sup> In addition to their inability to control the commercial exploitation of their genetic material, the free seed program crowded out private breeders from the marketplace.<sup>50</sup>

As early as 1885, private interests successfully lobbied the government for a plant patent system.<sup>51</sup> Seed companies began to invest in plant variety research, increasing their ability to express desirable traits.<sup>52</sup> Hybrid crops were a particularly lucrative source of investments

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<sup>42</sup> THOMAS JEFFERSON, THOMAS JEFFERSON: WRITINGS 703 (Merrill D. Peterson ed., 1984).

<sup>43</sup> Keith Aoki, *Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT’L & COMP. L. 247, 262 (2003).

<sup>44</sup> See ALFRED CHARLES TRUE, A HISTORY OF AGRICULTURAL EXPERIMENTATION AND RESEARCH IN THE UNITED STATES 6–7 (1937); see also Nathan A. Busch, *Jack and the Beanstalk: Property Rights in Genetically Modified Plants*, 3 MINN. INTEL. PROP. REV. 1, 9 (2002) (“Because the common farmer could not gain membership to these agricultural societies he had either no or limited access to these new and exotic varieties. The common farmer was then economically disadvantaged in a system that granted an exclusive interest to those who could afford to develop the plant varieties best suited to agriculture in the United States.”).

<sup>45</sup> Aoki, *supra* note 43, at 265.

<sup>46</sup> An Act to Establish a Department of Agriculture, ch. 72, 12 Stat. 387 (1862); Busch, *supra* note 44, at 10–11 (“To rationalize and continue the centralized control of germplasm development and distribution, Congress in 1862 established the United States Department of Agriculture (USDA) to ‘acquire and to diffuse among the people of the United States useful information in subjects connected with agriculture in the most general and comprehensive sense of that word, and to procure, propagate, and distribute among the people new and valuable seeds and plants.’”).

<sup>47</sup> See Busch, *supra* note 44, at 14.

<sup>48</sup> *Id.* at 16 (“By the beginning of the twentieth century, the seed manufacturing industry had gained only a small fraction of the market for field crop seeds, a market that was almost exclusively dominated by on-farm production of the seed and sale of the seed through inter-farm commerce.”).

<sup>49</sup> Aoki, *supra* note 43, at 268.

<sup>50</sup> JACK RALPH KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY (1988).

<sup>51</sup> *Id.*

<sup>52</sup> See also Jorge Fernandez-Cornejo, *The Seed Industry in U.S. Agriculture: An Exploration of*

because their high yields did not carry forward to subsequent generations.<sup>53</sup> Having tasted a bountiful harvest, farmers returned each year for seeds for their next season.<sup>54</sup> This led to a progressive shift from seed saving to seed buying for replanting.<sup>55</sup> The technologies were kept as trade secrets.<sup>56</sup> However, self-pollinating crops, such as soybeans, could not be feasibly protected by trade secrets because, unlike inbred parent lines of hybrid crops, which could be kept off market and thus kept secret, self-pollinating crops were self-disclosing.<sup>57</sup>

One commentator noted that “the private seed industry was occupied with efforts to eliminate governmental seed distribution.”<sup>58</sup> By 1924, the Department of Agriculture (“USDA”) turned its focus to basic agricultural research and ended its seed program.<sup>59</sup> In 1930, Congress passed the Plant Patent Act (“PPA”).<sup>60</sup> The PPA recognized that asexually bred plants, produced via budding, cutting and grafting, could be protected under patent law.<sup>61</sup> Under the PPA, breeders can prevent buyers from asexually reproducing a patented plant, even after an authorized sale.<sup>62</sup> The passage of the PPA also confirmed that plant life was patentable subject matter.<sup>63</sup> PPA protection was conferred under less stringent standards than utility patents.<sup>64</sup> In addition, farmers were

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Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development 41–42, available at <http://www.ers.usda.gov/publications/aib-agricultural-information-bulletin/aib786.aspx#.UmHdsRbvNSU> (From 1960 to 1965 U.S. private research and development (“R&D”) expenditures increased by around \$514 million while public R&D expenditures remained flat, resulting in a marked “shift of more R&D activity to the private sector.”).

<sup>53</sup> Aoki, *supra* note 43, at 250.

<sup>54</sup> *Id.*

<sup>55</sup> Fernandez-Cornejo, *supra* note 52.

<sup>56</sup> Rita S. Heimes, *Post-Sale Restrictions on Patented Seeds: Which Law Governs?*, 10 WAKE FOREST INTELL. PROP. L.J. 98, 105 (2010).

<sup>57</sup> See Debra L. Blair, *Intellectual Property Protection and its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 308–09 (1999) (“Trade secret laws require that the information to be protected be held confidential and without disclosure to the public. . . . [Thus,] inbred lines used to create hybrids can be protected as trade secrets.”).

<sup>58</sup> Jennifer Wai-Shing Maguire, *The Seed 2.0: Evolving Intellectual Property Rights of Agricultural Germplasm*, 8 BUFF. INTELL. PROP. L.J. 51, 56 (2012).

<sup>59</sup> *Id.* at 56.

<sup>60</sup> 35 U.S.C. § 161 (1954) (providing patent protection for “[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant.”).

<sup>61</sup> *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 125 (2001) (“The 1930 PPA amended the general patent provision to protect only the asexual reproduction of a plant.”).

<sup>62</sup> *Id.* at 136 (noting that statute’s purpose was to protect covered plants from being “regularly copied, draining profits from those who discovered or bred new varieties”).

<sup>63</sup> *Id.* at 127. In *J.E.M.*, the Court noted that moving plant protection provisions to § 161 was statutory “housekeeping.” *Id.* at 133. It does not follow that Congress intended § 161 to be the exclusive provision governing plant patents. *Id.*

<sup>64</sup> *Id.* at 125 (“Plant patents under the PPA . . . have very limited coverage and less stringent requirements than [35 U.S.C.] § 101 utility patents.”).

minimally affected by the passage of the PPA because their crops were produced via sexual reproduction.<sup>65</sup>

This changed when Congress passed the Plant Variety Protection Act (“PVPA”) in 1970.<sup>66</sup> Similarly to the PPA, the requirements for obtaining a plant variety protection certificate are less stringent, and the protection provided to the patentee is less extensive than a utility patent.<sup>67</sup> The PVPA empowered the USDA to grant Certificates of Protection for novel sexually protected plant varieties grown from seed.<sup>68</sup> Certificate holders had exclusive marketing rights.<sup>69</sup> Under the PVPA, breeders could restrict buyers from sexually reproducing the plant “as a step in marketing (for growing purposes) the variety,” and from selling progeny seed for replanting beyond the amount needed to replant the farmer’s own acreage.<sup>70</sup>

As a concession, farmers were allowed to save seeds for replanting, known as the “bin run” or “brown-bag” sales.<sup>71</sup> Brown bag sales enabled farmers to go directly into the business of selling PVPA-protected seeds alongside the plant breeders.<sup>72</sup> In addition, the PVPA

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<sup>65</sup> See Blair, *supra* note 57, at 308–10.

<sup>66</sup> 7 U.S.C. §§ 2321–2582 (2006).

<sup>67</sup> Utility patents, in turn, have more stringent standards including usefulness, novelty, nonobviousness, enablement, and written description; and they also confer greater rights, including the elimination of “brown bag” and seed saving exemptions. See *J.E.M.*, 534 U.S. at 142 (In contrast to the requirements for obtaining a utility patent, “a plant variety may receive a PVP certificate without a showing of usefulness or nonobviousness.”). Seed must also be deposited in a public depository; however, “neither the statute nor the applicable regulation mandates that such material be accessible to the general public during the term of the PVP certificate.” *Id.* at 143. By contrast, a utility patent protects “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101 (1952) (including inventions embodied in sexually and asexually reproduced plants). See also *J.E.M.*, 534 U.S. at 143 (“Because of the more stringent requirements, utility patent holders receive greater rights of exclusion than holders of a PVP certificate [or a plant patent under the PPA].”).

<sup>68</sup> 7 U.S.C. §§ 2421, 2422, 2481–83.

<sup>69</sup> The PVPA protects rights in “sexually reproduced . . . plant variet[ies].” 7 U.S.C. § 2402(a) (1996). This includes the right to exclude others from “sexually multiply[ing], or propagat[ing]” the variety. 7 U.S.C. § 2541(a)(3) (1994).

<sup>70</sup> 7 U.S.C. § 2541(a)(3); see *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 186 (1995) (quoting 7 U.S.C. § 2541(a)(3)).

<sup>71</sup> 7 U.S.C. § 2543 (2003); see *Asgrow Seed Co.*, 513 U.S. at 184 (permitting farmers to “save seed produced by [them] from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and [to] use such saved seed in the production of a crop” and “a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes”); see also *Asgrow Seed Company*, 513 U.S. at 182 (“A brown-bag sale occurs when a farmer purchases seeds from a seed company, . . . plants the seeds in his own fields, harvests the crop, cleans it, and then sells the reproduced seed to other farmers (usually in nondescript brown bags) for them to plant as crop seed on their own farms.”).

<sup>72</sup> *Asgrow Seed Co.*, 513 U.S. at 182 (“A brown-bag sale occurs when a farmer purchases seed from a seed company, such as Asgrow, plants the seed in his own fields, harvests the crop, cleans it, and then sells the reproduced seed to other farmers (usually in nondescript brown bags) for

also allowed “bona fide research” involving “use and reproduction” of PVPA protected seeds.<sup>73</sup> Congress thus intended the PVPA to encourage research and marketing of new varieties with the guarantee of enhanced protection while recognizing the partnership between breeders and farmers.<sup>74</sup>

In the case of soybean seeds, bin runs have been compared to a “robust version of copyright law’s ‘first sale’ doctrine” because a breeder “gets exactly one chance to sell the information ‘encoded’ in PVPA-certified seed to any individual farmer.”<sup>75</sup> In 1983, the Fifth Circuit noted that brown-bag exemptions were deemed incompatible with the purpose of the PVPA.<sup>76</sup> The PVPA failed to achieve these goals because “withering competition from brown-bag sales prompted commercial plant breeders to shift their research from self-pollinated crops to hybrids . . . [which] enjoy a biological immunity from easy duplication.”<sup>77</sup>

Reflecting on the PVPA, Professor Jim Chen noted that it “represents a rare instance in the annals of contemporary intellectual property law in which proprietary protection is not excessive, but rather insufficiently robust.”<sup>78</sup> He observes that it “provided at most modest incentives for private investment in agricultural research and development . . . [and has not] generated significant improvements in crop quality, crop yields, or any other measure of agronomic performance.”<sup>79</sup> More broadly, Professor Chen noted that the “distortion of agricultural research brings with it a lamentable preference for the law of trade secrets over the PVPA and patent law. Whatever their flaws, federal intellectual property laws boast the singular virtue of forcing inventions into the public domain once their terms of protection

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them to plant as crop seed on their own farms.”).

<sup>73</sup> 7 U. S. C. § 2544.

<sup>74</sup> See *Asgrow Seed Co.*, 513 U.S. at 181; Brief of Am. Soybean Ass’n et al. as Amici Curiae in Support of Respondents, *supra* note 31, at 5 (“[E]normous progress has been made in improving new seed varieties based upon the protections initially afforded by the Plant Variety Protection Act of 1970.”).

<sup>75</sup> Jim Chen, *The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy*, 81 NOTRE DAME L. REV. 105, 128 (2005).

<sup>76</sup> *Delta & Pine Land Co. v. Peoples Gin Co.*, 694 F.2d 1012, 1016 (5th Cir. 1983) (“In purpose and operation, the farmer exemption appears to be at odds with the primary purpose of the Act. While the main body of the Act assures developers of novel varieties the exclusive right to sell and reproduce that variety, the crop exemption dilutes that exclusivity by allowing individual farmers to sell the protected variety without liability. The broader the construction given the exemption, the smaller the incentive for breeders to invest the substantial time and effort necessary to develop new strains. The less time and effort that is invested, the smaller the chance of discovering superior agricultural products. If less time and effort is invested, long-term benefits to the farmer in the form of superior crops and higher yields will be lost.”).

<sup>77</sup> Chen, *supra* note 75, at 155–56

<sup>78</sup> *Id.* at 157.

<sup>79</sup> *Id.* at 155.

expire.”<sup>80</sup>

By 1994, the PVPA was amended to prohibit farmers from selling PVPA-protected seed to other farmers for planting.<sup>81</sup> Congress intended this additional enhancement to both meet international treaty obligations and incentivize research and commercialization of seed.<sup>82</sup> In 1995, the Court in *Asgrow Seed Co. v. Winterboer* limited brown-bag sales to “only such seed as [a farmer] has saved for the purpose of replanting his own acreage.”<sup>83</sup> Professor Rita Heimes observed that:

[This] signaled a shift in enforcement of plant intellectual property rights from litigation against corporate competitors to lawsuits against the end-user farmer. The [Asgrow] case also marks the “transformation of the seed as a good that was purchased with no strings attached into a good subject to numerous statutory and contractual conditions. The seed is not only a commodity, but may also be licensed, as opposed to only purchased.”<sup>84</sup>

Concurrent with these developments, in 1980, the Court in *Diamond v. Chakrabarty* held that genetically engineered microorganisms were eligible for a utility patent.<sup>85</sup> This was particularly significant for soybean-related research. Unlike hybrid crops like corn, sorghum, and sunflowers, soybean plants are self-pollinating and produce genetically identical progeny.<sup>86</sup> Without utility patent protection, soybean seed can be replanted for multiple generations without losing its beneficial traits.<sup>87</sup> The inability of biotech companies to appropriate those benefits discouraged them from investing in

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<sup>80</sup> *Id.* at 156.

<sup>81</sup> *Id.* at 129.

<sup>82</sup> See Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, 108 Stat. 3136 (amending the PVPA for conformance with the UPOV (International Union for the Protection of New Varieties of Plants) Convention).

<sup>83</sup> *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 192 (1995).

<sup>84</sup> Heimes, *supra* note 56, at 109 (quoting Keith Aoki & Kennedy Luvai, *Seed Wars: Controversies over Access to and Control of Plant Genetic Resources*, in 2 INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE 265 (Peter K. Yu ed., 2007)).

<sup>85</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>86</sup> See generally Rattan Lal Agrawal, *Fundamentals of Plant Breeding and Hybrid Seed Production* (1998).

<sup>87</sup> Jon Entine, *Bowman v Monsanto: Genetic Innovation in the Crosshairs?*, GENETIC LITERACY PROJECT (Feb. 18, 2013), <http://www.geneticliteracyproject.org/2013/02/18/bowman-vs-monsanto-genetic-innovation-in-the-crosshairs/> (“Genetic innovation in soybeans grew exponentially, like Jack’s magical beanstalk, after this Court’s 1980 decision in *Diamond v. Chakrabarty*, . . . which confirmed the applicability of utility patent protection to qualifying organisms.”); see also Brief of Am. Soybean Ass’n et al. as Amici Curiae in Support of Respondents, *supra* note 31, at 6 (“Innovation spurred by the *Chakrabarty* decision resulted in impressive gains in nutrition and environmental stewardship.”).

soybean seed research.<sup>88</sup>

After *Chakrabarty*, “plant breeders began developing new varieties and traits with the confidence that their intellectual property would be protected.”<sup>89</sup> These super-crops resist herbicides, pests, and disease, allowing them to thrive under conditions that previously would have decimated entire crop populations.<sup>90</sup> Growers also enjoyed higher yields and the environment benefited from less degradation.<sup>91</sup>

In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the Supreme Court held that the PPA and PVPA did not exclude those who wanted to protect seed technology with utility patents, so long as the requirements for patentability were met.<sup>92</sup> It observed that, unlike the PVPA, utility patents conferred no seed-saving or research exemptions.<sup>93</sup> In order to read rights conferred under the PVPA and PPA coherently alongside protection for utility patents, patentees must be allowed to prevent buyers from reproducing the traired plants. The Court found that farmers had no right to save seeds or use them for research without the patentee’s authorization, a point reiterated in *Bowman v. Monsanto*.<sup>94</sup> *J.E.M.* adhered to the policy that was “sought by seed producers as a means of assuring a return of the research and development costs required to create and patent the modified seed.”<sup>95</sup>

Since *Chakrabaty*, the privatization of agriculture has displaced public sector research because Congress deemed it more efficient.<sup>96</sup>

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<sup>88</sup> Brief of Am. Soybean Ass’n et al. as Amici Curiae in Support of Respondents, *supra* note 31, at 15–16 (noting that “[a]bsent clear utility patent protection, soybean breeders had little incentive to invest resources in developing new varieties.”).

<sup>89</sup> *Id.* at 16.

<sup>90</sup> For example, in 1999 a major freeze cost California’s citrus growers \$600 million in crop losses. Brief Amicus Curiae of the Am. Seed Trade Ass’n in Support of Neither Party at 10, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008) (No. 06-937), 2007 WL 3353100; *see also* Brief Amicus Curiae of the Am. Seed Trade Ass’n in Support of Respondents at 6, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 267021. While it is also possible to develop these traits through cross-breeding, scientists estimate that it would take upwards of fifteen years. *See* Brief Amicus Curiae of the Am. Seed Trade Ass’n in Support of Neither Party, *supra* at 6.

<sup>91</sup> *See* U.S. DEP’T OF JUSTICE, *supra* note 11, at 13; *see also* Madison Smith, *Who Owns Your Dinner? A Discussion of America’s Patented Genetically Engineered Food Sources, and Why Reform Is Necessary*, 23 LOY. CONSUMER L. REV. 182, 196 (2010) (“It has been suggested that use of herbicide tolerant crops can reduce total production costs by 6% in some cases.”).

<sup>92</sup> *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.* 534 U.S. 124, 145 (2001). Notably the PVPA only requires that the plant variety is new, distinct and uniform; it does not require showing utility and nonobviousness. *See id.* at 154.

<sup>93</sup> *Id.* at 143.

<sup>94</sup> *Id.* at 140 (“The utility patent statute does not contain . . . exemptions” for saving seed and for research.); *see also* *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1767 (2013).

<sup>95</sup> Marcella Downing-Howk, Comment, *The Horns of a Dilemma: The Application of the Doctrine of Patent Exhaustion and Licensing of Patented Seed*, 14 SAN JOAQUIN AGRIC. L. REV. 39, 50 (2004).

<sup>96</sup> United States Department of Justice & United States Department of Agriculture, *A Dialogue on Competition Issues Facing Farmers in Today’s Agricultural Marketplace* (Mar. 12, 2010),

Once the backbone of seed germplasm research, public expenditure leveled off in the 1970s and began to decrease by the mid-1990s.<sup>97</sup> In contrast, private investment in seeds and genetic trait research doubled from \$146 million to \$305 million between 1979 and 1980, and domestic soybean production has increased 96% and yields per acre have increased 55%.<sup>98</sup> By 2010, private investment rose to \$2 billion.<sup>99</sup> Private spending continues to outpace government spending.<sup>100</sup>

The trend toward a greater reliance on utility patents is clear. Between 2004 and 2008, Monsanto owned a third of all utility plant patents but only a fifth of all PVPA certificates.<sup>101</sup> This trend is mirrored by its closest rivals, as shown below.<sup>102</sup> The six largest seed companies today invest \$2.2 billion annually on crop research and development, nearly ten times the amount of the USDA, and three (Monsanto, Syngenta and Pioneer) account for 75% of all utility patents on plant varieties and only 44% on PVPA certificates.<sup>103</sup> “[E]conomists say that an industry has lost its competitive character when the

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<http://meetings.abanet.org/webupload/commupload/AT800006/relatedresources/AnkenyIowaTranscript.pdf> (“[I]f you look at the wheat example, there is public sector research on wheat, but I think university professors are not real good at making cold sale calls and meeting deadlines and forming teams, and so probably we’re not as good as we could be, as the private sector is, at taking that basic research and turning it into a sales product. And therefore, I think there’s a natural break-even point, and that is the public sector does a lot of basic research and should get funding for that, but when it gets to the point where a private sector company can do it more efficiently, then I think we need to turn it back over.”).

<sup>97</sup> KEITH O. FUGLIE ET. AL., RESEARCH INVESTMENTS AND MARKET STRUCTURE IN THE FOOD PROCESSING, AGRICULTURAL INPUT, AND BIOFUEL INDUSTRIES WORLDWIDE 132 fig.10 (2011) available at <http://ageconsearch.umn.edu/bitstream/120324/2/err-130.pdf>.

<sup>98</sup> Brief of Am. Soybean Ass’n et al. as Amici Curiae in Support of Respondents, *supra* note 31, at 6 (“Innovation spurred by the *Chakrabarty* decision resulted in impressive gains in nutrition and environmental stewardship. Since 1980, total domestic soybean production has increased 96% and yields per acre have increased 55%. Soybean production has also become more environmentally friendly. On a per-bushel basis, the land needed to produce a bushel of soybeans declined by 35%, soil erosion decreased 66%, irrigation water applied declined by 42%, fuel consumption decreased 42%, and greenhouse gas emissions declined by 41%.”).

<sup>99</sup> KEITH O. FUGLIE ET. AL., *supra* note 97.

<sup>100</sup> Jorge Fernandez-Cornejo & Margriet Caswell, The First Decade of Genetically Engineered Crops in the United States 2 (2006), available at [http://www.ers.usda.gov/media/255908/eib11\\_1\\_.pdf](http://www.ers.usda.gov/media/255908/eib11_1_.pdf) (“Private spending on crop variety R&D increased fourteenfold between 1960 and 1996 (adjusted for inflation), while public expenditures changed little.”); see also GianCarlo Moschini, *Competition Issues in the Seed Industry and the Role of Intellectual Property* 1 (Iowa State Univ. Dep’t of Econ., Working Paper No. 10015, 2010), available at <http://www.econ.iastate.edu/sites/default/files/publications/papers/p11611-2010-06-08.pdf> (“[I]n agriculture, private R&D has exceeded public R&D expenditures since the early 1980s.”).

<sup>101</sup> See *infra* Figure 1.

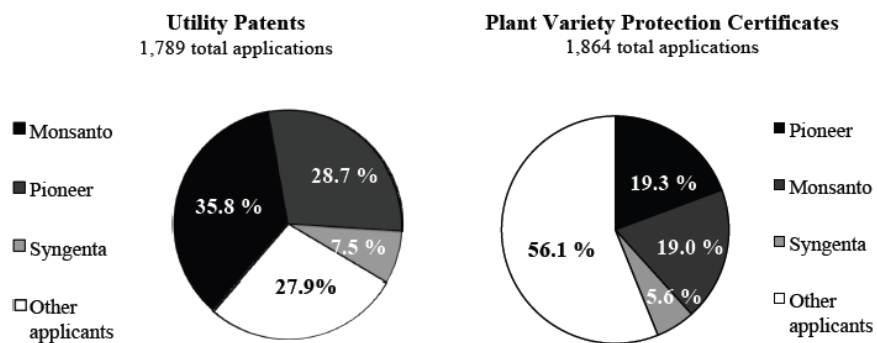
<sup>102</sup> *Id.*

<sup>103</sup> Hope Shand, *The Big Six: A Profile of Corporate Power in Seeds Agrochemicals and Biotech*, THE HERITAGE FARM COMPANION (2012), available at [www.seedsavers.org/site/pdf/HeritageFarmCompanion\\_BigSix.pdf](http://www.seedsavers.org/site/pdf/HeritageFarmCompanion_BigSix.pdf); see *infra* Figure 1; see also KEITH O. FUGLIE ET. AL., *supra* note 97, at 19.



concentration ratio of the top four firms . . . is 40 percent or higher.”<sup>104</sup> “As smaller, independent companies vanish from the landscape, farmers see fewer options and higher prices in the marketplace.”<sup>105</sup>

Today, agro-biotech companies have applied for and received patents for genes related to abiotic stress tolerance, insect resistance, and improved yields.<sup>106</sup> Monsanto itself is expected to introduce a stocked soybean variety to resist herbicides needed to counter weed varieties that have developed glyphosate resistance.<sup>107</sup>



**FIGURE 1:** U.S. Applications for IP Protection on Plant Varieties (2004–2008).<sup>108</sup>

With the move towards utility patents, patent owners increasingly licensed rather than sold their seeds.<sup>109</sup> A report by the Center for Food Safety and Save Our Seeds summed up that:

<sup>104</sup> KRISTINA HUBBARD, OUT OF HAND: FARMERS FACE THE CONSEQUENCES OF A CONSOLIDATED SEED INDUSTRY 4 (2009), available at <http://www.farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf>.

<sup>105</sup> *Id.*

<sup>106</sup> See ETC GROUP, CAPTURING ‘CLIMATE GENES’: GENE GIANTS STOCKPILE ‘CLIMATE-READY’ PATENTS 5 (2010) (traits related to environmental stress, such as drought, salinity, heat, cold, chilling, freezing, nutrient levels, high light intensity, ozone, and anaerobic stresses).

<sup>107</sup> CROPLIFE INT’L, PLANT BIOTECHNOLOGY PIPELINE (2011), available at [www.croplife.org/view\\_document.aspx?docId=3457](http://www.croplife.org/view_document.aspx?docId=3457).

<sup>108</sup> ETC GROUP, GENE GIANTS SEEK “PHILANTHROGOPOLY” 7 (2013), available at [http://www.etcgroup.org/sites/www.etcgroup.org/files/ETCCommCharityCartel\\_March2013\\_final.pdf](http://www.etcgroup.org/sites/www.etcgroup.org/files/ETCCommCharityCartel_March2013_final.pdf).

<sup>109</sup> Elizabeth I. Winston, Note, *What if Seeds Were Not Patentable?*, 2008 MICH. ST. L. REV. 321, 327 (2008) (“Given the limitations inherent in any form of public protection for agricultural innovation, seed companies turned to private ordering to protect their research and development. No longer is seed sold; now it is licensed, and with these licenses, the seed market has fundamentally changed.”).

Henceforth, plants and plant parts became eligible for utility patents, setting the stage for prohibition of farmer seed saving and breeding as forms of patent infringement. Today, utility patents have largely superseded PVPA Certificates of Protection as the preferred vehicle for intellectual property rights to new plant varieties, particularly those developed with use of genetic engineering.<sup>110</sup>

With patent protection, crop prices have also increased. According to the Center for Food Safety and Save Our Seeds, “[t]hese price hikes are chiefly attributable to a ‘technology fee’ premium that the companies charge for each GE ‘trait’ introduced into a seed line.”<sup>111</sup> Between 1995 and 2011, the average cost of planting one acre of soybeans rose 325%, as illustrated below.<sup>112</sup> In particular, the cost of Monsanto’s Roundup Ready trait has risen from \$4.50 per bag in 1996 to \$17.50 over a decade.<sup>113</sup> Between 2009 and 2010, the price of Monsanto’s seeds rose 42%.<sup>114</sup>

CROP SEED COST (\$/planted acre)	1975	1995	2011	1975-1995 (% increase)	1995-2011 (% increase)
SOYBEANS	\$8.32	\$13.32	\$56.58	60%	325%
CORN	\$9.30	\$23.98	\$86.16	158%	259%
COTTON	\$5.88	\$15.67	\$96.48	166%	516%

Figures from USDA Economic Research Service: Commodity Costs and Returns: U.S. and Regional Cost and Return Data. Datasets accessible at: <http://www.ers.usda.gov/Data/CostsAndReturns/estpick.htm>.

FIGURE 2: Crop Seed Cost Over Time (1975–2011).<sup>115</sup>

One reason for this price increase is market consolidation through vertical integration between trait developers and seed companies.<sup>116</sup> Independent seed companies, which have been an important channel to get competitively priced seeds to farmers, have dramatically decreased in

<sup>110</sup> CENTER FOR FOOD SAFETY & SAVE OUR SEEDS, *supra* note 3, at 15.

<sup>111</sup> *Id.* at 17.

<sup>112</sup> *See infra* Figure 2.

<sup>113</sup> HUBBARD, *supra* note 104, at 22.

<sup>114</sup> Jack Kaskey, *Monsanto to Charge as Much as 42% More for New Seeds (Update3)*, BLOOMBERG (Aug. 13, 2009, 5:15 PM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aLW8VZBkP3PA>.

<sup>115</sup> CENTER FOR FOOD SAFETY & SAVE OUR SEEDS, SEED GIANTS VS. U.S. FARMERS 16 (2013), available at [http://www.centerforfoodsafety.org/files/seed-giants\\_final\\_04424.pdf](http://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf).

<sup>116</sup> Kyle W. Stiegert et al., *Innovation, Integration, and the Biotechnology Revolution in U.S. Seed Markets*, CHOICES, [http://www.choicesmagazine.org/magazine/pdf/article\\_119.pdf](http://www.choicesmagazine.org/magazine/pdf/article_119.pdf) (last visited Mar. 22, 2013).



At first blush, it seems that farmers have been undeterred, with 38% of American soybean farmers using Roundup Ready seed in 1998<sup>120</sup> to 93% in 2012.<sup>121</sup> An amici curiae brief filed by the Association of Soybean Farmers stated that the swift adoption by farmers “attests to the value of biotechnology to growers . . . in efficiency, yield and profits,” despite the requirement of annual purchases and prohibitions on seed saving.<sup>122</sup> More than 90% of America’s soybean fields contain beans with the Roundup Ready trait,<sup>123</sup> as shown in Figure 4, with the top soybean states being Nebraska, Minnesota, Illinois, Iowa, and most relevant here, Indiana shown in Figure 5.

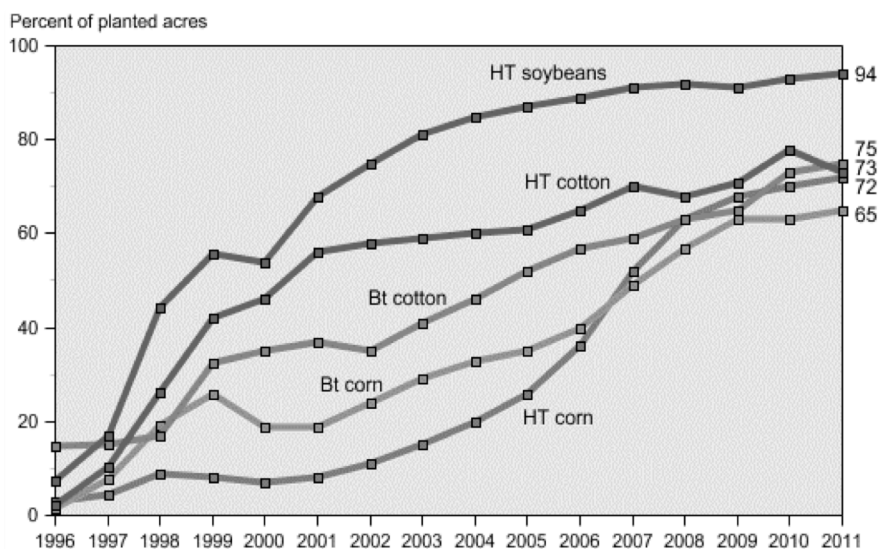


FIGURE 4: Adoption of GE Crops in the U.S.<sup>124</sup>

<sup>120</sup> Janet Carpenter & Leonard Gianessi, *Herbicide Tolerant Soybeans: Why Growers Are Adopting Roundup Ready Varieties*, AGBIOFORUM (1999), <http://agbioforum.org/v2n2/v2n2a02-carpenter.htm>.

<sup>121</sup> *Roundup Ready Soybeans*, SOURCEWATCH (Aug. 18, 2012), [http://www.sourcewatch.org/index.php/Roundup\\_Ready\\_Soybeans](http://www.sourcewatch.org/index.php/Roundup_Ready_Soybeans); Jorge Fernandez-Cornejo, *Adoption of Genetically Engineered Crops in the U.S.*, U.S. DEP’T. OF AGRIC., ECON. RES. SERV. (July 3, 2012), available at <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx#UmK0phbvMII>.

<sup>122</sup> Brief of Am. Soybean Ass’n et al. as Amici Curiae in Support of Respondents, *supra* note 31, at 18.

<sup>123</sup> U.S. Dep’t of Agric., *Genetically Engineered (GE) Soybean varieties by State and United States, 2000-2011*, USDA (July 7, 2012), <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>.

<sup>124</sup> Economic Research Service, *Recent Trends in GE Adoption*, U.S. DEP’T OF AGRIC. (July 9, 2013), <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx>.

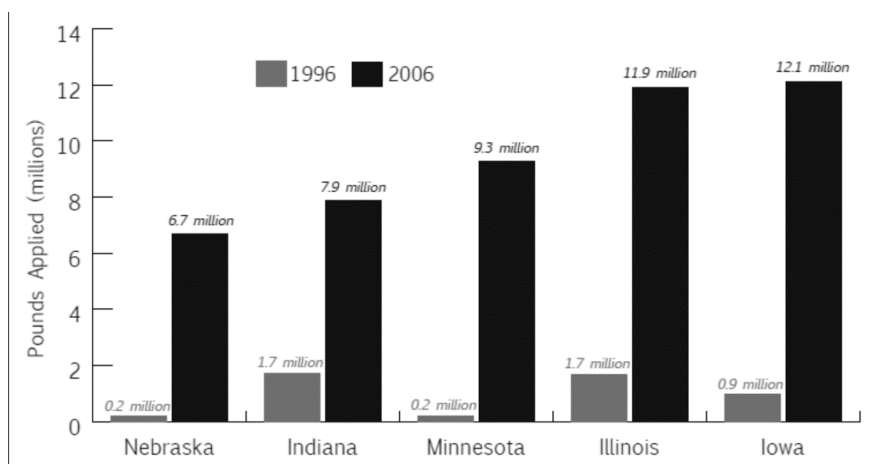


FIGURE 5: Pounds of Glyphosate Applied in Top Soybean States.<sup>125</sup>

### B. *The Road to the Supreme Court*

Monsanto commercializes its technology in two ways. First, it licenses the Roundup Ready gene to seed companies that insert the trait into the germplasm of their own seed, paying a royalty for each fifty pound bag of seed.<sup>126</sup> Seed companies then sell Roundup Ready seed to farmers.<sup>127</sup> Second, seed companies execute a license with each sale to farmers.<sup>128</sup> The seed companies are contractually restricted to selling recombinant seeds only to farmers licensed by Monsanto.<sup>129</sup>

Monsanto's license with farmers restricts them to single-season planting, and prohibits them from supplying the seed to others for planting as well as from saving harvest seed for replanting by themselves or anyone else.<sup>130</sup> Farmers typically sell their soybean

<sup>125</sup> KRISTINA HUBBARD, *OUT OF HAND: FARMERS FACE THE CONSEQUENCES OF A CONSOLIDATED SEED INDUSTRY* 38 (2009), available at <http://farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf>.

<sup>126</sup> CENTER FOR FOOD SAFETY & SAVE OUR SEEDS, *supra* note 3, at 17.

<sup>127</sup> *Monsanto Co. v. McFarling*, 488 F.3d 973, 979 (Fed. Cir. 2007).

<sup>128</sup> *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1344 (Fed. Cir. 2011).

<sup>129</sup> *Id.* at 1334–45 (“Under the Technology Agreement, the licensed grower agrees: (1) ‘to use the seed containing Monsanto gene technologies for planting a commercial crop only in a single season;’ (2) ‘to not supply any of this seed to any other person or entity for planting;’ (3) ‘to not save any crop produced from this seed for replanting, or supply saved seed to anyone for replanting;’ and (4) ‘to not use this seed or provide it to anyone for crop breeding, research, generation of herbicide registration data, or seed production.’ Monsanto restricts the grower’s use of the licensed Roundup Ready® seed to a single commercial crop season because the patented Roundup Ready® genetic trait carries forward into each successive seed generation.”) (citation omitted).

<sup>130</sup> *Monsanto Co. v. McFarling*, at 1339.

harvest directly to processors or through grain elevators.<sup>131</sup> Grain elevators do not typically sell those seeds to farmers for replanting.<sup>132</sup> Grain elevators buy a farmer's harvested crop and test the grain for weight, moisture, and impurities.<sup>133</sup> If acceptable, the grain is routinely co-mingled with grain of the same variety and sold as commodity grain used for animal feed.<sup>134</sup>

Patent law confers on Monsanto the ability to charge a fee from those seeking access to its technology. It follows from the ability to exclude that Monsanto can also control who can get access and on what terms. About 75% of agricultural patent infringement cases have involved Monsanto.<sup>135</sup> It aggressively protects its technology by suing competitors and farmers alike for patent infringement.<sup>136</sup> By January 2013, Monsanto had filed 144 infringement lawsuits against 410 farmers and 56 small businesses or farm companies, "in at least 27 different states."<sup>137</sup> Vernon Bowman, a soybean farmer from Knox County, Indiana, was one of them.

Bowman took a license from Pioneer Hi-Bred, one of Monsanto's licensed seed companies.<sup>138</sup> Each year Bowman bought seed from Pioneer for first planting of the season.<sup>139</sup> That sale was subject to a Technology Agreement restricting planting to a single season.<sup>140</sup> Bowman did not replant any of that seed.<sup>141</sup> Bowman also bought grain from a local grain elevator for more risky late season planting, as shown in Figure 6.<sup>142</sup>

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<sup>131</sup> See Brief of CropLife Am. as Amicus Curiae Supporting Affirmance, *supra* note 27, at 3.

<sup>132</sup> *Id.*

<sup>133</sup> Brief for Amicus Curiae CHS Inc. in Support of Respondents at 4, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 315222.

<sup>134</sup> *Id.*

<sup>135</sup> DIANA L. MOSS, TRANSGENIC SEED PLATFORMS: COMPETITION BETWEEN A ROCK AND A HARD PLACE?, AMERICAN ANTITRUST INSTITUTE WHITE PAPER 25 (Oct. 23, 2009), available at <http://www.antitrustinstitute.org/~antitrust/content/american-antitrust-institute-says-competition-transgenic-seed-industry-impaired-monsanto> ("About 55 percent of those cases involved Monsanto as the plaintiff and about 20 percent as the defendant. This means that the company has been involved in about three-quarters of all agricultural biotechnology litigation over the last ten years.").

<sup>136</sup> *Id.*

<sup>137</sup> See CENTER FOR FOOD SAFETY & SAVE OUR SEEDS, *supra* note 3, at 30.

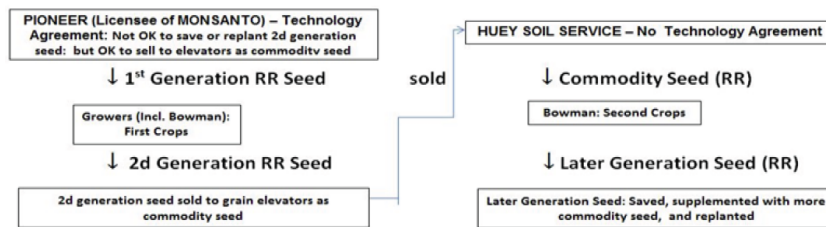
<sup>138</sup> *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1345 (Fed. Cir. 2011).

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*



**Figure 6:** Relationships Between Parties in *Bowman v. Monsanto*.<sup>143</sup>

Commodity grain is considerably cheaper than Monsanto's seed.<sup>144</sup> Monsanto had not required the grain elevator to differentiate the seeds.<sup>145</sup> Neither Monsanto nor the grain elevator imposed restrictions on Bowman's purchased grain.<sup>146</sup> Bowman applied glyphosate-based herbicide to the fields where he had planted the grain.<sup>147</sup> It is undisputed that Bowman intentionally planted the seed he bought from the grain elevator to grow a new crop of soybeans.<sup>148</sup> Bowman confirmed that many of the plants he planted in his fields in Indiana were indeed Roundup resistant.<sup>149</sup> He saved some of the crop to replant the next growing season, and continued to do so for eight successive harvests, while deliberately using the glyphosate-resistant properties.<sup>150</sup> He did not attempt to hide his activities and explained his practices to

<sup>143</sup> Judith U. Kim & Jorge A. Goldstein, *In Oral Arguments During Bowman v. Monsanto the Supreme Court Struggles with Exhaustion Doctrine for Patented Seeds*, STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. (Feb. 22, 2013), <http://skgf.com/media/pnc/1/media.1921.pdf>.

<sup>144</sup> *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1345 (Fed. Cir. 2011).

<sup>145</sup> See Brief for Amicus Curiae CHS Inc. in Support of Respondents, *supra* note 134, at 9. ("Grain is by far less expensive than seed *because* it is undifferentiated, commingled, being used for a different purpose and performs a different function than seed. Seed has a much higher margin than grain *because* it is certified, tested and tracked.")

<sup>146</sup> Daniel Winston & Margaret E. Ives, *How Bowman V. Monsanto May Wreak Havoc On Biotechnology*, LAW360 (Apr. 15, 2013), <http://www.choate.com/uploads/113/doc/How%20Bowman%20V.%20Monsanto%20May%20Wreak%20Havoc%20On%20Biotechnology.pdf>.

<sup>147</sup> *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1345 (Fed. Cir. 2011).

<sup>148</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1768 (2013).

<sup>149</sup> *Id.* at 1769.

<sup>150</sup> Brief for Respondents, *supra* note 1, at 7 ("Beginning in 1999, petitioner purchased commodity soybeans from a grain elevator and used them to grow 'second crop' soybeans—i.e., soybeans planted and harvested after another crop. As petitioner hoped and expected, most of those soybeans carried the Roundup Ready® trait. Petitioner then took advantage of the soybeans' glyphosate tolerance by spraying his fields with glyphosate, thereby killing not only the weeds but also all of the soybean plants that did not contain Monsanto's patented biotechnology. Petitioner sold most of his harvested crop to a grain elevator but saved some to plant the following year. He repeated this practice for the next eight years, adding to his stock of saved seeds by making periodic additional purchases of commodity soybeans from the grain elevator and killing off all plants that lacked the patented biotechnology by spraying his fields.")

Monsanto's representatives.<sup>151</sup>

The district court granted summary judgment on patent infringement in Monsanto's favor and the Federal Circuit affirmed for two reasons.<sup>152</sup> First, Monsanto neither made, nor permitted an unconditional sale of modified soybeans.<sup>153</sup> Rather, seeds for planting were only sold through authorized channels and subject to a license defining allowed uses.<sup>154</sup> Further, the grain sold to Bowman had various uses, including use as feed.<sup>155</sup> Second, even if exhaustion applied, each new soybean seed that Bowman grew violated Monsanto's exclusive right to "make" its invention.<sup>156</sup> The Federal Circuit justified its conclusion with the policy rationale that applying patent exhaustion to SRTs would eviscerate the rights of patent holders.<sup>157</sup> Monsanto won \$84,456 from its suit against Bowman.<sup>158</sup> Ironically, it was Bowman's bankruptcy that provided the financial insulation and impetus for continuing his struggle against Monsanto, first by representing himself pro se, and eventually through pro bono representation at the Supreme Court.<sup>159</sup>

On December 3, 2012, Bowman filed a petition for a writ of certiorari to the Supreme Court, placing before the Court two questions for consideration: "[w]hether the Federal Circuit erred by (1) refusing to find patent exhaustion in patented seeds even after an authorized sale and by (2) creating an exception to the doctrine of patent exhaustion for self-replicating technologies?"<sup>160</sup>

The Court invited the Solicitor General to file a brief expressing the government's views on the issue.<sup>161</sup> The Solicitor General recommended against taking the case, warning of unforeseen consequences for other SRTs such as "man-made cell lines, DNA molecules, [and] some nanotechnologies," advising instead that the Court allow case law to develop further before deciding on the limits of

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<sup>151</sup> *Monsanto Co. v. Bowman*, 657 F.3d at 1346.

<sup>152</sup> *Id.* at 1343.

<sup>153</sup> *Id.* (holding that the exhaustion doctrine was not implicated since the sales were conditional).

<sup>154</sup> *Id.*

<sup>155</sup> *Id.* at 1348.

<sup>156</sup> *Id.* ("Even if Monsanto's patent rights in the commodity seeds are exhausted, such a conclusion would be of no consequence because once a grower, like Bowman, plants the commodity seeds containing Monsanto's Roundup Ready® technology and the next generation of seed develops, the grower has created a newly infringing article.").

<sup>157</sup> *Monsanto Co. v. Bowman*, 657 F.3d at 1348.

<sup>158</sup> See Garofalo, *supra* note 3.

<sup>159</sup> *Id.*

<sup>160</sup> Petition for a Writ of Certiorari *Bowman v. Monsanto Co.*, No. 11-796 (Dec. 20, 2011), 2011 WL 6468161.

<sup>161</sup> See *U.S. Supreme Court Seeks Input from Solicitor General in Monsanto Patent Exhaustion Case*, V&E IP INSIGHTS E-COMMUNICATION (Apr. 4, 2012), <http://www.velaw.com/resources/SupremeCourtSeeksInputSolicitorGeneralMonsantoPatentExhaustionCase.aspx>.



patent exhaustion in this area.<sup>162</sup> Moreover, the brief urged Congress was “better equipped” to resolve competing policy considerations.<sup>163</sup> One such concern was the likelihood that Monsanto would be limited to charging for a single sale if exhaustion indeed applied, as farmers would be able to save and plant seeds from their harvests thereafter.<sup>164</sup> At the same time, while the issue did not arise in *Bowman v. Monsanto*, the brief implicitly cautioned that the Federal Circuit should scrupulously adopt the Supreme Court precedent in favor of the Federal Circuit’s own earlier precedent to avoid fueling a petition for review in some future case.<sup>165</sup>

Despite the Solicitor General’s recommendation to the contrary, the Court granted Bowman’s petition. The significance of the Court’s getting it right in the *Bowman v. Monsanto* case was not lost to Solicitor General Donald B. Verrilli, Jr., who noted at a public forum that the Court had “some very significant questions before it” and “its determination about whether a company’s patent for a genetically-modified seed extends to the seeds’ successive generations, which may have far-reaching implications beyond the soybean industry.”<sup>166</sup>

The case attracted an unusually large number of amicus briefs—twenty-three, filed by a wide range of interests, from companies selling software to those selling spare parts.<sup>167</sup> Eighteen briefs sided with Monsanto. Some of the briefs were from predictable sources—patent-centric businesses and associations, and Monsanto’s rival and licensee, Pioneer.<sup>168</sup> Notably, the American Soybean Association (“ASA”), representing 22,000 farmers in thirty-one states, was counted among the

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<sup>162</sup> Brief for the United States as Amicus Curiae, *supra* note 1, at 19 (“The Court should allow the case law to develop further before considering whether to adopt a more restrictive definition of “making” that could have unforeseen consequences for other present and future self-replicating technologies.”).

<sup>163</sup> *Id.* at 18.

<sup>164</sup> *Id.* at 17–18. For example, the brief recognized the reality that adopting the view that exhaustion applied to progeny seeds could mean that “[t]he incentive to invest in innovation and research might well be diminished if the patent term for genetically modified crops was effectively reduced from 20 years to a single year or even a single growing season.” *Id.* at 18.

<sup>165</sup> *Id.* at 32–33.

<sup>166</sup> Danielle Dellerson, Past, Present Solicitors General Shine Light on Overshadowed Cases, 85 PATENT, TRADEMARK & COPYRIGHT J. 649, 673 (2013); see *Clement and Verrilli: “Supreme Court Review: The Most Important Cases Affecting Business and Their Implications,”* GEORGETOWN LAW (Mar. 4, 2013), <http://www.law.georgetown.edu/news/clement-and-verrilli-supreme-court-review.cfm>.

<sup>167</sup> See Brief Amici Curiae of Auto. Aftermarket Indus. Ass’n et al. in Support of the Petitioner, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2012 WL 6203694; Brief of the BSA | The Software Alliance as Amicus Curiae in Support of Respondents, *Bowman v. Monsanto Co.*, No. 11-796 (Jan. 23, 2013), 2013 WL 267020.

<sup>168</sup> Some of those predictable sources include the American Intellectual Property Law Association, Biotechnology Industry Organization, CropLife International and CropLife America, Intellectual Property Owners Association, New York Intellectual Property Law Association, Pioneer Hi-Bred International, Inc., Wisconsin Alumni Research Foundation.

ranks of Monsanto's supporters.<sup>169</sup> The ASA declared that "[w]eeds are the most significant economic challenge to global food production,"<sup>170</sup> and that farmers "readily adopted" Roundup Ready seed even though it was "more expensive than conventional seed" because it "simplified weed management."<sup>171</sup> Bowman's supporters included after-market interests, food-related non-profits, and the American Antitrust Institute ("AAI").<sup>172</sup> One issue that parties on both sides agreed on was that exhaustion or infringement was an inappropriate means to address the issue.<sup>173</sup> Another was that Congress would be better placed to devise exceptions to the rule.<sup>174</sup>

Patent blogger and attorney Gene Quinn, in reflecting on the oral arguments on February 19, 2013, wrote "[i]n what can only be characterized as a *VERY* hot Supreme Court, the questions and banter did not cease."<sup>175</sup> A key recurring theme was raised by Chief Justice John Roberts at the very start: "Why in the world would anybody spend any money to try to improve the seed if as soon as they sold the first one anybody could grow more and have as many of those seeds as they want?"<sup>176</sup>

Justice Kagan noted that contracts seem an insufficient means for patent owners to appropriate their investments "because all that has to happen is that one seed escapes the web of these contracts, and that seed because it can self-replicate in the way that it can, essentially makes all the contracts worthless."<sup>177</sup> She also noted that a buyer does not have the right to make a copy of the article and Bowman was looking for an exception.<sup>178</sup>

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<sup>169</sup> See Brief of Am. Soybean Ass'n et al. as Amici Curiae in Support of Respondents, *supra* note 31.

<sup>170</sup> *Id.* at 4.

<sup>171</sup> *Id.* at 18.

<sup>172</sup> See Brief of Amici Curiae the Am. Antitrust Inst. et al., *Bowman*, 133 S. Ct. 1761 (No.11-796), 2012 WL 6208274; Brief of Auto. Aftermarket Indus. Ass'n et al. in Support of the Petitioner, *supra* note 167; Brief for Amici Curiae Ctr. for Food Safety & Save Our Seeds in Support of Petitioner, *Bowman*, 133 S. Ct. 1761 (No.11-796), *supra* note 110.

<sup>173</sup> See, e.g., Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 17 ("Rather, if petitioner's approach were adopted, the first authorized sale of a single Roundup Ready soybean would extinguish all of respondent's patent rights to that soybean and to all of its progeny.").

<sup>174</sup> *Id.* ("The carefully tailored exemptions and defenses Congress has enacted in similar contexts, including the PVPA, are simply unavailable to this Court.").

<sup>175</sup> Gene Quinn, *Argument Summary: Supreme Court Hears Bowman v. Monsanto*, IPWATCHDOG (Feb. 20, 2013, 2:54 PM), <http://www.ipwatchdog.com/2013/02/20/argument-summary-supreme-court-hears-bowman-v-monsanto/id=35787/>. Mark Walters represented Vernon Bowman, Melissa Arbus Sherry represented the United States (supporting Monsanto's position) and Seth Waxman represented Monsanto. *Id.*

<sup>176</sup> Transcript of Oral Argument at 3, *Bowman v. Monsanto Co.*, No. 11-796 (Feb. 19, 2013).

<sup>177</sup> *Id.* at 19.

<sup>178</sup> *Id.* at 14. Justice Breyer seemed to concur: "[w]hen you create a new generation, you have made a patented item, which you cannot do without the approval of the patent owner." *Id.* at 16.

In response to deference to Congressional action, Justice Ginsburg suggested that the issue of SRTs “need not be left to Congress because this issue had not come up before and the Court had never found that an exception does or does not apply and would therefore not be going against precedent in deciding the case.”<sup>179</sup> She replied that “the seeds are owned by the farmer. But when he uses them to grow more seeds, he’s infringing on that patent. So I don’t think that the ownership has anything to do with it.”<sup>180</sup> Echoing the Federal Circuit, the U.S. government argued that exhaustion was not at issue and that applying exhaustion would reduce twenty years of exclusivity conferred by patent law to a one-time sale.<sup>181</sup> In response, Chief Justice Roberts reiterated Justice Ginsburg’s willingness for the Court to speak on the issue and said that merely because the Court had not applied exhaustion in the context of SRTs did not rule out its applicability here.<sup>182</sup>

Justice Scalia expressed concern about “innocent” infringers, who did not intend to plant traited seeds, being sued,<sup>183</sup> a concern shared by Justices Kennedy and Kagan,<sup>184</sup> the latter noting that it was a “worrisome thing” because Monsanto’s position had “the capacity to make infringers out of everybody. And that is highlighted actually in this case by how successful this product is and how large a percentage of the market it has had.”<sup>185</sup> Justice Kagan also wanted the government’s view on whether the Federal Circuit’s conditional sale doctrine was “causing trouble as it presently exists in the Federal Circuit.” Again the government replied that the Court need not do anything about it in this case.<sup>186</sup>

The performance of former Solicitor General Seth Waxman, who represented Monsanto, was described as “a tour-de-force.”<sup>187</sup> Waxman argued that Roundup Ready was like a vaccine and that “it’s unsupportable to say that you cannot sell a quantity of that vaccine

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<sup>179</sup> Krista Cox, *SCOTUS Oral Arguments in Bowman v. Monsanto; Court to Decide Application of Patent Exhaustion to Self-Replicating Technology*, KNOWLEDGE ECOLOGY INTERNATIONAL (Feb. 19, 2013), <http://keionline.org/node/1654>; see Transcript of Oral Argument, *supra* note 176, at 13.

<sup>180</sup> Transcript of Oral Argument, *supra* note 176, at 17.

<sup>181</sup> *Id.* at 27.

<sup>182</sup> *Id.* at 25–26.

<sup>183</sup> Transcript of Oral Argument at 27, *Bowman v. Monsanto Co.*, No. 11-796 (Feb. 19, 2013).

<sup>184</sup> *Id.* at 54–55; *id.* at 41.

<sup>185</sup> *Id.* at 41.

<sup>186</sup> *Id.* at 34. The “conditional sale” doctrine, as articulated by the Court of Appeals for the Federal Circuit, allowed the patent owner to retain the right to sue for patent infringement as long as the payment received was less than the full value of the rights embodied in the patent sold.

<sup>187</sup> Dennis Crouch, *Oral Arguments in Bowman v. Monsanto*, PATENTLY-O (Feb. 20, 2013), <http://www.patentlyo.com/patent/2013/02/bowman-v-monsanto.html> [hereinafter Crouch, *Oral Arguments in Bowman v. Monsanto*].

without exhausting all of your rights in it.”<sup>188</sup> Chief Justice Roberts pointed out that was “not quite on point because it’s not a situation where the intended use of the vaccine necessarily results in regeneration of it.”<sup>189</sup> Justice Breyer wanted to know if there was a patent law provision that dealt with SRTs that “end[s] up inadvertently all over the place.”<sup>190</sup> Waxman conceded that infringement was a strict liability tort but required volitional conduct which was absent if infringement was truly inadvertent.<sup>191</sup>

### C. Judgment

Leading newspapers and intellectual property blogs guessed that the ruling would be unanimous.<sup>192</sup> And so it was.<sup>193</sup> The Court held that buying seed that had been legitimately sold did not confer on Bowman the right to replant and make new seeds without Monsanto’s permission.<sup>194</sup> What the patent exhaustion doctrine allowed Bowman to do was to “resell the patented soybeans he purchased from the grain elevator” and “consume the beans himself or feed them to his animals.”<sup>195</sup> It did “not enable Bowman to make *additional* patented soybeans without Monsanto’s permission (either express or implied).”<sup>196</sup> In doing so, the Court recognized that a “use” that impinged on the “make” right was an impermissible use since the

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<sup>188</sup> Transcript of Oral Argument, *supra* note 176, at 51. *Contra* Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 18 (“[These patents] would lose much of their value if purchasers of patented bacteria or other self-replicating products could reproduce and sell those items free from the restraints of patent law.”).

<sup>189</sup> Transcript of Oral Argument, *supra* note 176, at 52.

<sup>190</sup> *Id.* at 44.

<sup>191</sup> *Id.*

<sup>192</sup> Crouch, *Oral Arguments in Bowman v. Monsanto*, *supra* note 187 (“My expectation here is that the court will side with Monsanto and find that a sale of patents [sic] seeds does not exhaust the patent rights as to progeny seeds that are grown. I will not be surprised if that result is 9-0.”); Adam Liptak, *Supreme Court Appears to Defend Patent on Soybean*, NYTIMES.COM (Feb. 19, 2013), <http://www.nytimes.com/2013/02/20/business/justices-signal-a-monsanto-edge-in-patent-case.html> (“A lawyer for Monsanto, Seth P. Waxman, a former United States solicitor general, was allowed to talk uninterrupted for long stretches, which is usually a sign of impending victory.”); Quinn, *supra* note 175 (“While one can never know for certain how the Supreme Court will rule, even a casual observer has to conclude that the Supreme Court seems poised [to] rule in favor of Monsanto.”).

<sup>193</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1768 (2013).

<sup>194</sup> *Id.* at 1764 (2013) (“Under the doctrine of patent exhaustion, the authorized sale of a patented article gives the purchaser, or any subsequent owner, a right to use or resell that article. Such a sale, however, does not allow the purchaser to make new copies of the patented invention.”); *see also id.* (“The question in this case is whether a farmer who buys patented seeds may reproduce them through planting and harvesting without the patent holder’s permission. We hold that he may not.”).

<sup>195</sup> *Id.* at 1766.

<sup>196</sup> *Id.*

“make” right was not exhausted by Monsanto’s authorized first sale.<sup>197</sup> This conclusion also accords with the notion that exhaustion applies only to the particular article sold.<sup>198</sup> The Court noted that it would be contrary to its own precedent in *J.E.M.* which denied farmers the right to save harvested seed for replanting where the technology was patented, unlike protection under the PVPA, which allowed replanting.<sup>199</sup>

At its core, the judgment sought to ensure that Monsanto’s inventive concept was adequately protected against unjustified freeriding. The Court rejected Bowman’s “blame the bean” defense.<sup>200</sup> According to the Court, Bowman was not a passive observer, nor did his seeds spontaneously create successive soybean crops.<sup>201</sup> Since most of the local farms use Roundup Ready soybean seeds, Bowman “could anticipate that many of the purchased soybeans would contain Monsanto’s patented technology.”<sup>202</sup> Over eight successive harvests, he openly “planted Monsanto’s patented soybeans solely to make and market replicas of them, thus depriving the company of the reward patent law provides for the sale of each article. Patent exhaustion provides no haven for that conduct.”<sup>203</sup>

The Court reasoned that if Bowman could make and sell endless copies of Monsanto’s seed, the patent would effectively protect just a single sale.<sup>204</sup> Here Bowman faced the difficult task of convincing the Court that his conduct was a fair exploitation of a legal loophole that, if upheld, would not critically undermine a system of appropriation that underlies innovation in crops upon which farmers like Bowman depend.<sup>205</sup> The Court thereby drew a line at “making” the seeds by using them, finding that such a “use” would cause patents to “plummet in value after the first sale of the first item containing the invention.”<sup>206</sup>

The Court also addressed the broader issue of SRTs, albeit obliquely. It recognized that such technologies were “becoming ever

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<sup>197</sup> *Id.* at 1764.

<sup>198</sup> *Id.* at 1766 (“Consistent with that rationale, the doctrine restricts a patentee’s rights only as to the “particular article” sold . . . .”).

<sup>199</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1768.

<sup>200</sup> *Id.* at 1769 (“But we think that blame-the-bean defense tough to credit.”).

<sup>201</sup> *Id.* (“In all this, the bean surely figured. But it was Bowman, and not the bean, who controlled the reproduction (unto the eighth generation) of Monsanto’s patented invention.”).

<sup>202</sup> *Id.* at 1765.

<sup>203</sup> *Id.* at 1769.

<sup>204</sup> *Id.* at 1766.

<sup>205</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1769 (2013) (“Our holding today is limited—addressing the situation before us, rather than every one involving a self-replicating product.”).

<sup>206</sup> *Id.* at 1768 (“Reproducing a patented article no doubt ‘uses’ it after a fashion. But as already explained, we have always drawn the boundaries of the exhaustion doctrine to exclude that activity, so that the patentee retains an undiminished right to prohibit others from making the thing his patent protects.”).

more prevalent, complex, and diverse,” and sought to find the correct balance between innovation and reward.<sup>207</sup> On one hand, it seems clear that the Court recognized that siding with Bowman may result in more robust rights for farmers and users of patented technology in general. At the same time, interpreting this “first sale” doctrine too broadly could destabilize innovation incentives in these industries.

Recognizing the potential for unintended consequences, the Court stressed the limited nature of its holding. It noted that in another case, reproduction “might occur outside the purchaser’s control” or “might be a necessary but incidental step in using the item for another purpose.”<sup>208</sup> An example of the former would be pollen drift. The threat of transgenic contamination troubled organic farmers sufficiently for them to seek a declaratory action for invalidity against Monsanto.<sup>209</sup> An example of the latter would be replicating pluripotent stem cells, plasmids or recombinant genes for diagnostic or therapeutic uses.<sup>210</sup> This issue is discussed further in the next part of the Article.

One commentator, troubled by the Court’s lack of guidance in these areas, observed that “the question persists as to whether such replication will be permitted or considered an unlicensed ‘remanufacture’ or new making of the original, patented item.”<sup>211</sup> Commentators have uniformly regarded the cabining of *Bowman v. Monsanto* to its particular facts as more illusory than real.<sup>212</sup> More

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<sup>207</sup> *Id.* at 1769.

<sup>208</sup> *Id.*

<sup>209</sup> *Organic Seed Growers & Trade Ass’n v. Monsanto Co.*, 718 F.3d 1350 (Fed. Cir. 2013).

<sup>210</sup> *See, e.g.*, Tony Dutra, *Unanimous Supreme Court Says No Patent Exhaustion for Monsanto Roundup Seeds*, BLOOMBERG BNA (May 14, 2013), <http://www.bna.com/unanimous-supreme-court-n17179874022/>.

<sup>211</sup> Chris Jeffers et al., *How Monsanto Applies to Nonagricultural Biotechnology*, LEXOLOGY (May 23, 2013), <http://www.lexology.com/library/detail.aspx?g=014a4e9a-35fa-4010-a8d1-f2ddcbf33fd2> (“Biotechnology inventions such as cell lines, bacteria, and other living material often must exist in a condition of continuous self-replication simply to be maintained for any use. Vectors, plasmids, *etc.*, replicate within cells, and from generation to generation within host cells, allowing for production of vastly more nucleic acid copies than initially used for transfection. Even small linear nucleic acids such as those used for primers and probes may be ‘replicated’ to generate large quantities relatively easily using PCR or other methods in molecular biology. In each case, (cells, viruses, vectors, probes), something analogous to planting, watering, cultivating, is required.”).

<sup>212</sup> Dutra, *supra* note 210 (“Though she acknowledged that the court explicitly limited its decision to the facts of this case, Jean [Patrice P. Jean of Kenyon & Kenyon, New York] asserted that the court’s language related to the economic benefit concern “suggested that the court can and might apply an exclusion of the exhaustion doctrine to other self-replicating technologies on a case by case basis depending on whether it believes application of the doctrine would stifle innovation.”); *see also* Paul Warden-Hutton & Nigel J. Parker, *Fe fi fo fum—Bowman [sic], Monsanto and the Soybeanstalk*, LEXOLOGY (May 22, 2013), <http://www.lexology.com/library/detail.aspx?g=d52ab8de-b571-4365-ae66-85c993f6a206> (“[T]he Decision in this US case has broader application than just the field of biological sciences because self-replication occurs in other arts, such as the electronic arts, in for example, code replication and in the Chemical arts in, for example, polymerization reactions. . . . [T]he Court’s rationale should be of benefit to future

fundamentally, the Court seemed to be carving out judicial exceptions for SRTs. The patent statute establishes strict liability for patent infringement.<sup>213</sup> The intent of those using, making, or selling the patented plant without authorization is irrelevant. If industry-specific exceptions to infringement are warranted for incidental or unintentional reproduction of the patented article, then Congress rather than the courts must be the appropriate forum for the balancing of competing interests.<sup>214</sup>

Another issue that remained unresolved in the wake of *Bowman v. Monsanto* was the Federal Circuit's "conditional sale" doctrine, which would have allowed patent owners to sue for patent infringement if a purchaser breached a contractual term restricting it from reselling or using the article in a specified manner.<sup>215</sup> In its brief, the U.S. government had expressly noted that the doctrine allowed "patent holders to retain control over the use or resale of a patented article even after an authorized sale of that article has occurred—the very thing the exhaustion doctrine is intended to prevent."<sup>216</sup> Justice Sonia Sotomayor had asked whether the Court was "explicit enough in *Quanta*" that it did not "have to address whatever lingering confusion the Federal Circuit may have with respect to conditional sales at all in this case[.]"<sup>217</sup> Monsanto's counsel, Seth Waxman, avoided the issue by responding that the Federal Circuit did not rely on it in *Bowman v. Monsanto*, and nothing was said about it in the Court's opinion.<sup>218</sup>

As early as at the end of the oral arguments, it was clear that the biggest question was not who would win. Rather, it was why the Supreme Court had even taken the case. Against the Solicitor General's advice, at least four justices wanted to hear the case.<sup>219</sup> Yet both the oral arguments and judgment showed that Bowman's attorney, Mark Walters, seemed alone on the view that the patent rights of Monsanto should not extend to the progeny of seeds that it had sold with its full

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considerations of self-replicating technologies, regardless of the technical field, because a determination of whether or not the alleged infringing act has derived the benefit of the patented invention will be pertinent to a finding of infringement or otherwise.").

<sup>213</sup> 35 U.S.C. § 271(a) (2010) (intent or fault are not listed as elements of patent infringement); see also Jessica Lynd, Comment, *Gone with the Wind: Why Even Utility Patents Cannot Fence in Self-Replicating Technologies*, 62 AM. U. L. REV. 663, 666 (2013) ("Patent infringement is a strict liability offense, and, as such, intent or fault on the part of the alleged infringer is irrelevant. In addition, courts have not found it relevant to infringement that the GM contamination actually causes financial and legal harm to the alleged infringer by contaminating his or her conventional crop and trespassing onto his or her land.").

<sup>214</sup> See *infra* note 278.

<sup>215</sup> *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992).

<sup>216</sup> Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 7.

<sup>217</sup> Transcript of Oral Argument at 49, *Bowman v. Monsanto Co.*, No. 11-796 (Feb. 19, 2013).

<sup>218</sup> *Id.* at 3.

<sup>219</sup> On the "rule of four", see generally *Rogers v. Missouri Pac. R. Co.*, 352 U.S. 521 (1957).

permission, and which had been bought by Bowman without any restrictions for over eight years.

The answer may well be that *Bowman v. Monsanto* was never just about Bowman. In *Bilski v. Kappos*, the Court was asked to determine whether a method of risk hedging was patentable subject matter.<sup>220</sup> Observers largely agreed that the case was straightforward on facts but called into question broader issues which the Court wanted to address.<sup>221</sup> In *Bilski*, it was the rejection of the Federal Circuit's "machine-or-transformation" test as the sole test for determining patent eligibility.<sup>222</sup>

What about *Bowman v. Monsanto*? The oral arguments and judgment indicate that there are three themes that concerned the Court. First, the Court sought to draw a workable distinction between the exclusive right to "use" and "make" in the context of SRTs.<sup>223</sup> Second and relatedly, the Court sought to determine whether there was a more appropriate business model to reconcile the competing interests of the owners and users of SRTs.<sup>224</sup> Third, the Court was concerned about how the strict liability nature of patent infringement would potentially ensnare those who unknowingly or even unwillingly "make" the invention in the course of normal business or social activities.<sup>225</sup> It is to these that the discussion will now turn.

## II. THE LIMITS OF EXHAUSTION

Patent exhaustion is over a hundred and fifty years old.<sup>226</sup> New technologies continue to challenge its limits, and those that self-replicate join a long line of predecessors. Part A highlights three important lessons that may be gleaned about patent exhaustion: first, that an authorized sale exhausts general "use" restrictions on a patented

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<sup>220</sup> *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>221</sup> See, e.g., *Patentable Subject Matter: In re Bilski*, WILMERHALE, [http://www.wilmerhale.com/Patentable\\_Subject\\_Matter\\_In\\_re\\_Bilskii\\_Current\\_Development/](http://www.wilmerhale.com/Patentable_Subject_Matter_In_re_Bilskii_Current_Development/) (last visited Mar. 22, 2013) ("As largely expected, the Supreme Court on June 28, 2010 held that the claims of Bernard Bilski's and Rand Warsaw's patent application were not directed to patentable subject matter.").

<sup>222</sup> *Bilski*, 130 S. Ct. at 3227 ("The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'").

<sup>223</sup> See e.g., *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1768 (2013) ("Reproducing a patented article no doubt 'uses' it after a fashion. But as already explained, we have always drawn the boundaries of the exhaustion doctrine to exclude that activity, so that the patentee retains an undiminished right to prohibit others from making the thing his patent protects.").

<sup>224</sup> *Id.* ("[I]f simple copying were a protected use, a patent would plummet in value after the first sale of the first item containing the invention.").

<sup>225</sup> *Id.* at 1769.

<sup>226</sup> *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008) ("For over 150 years this Court has applied the doctrine of patent exhaustion to limit the patent rights that survive the initial authorized sale of a patented item.").



article; second, that post-sale restrictions are enforced under contract law, not patent law; third, the sale of articles substantially embodying patented technologies can exhaust those technologies, and even other associated patented technologies associated with its use, if no creative or inventive decision is required in practicing the invention.

An argument may be offered that no creative or inventive decision was required to “making” new seed from the old in *Bowman v. Monsanto*. But the Court was closed to a reading of uses of the seed that would result in the reproduction of new seed. Part B examines the dichotomy between “make” and “use”, and proposes a three-step test to provide a commercially workable balance between the interests of innovators in self-replicating technologies and their users. Part C surveys five alternatives to patent infringement, and explains why their limitations justify the Court’s holding in *Bowman*. Part D confronts the externalities created by the Court’s holding—the risk of “innocent” and “incidental” infringement, as well as those who remain liable for patent infringement under the Federal Circuit’s “conditional sale” doctrine.

#### A. Three Lessons from History

Patent exhaustion dates back at least to the 1873 decision of *Adams v. Burke*.<sup>227</sup> Burke, an undertaker, bought coffin lids from a company licensed to sell them only within a ten-mile radius of Boston.<sup>228</sup> The assignee sued Burke for using the lids he bought in its territory, which fell outside the territorial restriction. In finding for Burke, the Supreme Court recognized the separability of rights conferred by the patent to sell, make, and use.<sup>229</sup> At the same time, once the patented article is sold, the patentee has received its reward, and the buyer obtains a right to use it free of the restraint.<sup>230</sup> In the context of seeds and other SRTs it is significant that the Court noted that this principle “must be much more applicable to an instrument or product of patented manufacture which perishes in the first use of it, or which, by

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<sup>227</sup> *Adams v. Burke*, 84 U.S. 453, 455 (1873) (“The question presented by the plea in this case is a very interesting one in patent law, and the precise point in it has never been decided by this Court, though cases involving some of the considerations which apply to it have been decided, and others of analogous character are frequently recurring.”). “When a machine passes to the hands of a purchaser, it is no longer within the limits of the monopoly; it passes outside of it, and is no longer under the protection of the act of Congress.” *Id.* at 460 (referring to the lower court’s reliance on the principle enunciated in *Bloomer v. McQuewan*, 55 U.S. 539 (1852)).

<sup>228</sup> *Adams v. Burke*, 84 U.S. 453, 457 (1873).

<sup>229</sup> *Id.* at 456 (“The right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee.”).

<sup>230</sup> *Id.* at 455 (“[T]he sale by a person who has the full right to make, sell and use . . . a machine carries with it the right to the use of that machine to the full extent to which it can be used in point of time.”); *id.* at 456 (reasoning that the sale constitutes “all the royalty or consideration which he claims for the use of his invention in that particular machine or instrument”).

that first use, becomes incapable of further use, and of no further value.”<sup>231</sup>

*Adams* thus introduces the first aspect of patent exhaustion: that an authorized sale exhausts general “use” restrictions on a patented article. As Alfred Server and William Casey observe, a cornerstone of the *Adams* Court’s decision—that the patent owner had received its reward—“has been interpreted differently by the courts over the years.”<sup>232</sup> One interpretation is the “single reward” view expressed by the Supreme Court in *Hobbie v. Jennison*, self-styled as “the true interpretation of the decision in *Adams v. Burke*,” where the patent owner is entitled to a single payment at the time of sale.<sup>233</sup> Another is the “conditional sales” doctrine articulated by the Court of Appeals for the Federal Circuit in *Mallinckrodt, Inc. v. Medipart, Inc.*, where the patent owner retained the right to sue for patent infringement as long as the payment received was less than the full value of the rights embodied in the patent sold.<sup>234</sup> *Mallinckrodt* re-animated, within articles that had been sold, the rights of patent owners to control patented articles as they made their way through downstream channels of trade.<sup>235</sup> Only if it “ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason” would those conditions be prohibited.<sup>236</sup> This split was central to the outcome in *Bowman v. Monsanto*; the missed opportunity to clarify the issue will mean that it will likely to resurface in future cases.

The second important proposition of law was articulated in 1895 by the Court in *Keeler v. Standard Folding-Bed Co.*<sup>237</sup> In holding that patent rights over beds re-sold in Massachusetts were exhausted by a first sale in Michigan, the Court recognized that post-sale restrictions were enforced under contract law and not patent law.<sup>238</sup> In 1938, the

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<sup>231</sup> *Id.* at 456.

<sup>232</sup> Alfred C. Server & William J. Casey, *Contract-Based Post-Sale Restrictions on Patented Products Following Quanta*, 64 HASTINGS L.J. 561, 567 (2013).

<sup>233</sup> *Hobbie v. Jennison*, 149 U.S. 355, 361 (1893).

<sup>234</sup> *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (1992) (holding that a manufacturer of medical equipment could sue a company that refurbished equipment covered by “single use” licensing restrictions for infringement). The *Mallinckrodt* court reasoned that because the sale was conditional, patent exhaustion did not apply. *Id.* In *B. Braun Medical, Inc. v. Abbott Labs.*, the court elaborated that with conditional sales, the patent owner did not receive “an amount equal to the full value of the goods.” 124 F.3d 1419, 1426 (Fed. Cir. 1997). It was “more reasonable to infer that the parties negotiated a price that reflects only the value of the ‘use’ rights conferred by the patentee.” *Id.*

<sup>235</sup> Downing-Howk, *supra* note 95, at 53 (“Restrictions on sales which would have been forbidden under the Doctrine of Patent Exhaustion were allowed as a result of the *Mallinckrodt* decision if the sale was rewritten as a limitation on the scope of a license.”).

<sup>236</sup> See *Mallinckrodt*, 976 F.2d at 708.

<sup>237</sup> *Keeler v. Standard Folding-Bed Co.*, 157 U.S. 659 (1895).

<sup>238</sup> *Id.* at 666 (“[O]ne who buys patented articles of manufacture from one authorized to sell them becomes possessed of an absolute property in such articles, unrestricted in time or place. Whether

Court in *General Talking Pictures Corp. v. Western Electric Co.* provided an important caveat to this proposition.<sup>239</sup> The patentee in that case restricted licensees in selling patented amplifiers to private home radio users and not for commercial use in theatres.<sup>240</sup> In finding that exhaustion was not triggered because the patentee had expressly prohibited sale for commercial use, the Court found both the licensee and the buyer infringed the patents.<sup>241</sup>

In 1942, the Court articulated the third important proposition of law in a case blending antitrust into the law of exhaustion.<sup>242</sup> The Univis Lens Company was licensed to make and sell lens blanks to other licensees for use in eyeglasses at a price specified by the patent owner.<sup>243</sup> The government challenged the resale price maintenance arrangement as a violation of the Sherman Act.<sup>244</sup> The Court held that the exhaustion of its patents removed any justification for controlling the prices of the lens blanks sold, even though the lens blanks did not fully embody the patent until they were finished as multifocal eyeglass lenses.<sup>245</sup> The Court found that the lens blanks embodied the “essential features” of the patent and “has destined . . . to be finished by the purchaser in conformity to the patent, he has sold his invention so far as it . . . may be embodied in that particular article.”<sup>246</sup> In light of the Court’s recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, one might say that the last step amounted to “insignificant post-solution activity.”<sup>247</sup> *Univis* left open the question of whether “essential features” meant all the elements recited in the

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a patentee may protect himself and his assignees by special contracts brought home to the purchasers is not a question before us, and upon which we express no opinion. It is, however, obvious that such a question would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws.”).

<sup>239</sup> *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175 (1938), *reh’g granted*, 305 U.S. 124 (1938), *reh’g denied*, 305 U.S. 675 (1939).

<sup>240</sup> *Id.* at 180.

<sup>241</sup> *Id.* at 182.

<sup>242</sup> *United States v. Univis Lens Co.*, 316 U.S. 241 (1942).

<sup>243</sup> *Id.* at 243–44.

<sup>244</sup> *Id.* at 242–43.

<sup>245</sup> *Id.* at 252 (“Whether the licensee sells the patented article in its completed form or sells it before completion for the purpose of enabling the buyer to finish and sell it, he has equally parted with the article, and made it the vehicle for transferring to the buyer ownership of the invention with respect to that article. To that extent he has parted with his patent monopoly in either case, and has received in the purchase price every benefit of that monopoly which the patent law secures to him.”).

<sup>246</sup> *Id.* at 251; *see id.* at 249 (“[E]ach blank . . . embodies essential features of the patented device and is without utility until it is ground and polished as the finished lens of the patent.”).

<sup>247</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1298 (2012) (quoting *Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); *see also id.* (“[A]ny additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.”).

claim.<sup>248</sup> This question had to wait half a century more for its answer.

*Univis* also showed that patentees who find themselves on the wrong side of an exhaustion finding might be in peril of violating the antitrust laws.<sup>249</sup> In light of the more permissive view of resale price maintenance agreements following from *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, while patent owners may find themselves with exhausted patent rights, antitrust liability is no longer automatic.<sup>250</sup> At the time, patent owners would do well to recognize from *Univis* that acting within the scope of their patent rights is no bar to exhaustion.<sup>251</sup> And indeed, as the Court in *Federal Trade Commission v. Actavis, Inc.* recently held, neither will this justification shield them from antitrust violations.<sup>252</sup>

These three propositions of law came together in 2008 in *Quanta Computer, Inc. v. LG Electronics, Inc.*<sup>253</sup> LG Electronics licensed software patents to Intel Corp. with rights to “make, use, sell (directly and indirectly), offer to sell, [or] import” products practicing its patents, but restricted those rights to Intel and not to third party buyers.<sup>254</sup> Ostensibly to avoid falling afoul of federal preemption, the license noted that it was not intended to modify the principles of patent exhaustion.<sup>255</sup> Quanta Computer bought microprocessors and chipsets from Intel and combined them with non-Intel components in violation of a separate agreement between LG and Intel that the latter would notify its buyers not to engage in the prohibited combination.<sup>256</sup>

The Court reiterated its earlier position in *Univis*, stating that exhaustion applied even if the articles themselves did not fully embody the patent as long as they embodied its “essential features” and their “only reasonable and intended use” was to practice the patent.<sup>257</sup> Intel’s products had “no reasonable noninfringing use” because there was no reasonable way to use Intel’s chipsets until the chipsets were connected to buses and memory by computer manufacturers such as Quanta.<sup>258</sup>

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<sup>248</sup> Yuichi Watanabe, *The Doctrine of Patent Exhaustion: The Impact of Quanta Computer, Inc. v. LG Elecs., Inc.*, 14 VA. J.L. & TECH. 273 (2009).

<sup>249</sup> See *United States v. Univis Lens Co.*, 316 U.S. 241, 252 (1942) (finding violation of the Sherman Act for illegal price-fixing).

<sup>250</sup> *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007).

<sup>251</sup> See also *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (holding that the patent exhaustion doctrine also applies “to a sale of a patented product manufactured by a licensee acting within the scope of its license”).

<sup>252</sup> *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>253</sup> *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008).

<sup>254</sup> *Id.* at 623.

<sup>255</sup> *Id.*

<sup>256</sup> *Id.* at 624.

<sup>257</sup> *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 630 (2008).

<sup>258</sup> *Id.* at 638; see also *id.* at 632 (“LGE has suggested no reasonable use for the Intel Products other than incorporating them into computer systems that practice the LGE Patents. Nor can we

The products also included “all the inventive aspects” of the patents.<sup>259</sup> The only required steps to practice the patents involved connecting buses and adding memory, both of which were routine and ancillary steps.<sup>260</sup> The item sold then carried with it the right to use it “to the full extent to which it can be used.”<sup>261</sup> Since Intel’s chipsets included all the inventive aspects and “all but practiced” LG’s patents, the Court concluded that LG’s patents were exhausted when Intel sold chipsets practicing LG’s method patents to Quanta.<sup>262</sup>

Referring to *Keeler*, the Court held that LG had no patent remedy against Quanta since its patents were exhausted.<sup>263</sup> Unlike the infringer-licensee in *General Talking Pictures*,<sup>264</sup> Intel was authorized to sell the patented-laden chipsets to Quanta.<sup>265</sup> The fact that Quanta went and acted in violation of the agreement between Intel and LG was a matter of contract law.<sup>266</sup> While the Court refrained from discussing the conditional sale doctrine, courts and commentators alike have read the doctrine to be extinguished.<sup>267</sup>

From the foregoing one can conclude that the first authorized and unrestricted sale of a patented article exhausts the rights in that article in order to prevent patent owners from obtaining royalties by double dipping.<sup>268</sup> If patent owners like Monsanto could control every use, sale or making of the seeds in the marketplace, the property rights of end-consumers such as farmers would be eroded, and intermediate service providers such as seed cleaners and grain elevators could become

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can discern one: A microprocessor or chipset cannot function until it is connected to buses and memory.”) (footnote omitted).

<sup>259</sup> *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 638 (“Intel’s microprocessors and chipsets substantially embodied the LGE Patents because they had no reasonable noninfringing use and included all the inventive aspects of the patented methods.”).

<sup>260</sup> *Id.* at 637.

<sup>261</sup> *Adams v. Burke*, 84 U.S. 453, 455 (1873) (“[T]he traditional bar on patent restrictions following the sale of an item applies when the item sufficiently embodies the patent—even if it does not completely practice the patent—such that its only and intended use is to be finished under the terms of the patent.”).

<sup>262</sup> *See Quanta*, 553 U.S. at 634 (“Intel all but practiced the patent itself by designing its products to practice the patents.”).

<sup>263</sup> *Id.* at 637, n.7. (“We note that the authorized nature of the sale to Quanta does not necessarily limit LGE’s other contract rights. LGE’s complaint does not include a breach-of-contract claim, and we express no opinion on whether contract damages might be available even though exhaustion operates to eliminate patent damages.” (citing *Keeler*)).

<sup>264</sup> *General Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175 (1938).

<sup>265</sup> *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 636 (2008).

<sup>266</sup> *Id.*

<sup>267</sup> *See, e.g., Static Control Components, Inc. v. Lexmark Int’l, Inc.*, 615 F. Supp. 2d 575, 585 (E.D. Ky. 2009) (“After reviewing *Quanta*, *Mallinckrodt*, and the parties’ arguments, this Court is persuaded that *Quanta* overruled *Mallinckrodt* sub silentio.”).

<sup>268</sup> *Cyrix Corp. v. Intel Corp.*, 846 F. Supp. 522, 539 (E.D. Tex. 1994) (recognizing that the purpose of the patent exhaustion doctrine is to “prevent patentees from extracting double recoveries for an invention.”).

contributory infringers. The Court has been skeptical thus far of creating exhaustion-free categories and a conclusion that exhaustion in some form applies even to SRTs must then follow as logical. The ability of buyers to transact in patented articles without fear of patent infringement liability encourages vibrant downstream market competition.<sup>269</sup> Exhaustion also allows some consumers unable or unwilling to pay the monopoly price demanded by a patent owner to access its technology as it makes its way down the stream of commerce.<sup>270</sup>

At the same time, an important difference exists between technologies that self-replicate and others that do not. Patent owners of SRTs face two sources of competition in every product they commercialize: rival companies as well as customers. This is particularly true with soybean seeds, where “the crop is the seed.”<sup>271</sup> Being self-pollinating, soybeans can be saved and replanted without a degradation of the Roundup Ready trait.<sup>272</sup> A single acre of soybeans produce enough seed to plant twenty-six acres the next year.<sup>273</sup> Obtaining adequate protection is an existential issue for biotechnology companies like Monsanto. Monsanto spends 2.6 million dollars daily on research and development for a process that could take six to thirteen years to develop and commercialize, and with a success rate of 5%.<sup>274</sup> As Professor Jim Chen put it, “[d]irt and green thumbs come cheap.”<sup>275</sup> If exhaustion applies to extinguish all patent rights in the traited seed, trait developers like Monsanto would have little incentive to research

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<sup>269</sup> See Watanabe, *supra* note 248, at 273.

<sup>270</sup> R. Anthony Reese, *The First Sale Doctrine in the Era of Digital Networks*, 44 B.C. L. REV. 577, 583-92 (2003). (Describing how the exhaustion defense to copyright infringement allows expanded access to copyrighted work without unduly threatening the copyright owner’s ability to charge that monopoly price.)

<sup>271</sup> *Asgrow Seed Co.*, 513 U.S. at 188.

<sup>272</sup> See Brief of CropLife America as Amicus Curiae Supporting Affirmance, *supra* note 27, at 3.

<sup>273</sup> Brief for Respondents, *supra* note 1, at 5 n.4, *Bowman v. Monsanto Co.*, No. 11-796 (Jan. 13, 2013), 2013 WL 179941.

<sup>274</sup> *Monsanto | Why Does Monsanto Sue Farmers Who Save Seeds?*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/why-does-monsanto-sue-farmers-who-save-seeds.aspx> (last visited Oct. 19, 2013); MONSANTO, ANNUAL R&D PIPELINE REVIEW 9 (2011), available at [http://www.monsanto.com/products/Documents/pipeline-brochures/pipeline\\_2011\\_presentation.pdf](http://www.monsanto.com/products/Documents/pipeline-brochures/pipeline_2011_presentation.pdf); ERNST & YOUNG, BEYOND BORDERS: GLOBAL BIOTECHNOLOGY REPORT 2011 37 (2011), available at [http://www.ey.com/Publication/vwLUAssets/Beyond\\_borders\\_global\\_biotechnology\\_report\\_2011/\\$FILE/Beyond\\_borders\\_global\\_biotechnology\\_report\\_2011.pdf](http://www.ey.com/Publication/vwLUAssets/Beyond_borders_global_biotechnology_report_2011/$FILE/Beyond_borders_global_biotechnology_report_2011.pdf) (noting that in 2010 alone, publicly traded biotechnology companies in the United States spent \$22.8 billion on research and development); see also Brief of the Biotechnology Indus. Org. as Amicus Curiae in Support of Respondents at 6–7, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 267024 (quoting *NIH: Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 108th Cong. 49 (2003) (statement of Phyllis Gardner, M.D., Senior Associate Dean for Education and Student Affairs, Stanford University)).

<sup>275</sup> Chen, *supra* note 75, at 110.

and develop new traits, the result being that beneficial new plant varieties would not be introduced. This begs the question: should SRTs warrant a special set of legal rules?

Professors Dan Burk and Mark Lemley note “[p]atent law has a general set of legal rules to govern the validity and infringement of patents in a wide variety of technologies. With very few exceptions, the statute does not distinguish between different technologies in setting and applying legal standards.”<sup>276</sup> The tension between sector specific rules and rules of general applicability recently arose in *CLS Bank International v. Alice Corp.*, and Judges Linn and O’Malley recognized that sector specific rules were for Congress and not the courts.<sup>277</sup> Articulating the reason for this deference to Congress, the Court in *Chakrabarty* noted:

The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.<sup>278</sup>

In *Mayo*, the Court noted that “patent law’s general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another.”<sup>279</sup> In delineating the boundaries between permissible and impermissible behavior, can the courts develop a rule that is technology neutral yet supple enough to take into account the special challenges arising from SRTs? The answer is yes, but it lies further afield.

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<sup>276</sup> Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002).

<sup>277</sup> 717 F.3d 1269, 1333 (Fed. Cir. 2013) (Linn, J. & O’Malley, J., dissenting) (“Congress can, and perhaps should, develop special rules for software patents. . . . While Congress may, this court may not change the law to address one technological field or the concerns of a single industry.”).

<sup>278</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980); *see also* *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 458–59 (2007) (“If the patent law is to be adjusted better ‘to account for the realities of software distribution,’ the alteration should be made after focused legislative consideration, and not by the Judiciary forecasting Congress’ likely disposition.”) (citation omitted).

<sup>279</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

### B. *The Make-Use Dichotomy*

The Court in *Bowman v. Monsanto* identified a “making” and as *per se* infringing.<sup>280</sup> However, an opinion that responded to Bowman’s argument that *Quanta*’s instruction that exhaustion terminates “all patent rights to that item” necessarily includes the right to “make” embodiments of SRTs because replication is an innate characteristic of the invention would have been helpful in providing guidance to the rights of users and owners of SRTs.<sup>281</sup>

Recently the U.K. Supreme Court, in *Schütz v. Werit*, had occasion to consider and articulate a framework for what constitutes an impermissible “making.”<sup>282</sup> The patent claim covered a container consisting of a pallet and a plastic bottle within a lattice metal cage.<sup>283</sup> The aspect of the container that was considered to be inventive was the particular construction of the lattice bars of the metal cage.<sup>284</sup> The issue was whether a third party’s replacing old bottles in used containers with new bottles constituted the “making” of the patented container.<sup>285</sup>

The *Schütz* court held that “making” had to be interpreted contextually, and provided three guiding principles.<sup>286</sup> First, “making” should be interpreted by reference to the facts of the particular case and should be sufficiently clear and certain for patentees and others.<sup>287</sup> Second, that interpretation should “protect the patentee’s monopoly while not stifling reasonable competition.”<sup>288</sup> In weighing this interest, customary expectations are relevant.<sup>289</sup> Where the article “embodies essential elements of the inventive concept,” the expectation is that its unauthorized recreation will fall within the scope of the patentee’s legitimate rights.<sup>290</sup> Third, it is “illogical and unprincipled” that whether

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<sup>280</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1764 (2013).

<sup>281</sup> *Quanta*, 553 U.S. at 625; *see also* Kevin Rodkey, *Exhaustion and Validity of Single-Use Licenses for Transgenic Seeds in the Wake of Quanta v. LG Electronics*, 19 FED. CIR. B.J. 579, 602 (2010) (“Although transgenic seeds need water, sunlight, and nutrients to grow, none of these alter the fact that the patented item, the transgenic gene itself, is already present (i.e. embodied) in the product. The gene will be expressed once the seeds begin to grow, irrespective of the end-user’s actions.”).

<sup>282</sup> *Schütz v. Werit*, [2013] UKSC 16. The Court has referred to foreign law on at least one occasion. *Lawrence v. Texas*, 539 U.S. 558 (2003). Besides flowing from the same common law tradition as the United States, the approach by the U.K. Supreme Court in *Schütz* is consistent with the most recent direction by Supreme Court in its patent cases and in *Bowman v. Monsanto* itself.

<sup>283</sup> *Schütz v. Werit*, [2013] UKSC 16 at 2.

<sup>284</sup> *Id.* at 5.

<sup>285</sup> *Id.* at 7.

<sup>286</sup> *Id.* at 8–9.

<sup>287</sup> *Schütz v. Werit*, [2013] UKSC 16 at paras. 26–29; *see, e.g.*, Brief of the Biotechnology Indus. Org. as Amicus Curiae in Support of Respondents, *supra* note 274, at 24.

<sup>288</sup> *Schütz v. Werit*, [2013] UKSC 16 at para. 27.

<sup>289</sup> *Id.* at para. 17.

<sup>290</sup> *Id.* at para. 42.



a new article is made depends on “who carries out the work involved.”<sup>291</sup> Neither is it relevant “how a party views or markets its products,” but instead the court should look at “how those products should be characterized.”<sup>292</sup> In doing so, the court found it “both legitimate and helpful” to look at the relative life expectancies of the patented and unpatented portions of the article.<sup>293</sup>

### 1. The Meaning of “Making”

As to the first factor, the Court in *Bilski* stated that absent some contrary indication, a term in the Patent Act is presumed to have its “ordinary, contemporary, [and] common meaning.”<sup>294</sup> The ordinary meaning of “making” encompasses the creation of new articles—including the production of new soybeans through the act of farming.<sup>295</sup> Thus, “making” and “using” need not be mutually exclusive.<sup>296</sup> Since the seeds sold by Monsanto to the unknown farmer were consumed in the first planting, Bowman’s harvest constituted a “making” as part of its use.<sup>297</sup> This result is consistent with *Adams*, where the Court recognized that because exclusive rights conferred by the Patent Act are separate and independent, the effect of patent exhaustion does not affect them all.<sup>298</sup> Thus, a licensee with a right to “make and sell” obtains a share in the patent monopoly only with respect to those rights and cannot “use” the invention.<sup>299</sup>

Patent attorney Kevin Rodkey objected to this reasoning, arguing that “if *all* of the patent owner’s rights on the first-generation are exhausted, then the right to ‘make’ through common and noninventive

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<sup>291</sup> *Id.* at para. 46.

<sup>292</sup> *Id.* at para. 47.

<sup>293</sup> *Id.* at para. 61–66.

<sup>294</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3221 (2010) (quoting *Diamond v. Diehr*, 450 U.S. 175, 182 (1981)).

<sup>295</sup> *See, e.g.*, WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1363 (3d ed. 2002) (One meaning of “make” is “to plant and raise (a crop).”).

<sup>296</sup> Brief for Respondents, *supra* note 1, at 26–28 (“Courts customarily do not read two statutory prohibitions as mutually exclusive, such that a violation of one provision cannot constitute a violation of the other.”); *see, e.g.*, *United States v. Wright*, 742 F.2d 1215, 1219 (9th Cir. 1984) (“However, the cultivation and possession provisions are not mutually exclusive but overlapping. It is quite possible to possess with intent to distribute the marijuana that is being cultivated.”); *Ferrell v. United States*, 963 F. Supp. 615, 621 (E.D. Mich. 1997) (“[J]ust because the Defendant’s conduct may constitute ‘carrying’ under the statute does not mean that conduct may not also be a ‘use’ within the definition of the statute.”).

<sup>297</sup> Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 6.

<sup>298</sup> *Adams v. Burke*, 84 U.S. 453, 456 (1873) (“The right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee.”).

<sup>299</sup> Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 22 (“Case law exemplifies a critical qualification to the exhaustion doctrine—that, absent an express or implied license, the authorized sale of an article embodying a patented invention does not give the purchaser the right to make a new patented article.”).

means (i.e., traditional farming techniques) is also exhausted.”<sup>300</sup> The reason, according to Rodkey, is that the Roundup Ready gene “has no benefit to anyone who wishes to use the seed for any purpose other than planting. It does not produce additional nutritional value or confer disease resistance, so it does not benefit farmers to feed herbicide resistant seeds to livestock.”<sup>301</sup> It follows,

[That if farmers] did not use RoundUp [sic] herbicide (to which their seeds were resistant), they would still have been practicing the Monsanto patent by the very presence and expression of the gene, along with the fact that the crops were resistant to the herbicide. Therefore, the first-generation seeds include all the inventive aspects of the patent.<sup>302</sup>

Rodkey concludes that farmers “would not have purchased the first-generation seed for any purpose other than growing crops.”<sup>303</sup>

This reasoning has intuitive appeal. One who buys a cow expects to own her calf.<sup>304</sup> Like Russian dolls, one who buys the doll really buys a set of dolls, one embodied in another in the same way that “[a] patented product always ‘substantially embodies’ the patent. Otherwise it would not be patented,” as even the American Seed Trade Association, supporting Monsanto, acknowledged.<sup>305</sup>

The problem with this argument is that both the buyer and seller of a Russian doll know exactly how many baby dolls are sheathed within its wooden bosom, and its market price is set accordingly. With SRTs in general, and with soybeans in particular, no such number can be determined *ex ante*, or can be assumed to be infinite. Such a conclusion would make nonsense of the careful calibration that the *Quanta* Court sought to achieve between the rights of the owner and the buyer.

In order for transactions to occur in the real world, an approach that gives effect to these market expectations provides a better means of calibrating the balance of interests between parties. Even if a price point could be calculated, the *quid pro quo* of arguing that every seed embodies the right to make every future generation inherent in that seed is that the buyer must pay for every one of those generations as well. Monsanto and its amici cautioned that if the Court held that patent

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<sup>300</sup> Rodkey, *supra* note 281, at 601.

<sup>301</sup> *Id.* at 600. Unlike “nutritionally modified seed [that] may have a reasonable noninfringing use,” seed traits that “confer insect-, herbicide-, drought-, temperature-, or other environmental resistance” are limited to use as crops. *Id.* at 600–01.

<sup>302</sup> *Id.* at 602.

<sup>303</sup> *Id.* at 601.

<sup>304</sup> See *Sherwood v. Walker*, 66 Mich. 568 (1887).

<sup>305</sup> Brief Amicus Curiae of the Am. Seed Trade Ass’n in Support of Respondents, *supra* note 90, at 22.

exhaustion applied, then owners of patents over SRTs would be forced to recoup their investments through a “billion dollar” first sale since the initial sale price reflects only the value of first-generation seeds and the attendant restrictions on use of progeny seeds.<sup>306</sup> If exhaustion does apply, progeny seeds will quickly compete with seed sold by Monsanto or its seed company licensees, depressing the market price toward the competitive price. Anticipating this, owners would charge a price for the first sale based on the present discounted value of its expected future income. The prohibitively high price would lead to market failure, unless farmers formed a consortium wealthy enough to induce a sale.

Besides being inconsistent with the twenty-year monopoly patent holders generally enjoy, telescoping Monsanto’s commercialization into a single sale could lead to a less-competitive seed market and one that discourages disclosure of new technologies. For example, instead of licensing other seed companies, Monsanto might vertically integrate downstream and keep plant technologies as trade secrets.<sup>307</sup> Granted, trade secret law is unsuitable for some technologies, since it does not protect against reverse engineering.<sup>308</sup> This is particularly true for soybeans owing to their self-propagating nature.<sup>309</sup> However, non-self-pollinating plant varieties and other SRTs may be more susceptible to trade secret protection. With even intra-brand competition eliminated, farmers can expect even higher prices and lower output in the traited seed market.

Market expectations will play a role in determining when unauthorized “making” has taken place, and some like Professor Dennis Crouch correctly predicted that it “could win the day.”<sup>310</sup> In *Bowman v. Monsanto*, the proportion of soybeans used as feed far outweighs those used as seed, and grain elevators are not meant to sell seed.<sup>311</sup> Bowman

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<sup>306</sup> See, e.g., *id.* (“[T]hat a first generation of (patented) seed ‘substantially embodies’ all subsequent generations of seed, such that the sale of one generation of seed exhausts all rights in subsequent generations.”).

<sup>307</sup> Jeremy N. Sheff, *Self-Replicating Technologies*, 16 STAN. TECH. L. REV. 229, 245 (2013).

<sup>308</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974) (“A trade secret law,” generally speaking, “does not offer protection against discovery by fair and honest means.”).

<sup>309</sup> Sheff, *supra* note 307, at 242 (“[S]elf-replication is an extreme form of self-disclosure. Self-replicating technologies don’t merely teach competitors how to practice a new invention, they supply such competitors with a factory as well.”).

<sup>310</sup> Dennis Crouch, *Patent Exhaustion for GM Seeds*, PATENTLY-O (Dec. 4, 2012), <http://www.patentlyo.com/patent/2012/12/patent-exhaustion-gmo.html>; see also Brief for the New York Intellectual Prop. Law Ass’n as Amicus Curiae in Support of Respondents at 37, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 287732 (“The position taken by the parties in *Intervet* demonstrates the biotechnology sector’s acceptance and reasonable expectation that each successive generation of a patented self-replicating biological material is a separate “making” constituting an act of infringement under § 271(a).”).

<sup>311</sup> *Bowman v. Monsanto*, at 1765 (“Grain elevators, as indicated above, purchase grain from farmers and sell it for consumption; under federal and state law, they generally cannot package or market their grain for use as agricultural seed.”).

made deliberate choices, including where and when to plant the next season's crop, plant the seeds, apply insecticides and fungicides, control for weeds, and finally harvest the progeny seed.<sup>312</sup> Bowman's use of grain as seed therefore runs counter to those expectations. Further, the existence of a market for grains and processed soybean products indicates that traited seeds have substantial non-infringing uses independent of their reproductive capacity, which distinguishes *Bowman v. Monsanto* from *Quanta*. Finally, if sales of harvested soybeans to grain elevators exhausted patent rights, "an engine of gamesmanship" based on "pretextual transactions" could develop as farmers sold seeds to the elevator and bought them back for planting.<sup>313</sup>

It may also be said that a patented feature that confers high yields makes a compelling argument that duplication is necessary, whereas another that confers fluorescence on plant cells makes for a less compelling argument. Related to this issue is the question of whose perspective the Court should use to calibrate market expectations? Yuichi Watanabe suggests that a possible candidate is "one ordinarily skilled in the art."<sup>314</sup> It may be added that post-*KSR International Co. v. Teleflex Inc.*, this individual would have the common knowledge and common sense imbued in that case.<sup>315</sup> These are among the residual issues that the Court must grapple with.

The *Bowman v. Monsanto* Court's reasoning is consistent with the Canadian Supreme Court in *Monsanto Canada Inc. v. Schmeiser*.<sup>316</sup> The issue in *Schmeiser* was whether the farmer "used" Roundup Ready seed to infiltrate his canola fields when he discovered their herbicide resistance and saved the seed for replanting over subsequent seasons.<sup>317</sup> It is worth noting that Monsanto's Canadian claims were directed to genes and not to seeds.<sup>318</sup> Also, the Canadian case did not involve "making" of articles obtained through an authorized sale and so invoke

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<sup>312</sup> *Id.* at 1769 ("Bowman devised and executed a novel way to harvest crops from Roundup Ready seeds without paying the usual premium.").

<sup>313</sup> Brief for Respondents, *supra* note 1, at 49. As a commentator noted, "[p]atented seed goes in at the top. When it comes out at the bottom, somehow, it is no longer protected by patents. A farmer could sell his crop to the grain elevator, and buy some of it right back, and patents would no longer apply." Roy Zwahlen, *Seed Patents: How Innovation May Get Lost in the Grain Elevator*, BIOTECHNOW (June 28, 2012), <http://www.biotech-now.org/public-policy/patently-biotech/2012/06/seed-patents-how-innovation-may-get-lost-in-the-grain-elevator>.

<sup>314</sup> Watanabe, *supra* note 248, at 284.

<sup>315</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

<sup>316</sup> *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 (Can.). See Arash Amouzgar et al., *U.S. Patent Seed Case Ruling Aligns with Canadian Patent Protection Laws*, BLAKES (June 3, 2013), <http://www.blakes.com/English/Resources/Bulletins/Pages/Details.aspx?BulletinID=1746> ("*Bowman v. Monsanto Co. et al.* is broadly consistent with Canadian jurisprudence on the subject of patented seeds.").

<sup>317</sup> *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 (Can.), at para.60–62.

<sup>318</sup> *Id.* at para. 17.

exhaustion.<sup>319</sup> The Canadian court wrote that the farmer had “used” the seed even though the herbicide resistance was not actually used.<sup>320</sup> “Use” was given a broad meaning: “utilization with a view to production or advantage.”<sup>321</sup> While less clearly articulated in the Canadian case, in both instances, it is the making rather than the pairing of the herbicide and seed that constitutes the offensive conduct.

Once it is accepted that Bowman did “make” the seeds, the inquiry can then turn to whether that “making” constitutes the “normal use” of a product.<sup>322</sup> Does using the trait involve growing a new plant? Bowman argued that the embodiments of SRT cannot be used by buyers without creating new embodiments.<sup>323</sup> Some commentators agree that “the only likely ‘use’ of the purchased patented item, the seed, is planting.”<sup>324</sup> In the context of soybeans, because the crop is the seed, those seeds then have purposes other than simply being replanted, a fact buttressed by centuries of past practice.

## 2. Protecting the Inventive Core

As to the second factor, the policy inquiry of monopoly and market competition raised in *Schütz* illuminates the rationale behind the exhaustion doctrine. The Court, first in *Mayo* and more recently in *Ass’n for Molecular Pathology v. Myriad Genetic*, required the consideration of the patent’s inventive concept in order not to preempt future innovation and hamper innovation and competition.<sup>325</sup>

The doctrine of fair use in copyright and trademark law, and the experimental use defense in patent law all recognize that not every iota

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<sup>319</sup> See Mark Pidkowich, *U.S. Supreme Court Rules that the Authorized Sale of Patented Seed does not Convey a Right to Produce a Crop—Comparison to the Canadian Approach*, LEXOLOGY (July 11, 2013), <http://www.lexology.com/library/detail.aspx?g=4ae897eb-7720-4fa4-9934-a5130dd91f93>.

<sup>320</sup> *Schmeiser*, 1 S.C.R. 902 at para. 75.

<sup>321</sup> *Id.* at para. 69.

<sup>322</sup> Crouch, *Oral Arguments in Bowman v. Monsanto*, *supra* note 187.

<sup>323</sup> Supplemental Brief, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2012 WL 3866466.

<sup>324</sup> Yee Wah Chin, *Inexhaustible: Patents on Self-Replicating Technologies*, 3 LANDSLIDE 12, 16 (2011).

<sup>325</sup> *Mayo v. Prometheus*, 132 S. Ct. 1289, 1305 (2012) (“Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements.”). See also *id.* at 1293 (“[T]oo broad an interpretation of this exclusionary principle could eviscerate patent law.”); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013) (“Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the [§ 101] inquiry . . . [and] extensive effort alone is insufficient to satisfy the demands of [§ 101.]”).

of benefit derived from the intellectual property owner's product must be channeled back to the owner.<sup>326</sup> Similarly, copyright exhaustion "modifies the copyright owner's distribution right, but not his reproduction right."<sup>327</sup> A book buyer can distribute or destroy the book, but cannot copy it because that action impinges on the reproduction right of the owner, which the owner retains even as he parts with that single copy. In each case, what exonerates defendants from infringement is the effect on the owner's market for the product.

The argument may be made that by preventing the reuse of seed for growing, Monsanto is protecting its primary market from competition. Such attempts to create market leverage have generally been condemned under patent misuse or the antitrust laws.<sup>328</sup> But, as Professor Jeremy Sheff explains, the dichotomies in exhaustion protect the ability of patent owners to protect their primary market in order to secure the super competitive profits as returns on their investment.<sup>329</sup> The law thus allows forays into the fringes of the patentee's exclusive right, but it cannot appropriate the basis of that right itself. The nature of SRTs generate particular resistance to reading exhaustion to the "use" right to include the "making" right as well. That resistance rests on the ability to generate multiple copies of a patented invention. As Professor Sheff notes, while each chipset can be used to make at most one computer, each seed can generate an unlimited number of seeds.<sup>330</sup> This is especially true with self-pollinating soybeans.

Each soybean plant becomes a factory producing fungible products acceptable to the market. To illustrate, those who buy corn cannot grow it again and enjoy the same traits. They may use it for feed or process it into food, but those uses form distinct secondary markets from the primary market for corn. While soybean seeds may also be used as feed or be processed, each seed is genetically identical to its parent. That particular use makes farmers like Bowman more akin to purveyors of pirated CDs than sellers of used parts, taking them closer to the heart of what the intellectual property laws seek to protect.

Otherwise, as Monsanto pointed out "[e]ven the growers and seed companies that currently contract with [it] would have no reason to

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<sup>326</sup> See, e.g., *KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 543 U.S. 111, 124 (2004) (discussing fair use in the trademark context); *Harper & Row, Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 566, (1985) (noting that the effect on the potential market for the original (and the market for derivative works) is "undoubtedly the single most important element of fair use"); *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002) (discussing experimental use in patent law).

<sup>327</sup> Sheff, *supra* note 307, at 252 (citing 17 U.S.C. § 109(a) (2012) (qualifying the distribution right of 17 U.S.C. § 106(3), but not the reproduction right of 17 U.S.C. § 106(1))).

<sup>328</sup> See, e.g., *id.*

<sup>329</sup> *Id.*

<sup>330</sup> Sheff, *supra* note 307, at 240.

continue those contracts given how easy it would be to obtain a single ‘exhausted’ soybean that would eliminate the need to pay any royalties to [it].”<sup>331</sup> The *Bowman v. Monsanto* Court displayed some sensitivity to this balance when it wrote:

[I]n the more ordinary case, when a farmer purchases Roundup Ready seed *qua* seed—that is seed intended to grow a crop—he will be able to plant it. Monsanto, to be sure, conditions the farmer’s ability to reproduce Roundup Ready: but it does not—[and] could not realistically—preclude all planting. No sane farmer, after all, would buy the product without some ability to grow soybeans from it. And so Monsanto, predictably enough, sells Roundup Ready seed to farmers with a license to use it to make a crop . . . . Applying our usual rule in this context therefore will allow farmers to benefit from Roundup Ready, even as it rewards Monsanto for its innovation.<sup>332</sup>

The conclusion, as the Washington Legal Foundation points out in its brief, is that the exhaustion doctrine aims to prevent unreasonable restraints on trade while ensuring that a patentee “on average will receive a fair royalty . . . each time one of his patented products is placed into the stream of commerce.”<sup>333</sup> The nub of the issue seems to be whether Monsanto’s method of structuring its means of appropriation is the least restrictive option to promote technological progress, a balance articulated in 1995 by the antitrust agencies.<sup>334</sup>

### 3. Relative Lifespans

The third factor filters out the manner of making and focuses instead on the relative lifespan of the components. The fact that the original transgenic beans were produced using gene gun insertion, compared to Bowman’s seeds coming into being through natural propagation, is a distinction without significance.<sup>335</sup> This argument

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<sup>331</sup> Brief for Respondents, *supra* note 1, at 51–55.

<sup>332</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1768 (2013). *See also* Brief of CropLife America as Amicus Curiae Supporting Affirmance, *supra* note 27, at 22. (“[G]rain elevators [are] persuasive evidence that soybean seeds have significant value independent of their reproductive capacity.”).

<sup>333</sup> Brief of Washington Legal Foundation As Amicus Curiae in Support of Respondents at 6-7, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 267022.

<sup>334</sup> U.S. Dep’t of Justice & Fed. Trade Comm’n, *Antitrust Guidelines for the Licensing of Intellectual Property* (Apr. 6, 1995), <http://www.justice.gov/atr/public/guidelines/0558.htm> (“The existence of practical and significantly less restrictive alternatives is relevant to a determination of whether a restraint is reasonably necessary. If it is clear that the parties could have achieved similar efficiencies by means that are significantly less restrictive, then the Agencies will not give weight to the parties’ efficiency claim. In making this assessment, however, the Agencies will not engage in a search for a theoretically least restrictive alternative that is not realistic in the practical prospective business situation faced by the parties.”).

<sup>335</sup> Brief for Amici Curiae Ctr. for Food Safety & Save Our Seeds in Support of Petitioner, *supra*

seeks an exception to the exhaustion rule when applied to SRTs without offering “support for the position that normal exhaustion principles are inapplicable merely because an invention is ‘made’ in one particular way.”<sup>336</sup> The exclusive rights of product patents, unlike process patents, snare infringers regardless of the manner in which the articles are made.<sup>337</sup>

As Professor Crouch observes, “Bowman’s statement that ‘Roundup Ready® seeds have been engineered to include everything one needs to practice the invention’ is disingenuous.”<sup>338</sup> Had those seeds been left in the grain elevator from which they were bought, Monsanto would have no cause to argue that there was an unauthorized “making” since cellular division of the traited germplasm would not have occurred. If Bowman’s logic prevailed, other industries that require even less direct human intervention would be dramatically affected; patent owners would receive less protection against the copying of any commercialized invention embodied in living organisms than other types of inventions.<sup>339</sup>

Unlike past cases where there was a market expectation that the articles with longevity could have spare parts refurbished and those which were expandable or consumable were to be repurchased, the market expectation is based on the time-honored tradition of farmers being able to replant seeds from earlier harvests.<sup>340</sup> In looking at the relative life spans of the patented and unpatented portions of the bean, the dichotomy for repair and reconstruction is less useful because Bowman did not reconstruct a worn out soybean. But, the fact that the

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note 110, at 34–38.

<sup>336</sup> Brief for Respondents, *supra* note 1, at 31 (“Under petitioner’s view, the fact that an invention can be used to create more units of that invention renders normal exhaustion principles inapplicable.”).

<sup>337</sup> *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258, 261 (6th Cir. 1919). (“[T]he inventor of a new and useful product or article of manufacture may have a patent which covers it and gives a monopoly upon it regardless of great variations in the method of making.”); Brief of Amici Curiae Wisconsin Alumni Research Found. et al. in Support of Affirming the Federal Circuit at 24, *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 315226 (“There is, however, no support in this Court’s precedent for the notion that ‘making’ an infringing article necessarily involves building that article from its starting materials or building blocks . . . . Genetic modification is one way to ‘make’ Roundup Ready® seeds, but not the only way.”).

<sup>338</sup> CROUCH, *supra* note 310.

<sup>339</sup> For example, microchip circuitry is “arranged by a computer and constructed by computerized photolithography and etching equipment.” Brief for Respondents, *supra* note 1, at 26. Computer software is “made entirely by a machine based on an instruction that may not even come directly from a human.” *Id.* at 26.

<sup>340</sup> *Compare American Cotton-Tie Co. v. Simmons*, 106 U.S. 89 (1882) (reconstruction of the patented tie for cotton baling, which was destroyed during its use, was held to be infringing) with *Aro Manufacturing Co., Inc. v. Convertible Top Replacement Co., Inc.*, 365 U.S. 336 (1961) (repairing worn fabric on the patented convertible automobile was permissible based on the purchaser’s right to maintain the patented article for its intended use).



useful lives of both the trait and the bean are inextricably intertwined adds logical force to the argument that while its use and making for germination purposes are indistinguishable, the market expectation of permissible use relates to non-patent-related uses such as feed and food processing rather than reproduction. The better view is that in the ordinary sense of the word, Bowman “made” those seeds; his actions precipitated the seeds bought from the grain elevator germinating into the soybean plants, which in turn bore those seeds.

### C. Five Alternatives to Patent Protection

The outcome in *Bowman v. Monsanto* allows Monsanto to continue metering farmers’ use of Roundup Ready seeds and promotes a more efficient economic outcome as it spreads revenue over a larger number of consumers who each pay only for each round of use.<sup>341</sup> Professor Jay Kesan supports this form of differential pricing, which “allows many more transactions to clear in the marketplace than is the case if only unconditional sales were allowed[,] reduc[ing] some deadweight losses leading to an increase in social welfare.”<sup>342</sup> While this may be a good reason to support the outcome in *Bowman v. Monsanto*, it is worth considering five other alternatives to patent protection.

#### 1. Contract Law

The first alternative is contract law. It is useful to look from the point of view of the patent owners and then from that of users and buyers. *Bowman v. Monsanto* largely obviates the need for patent owners to rely on express license restrictions to enforce prohibitions on replication. In a footnote to the opinion, Justice Kagan made clear that even in the absence of a licensing agreement, courts would imply a license only to plant the first generation of seeds.<sup>343</sup> Buyers and subsequent sellers will be increasingly reliant on representations, warranties, and indemnities from sellers to protect themselves from potential liability for actual or contributory infringement.<sup>344</sup>

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<sup>341</sup> See, e.g., Brief for Respondents, *supra* note 1, at 13 (noting that the system of single season authorization allows it to “incrementally recover its research and development investment through multiple transactions over many years, making use of the invention affordable.”).

<sup>342</sup> Jay P. Kesan, *Licensing Restrictions and Appropriating Market Benefits from Plant Innovation*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1081, 1084 (2006). See also Brief of Washington Legal Foundation As Amicus Curiae in Support of Respondents, *supra* note 333, at 6–7, (noting that this efficiency-enhancing mechanism is inconsistent with the ability of a buyer of a single seed to “parlay that seed into a thousand new seeds, the commercial use of those thousand seeds will generate only one royalty for Monsanto.”).

<sup>343</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1767, n.3 (2013).

<sup>344</sup> Lauren E. Sprouse & Jeff Wolfson, *Monstanto Rounds Up Big Win for Self-replicating Tech*,

Server and Casey looked at the issue of whether a contract-based post sale restriction on a patented product should be enforced under contract law.<sup>345</sup> They concluded the contractual restrictions may be enforced under certain conditions. First, federal preemption requires that restrictions do not frustrate a federal patent policy; for example, one such frustration could be clawing back what is in the public domain.<sup>346</sup> In this regard, they note:

[I]t is questionable that a patented product that is the subject of a contract-based post-sale restriction truly enters the public domain upon authorized first sale, where a valid, unexpired patent covering the product is exhausted only with respect to the purchased product and where the buyer is the only party that is contractually bound to adhere to the agreed-to restrictions that are a condition of the sale.<sup>347</sup>

Second, restrictions would render patents unenforceable under the patent misuse doctrine if they impermissibly broaden the scope of the patent monopoly or violate the antitrust rules on vertical restraints.<sup>348</sup>

In their brief, Bowman and its amici argued that contract law would serve to protect Monsanto's incentives to innovate while ensuring affordability.<sup>349</sup> Antitrust attorney Yee Wah Chin agrees, explaining that Monsanto could have conditioned seed sales on farmers either consuming it or selling it only "to buyers who agree to either consume the seed or isolate that seed from other seed and sell the seed only for consumption" and include grain elevators in its web of license restrictions on seed sale and replanting.<sup>350</sup> Thus, grain elevators and farmers can "require representations, warranties, and indemnities from their suppliers, regarding the presence of any patented items in the purchase and the existence of any conditions placed by the patent holder on sales of the patented items that may be included in sale."<sup>351</sup>

The problem, as the Court pointed out, is that contractual remedies

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AIPLA NEWSTAND (May 23, 2013), <http://www.haynesboone.com/monsanto-self-replicating-tech/>.

<sup>345</sup> Server & Casey, *supra* note 232, at 599–640.

<sup>346</sup> *Id.* at 604.

<sup>347</sup> *Id.* at 607.

<sup>348</sup> Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 868 (Fed. Cir. 1997) ("Patent misuse is an affirmative defense to an accusation of patent infringement."); Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36 (1977) (applying the rule of reason to vertical restraints). See generally DARYL LIM, PATENT MISUSE AND ANTITRUST: DOCTRINAL, POLICY AND EMPIRICAL PERSPECTIVES (2013).

<sup>349</sup> Brief for Petitioner at 55, Bowman v. Monsanto Co., 133 S. Ct. 1761 (2013) (No. 11-796), 2012 WL 6063892.

<sup>350</sup> Yee Wah Chin, *Licensing, Patent Exhaustion, and Self-Replicating Technologies: A Case Study*, 32 THE LICENSING JOURNAL 7 (Aug. 2012), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2147155](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2147155).

<sup>351</sup> *Id.*

are ineffective against downstream purchasers not in contractual privity with the patent holder. As Monsanto stated in its brief, in a world where soybeans “could be purchased from another grower or a grain elevator, plucked from a field or road, or snatched off the back of a truck,” patent owners would have to establish “contractual privity with *every* person who might try to misappropriate its patented technology.”<sup>352</sup> Contracts, while similarly restraining alienation, would impose even greater transaction costs.<sup>353</sup> Further, since patent laws promote technological progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts, that incentive would necessarily be diminished if SRTs were only protected through a single round of replication instead of its statutory entitlement of twenty years.<sup>354</sup>

## 2. Terminator Genes

It has also been suggested that Monsanto could prevent cannibalizing of its sales in traited seed by stacking its seeds with a Terminator gene, which renders seed sterile, thus preventing replanting through technological rather than legal means.<sup>355</sup> Called genetic use restriction technologies (“GURTs”), these function by inserting toxin-producing genetic material that terminates the seed after the plant matures.<sup>356</sup> This produces an edible and sterile crop unsuitable for

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<sup>352</sup> Brief for Respondents, *supra* note 1, at 51–55.

<sup>353</sup> *Id.* at 53–54 (“Petitioner proposes that Monsanto require licensed farmers to sell only to grain elevators that separately contract with Monsanto. Presumably, petitioner imagines that those contracts would in turn permit sales only to parties that have also contracted with Monsanto. And so on, until every potential user of Monsanto’s patented technology has signed a Monsanto contract. The transaction costs, and disutility, of such an approach would be immense.” (citations omitted)).

<sup>354</sup> Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 17.

<sup>355</sup> See Jeremy P. Oczek, *In the Aftermath of the “Terminator” Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right To Save and Replant Seed*, 41 B.C. L. REV. 627, 627-28 (2000) (“On March 3, 1998, the United States Patent and Trademark Office granted Patent No. 5,723, 765, titled ‘Control of Plant Gene Expression,’ jointly to the United States Department of Agriculture (‘USDA’) and the Delta and Pine Land Co. (‘D&PL’) for a technology that blocks genetically altered seeds from germinating after one season. This new technology, officially named the ‘Technology Protection System,’ provides the ability to genetically alter seeds so that the crops produced from these seeds will in turn bear sterile seeds.”); Jason Savich, *Monsanto v. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology*, 22 BERKELEY TECH. L.J. 115, 132 (2007) (“These technologies function by introducing genetic elements into the plants which produce a toxin late in seed maturation. The toxin kills the seed after the plant has matured, producing a safe but sterile crop for the farmer, forcing him to purchase new seeds each year because the seeds produced in growing the crop are not viable for replanting.”).

<sup>356</sup> See MARTHA L. CROUCH, HOW THE TERMINATOR TERMINATES: AN EXPLANATION FOR THE NON-SCIENTIST OF A REMARKABLE PATENT FOR KILLING SECOND GENERATION SEEDS OF CROP PLANTS (1998), available at <http://www.sbs.utexas.edu/genetics/genweb/Essays/Terminator.htm>.

planting.<sup>357</sup> Like hybrid seeds, GURT seeds force farmers to buy new seeds each season. Like digital rights management (“DRM”) software, biotechnology allows technological “locks” to be programmed into genetic code.<sup>358</sup> Moreover, unlike DRM measures that are susceptible to hacking by the casual computer geek, the high startup costs involved in biotechnology research will severely limit those capable of “jailbreaking.”<sup>359</sup> Farmers would also be better placed than consumers of copyrighted work to lobby for and improve upon the counterbalancing measures such as those found in the DMCA. The same technology that makes Monsanto’s seed valuable also offers it a remedy to meter its use.

A patent was granted to Delta in 1998 for genetic modifications that rendered seeds sterile after planting.<sup>360</sup> Farmers were outraged that their right to save their seeds was taken from them. Public reaction smothered the commercial future of the Terminator gene and it was never introduced.<sup>361</sup> Public opinion however, seems to be changing. With the rise of organic farming, there is an appeal in restricting transgenic crops to a single season of growing, thereby reducing the risk of contamination.<sup>362</sup> Research has provided alternatives to sterile seeds. One way is to “switch off” the transgene in seeds, so that they grow into new plants but do not pass on the benefits of the engineered trait. Another way is to require use of a proprietary chemical in combination with a switch in order to activate the transgene, forcing buyers to return each year to purchase the chemical.<sup>363</sup> Scientists believe that “[t]he approach could even be used in nanotechnology, by making engineered

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<sup>357</sup> Savich, *supra* note 355, at 132.

<sup>358</sup> Dan L. Burk, *DNA Rules: Legal and Conceptual Implications of Biological “Lock-Out” Systems*, 92 CALIF. L. REV. 1553, 1553 (2004). However, others are less sanguine. *See, e.g.*, Chen, *supra* note 75, at 110 (arguing that GURTs represent a “legal failure” as “resources devoted to the enforcement of legal rights are spent at the expense of actual innovation.”).

<sup>359</sup> *Id.* at 1571. *See also* Heidi Ledford, *Seed-Patent Case in Supreme Court*, NATURE (Feb. 19, 2013), <http://www.nature.com/news/seed-patent-case-in-supreme-court-1.12445>.

<sup>360</sup> U.S. Patent No. 5,723,765 col. 36 ll. 22–60 (filed June 7, 1995). *See also* Elizabeth Winston, *A Patent Misperception*, 16 LEWIS & CLARK L. REV. 289, 297 n.50 (“This nickname is a misnomer, as the modification is not actually a gene, but rather a process for programming a plant’s genetic code so that the seed is fertile for only one planting and future generations are sterile.”).

<sup>361</sup> *See* Andrea Knox, *A Seed Firm Kills Plan to Use Terminator Gene*, PHILA. INQUIRER, (Oct. 10, 1999) (“Bowling to mounting pressure, Monsanto Co. last week pledged to call a halt to development of the so-called terminator gene.”). *See also* ETC Group Communiqué, *Gene Giants Seek “Philanthropopoly”* (March 2013) (describing the United Nations Convention on Biological Diversity’s moratorium on field-testing and commercial development of Terminator in 2000, which was re-affirmed in 2006 due to campaigns by civil society, farmers’ organizations and indigenous peoples).

<sup>362</sup> Ledford, *supra* note 359.

<sup>363</sup> *Id.* (describing “‘gene-guard’ technology: a genetic tweak that makes production of the desired chemical dependent on a proprietary additive, supplied by Ginkgo, in its fermentation medium.”).

nanobots that are dependent on a proprietary raw material.”<sup>364</sup> These are, however, the early days yet and progress is difficult. Monsanto’s Terminator technology requires three different genes to be inserted into the plant genome.<sup>365</sup> Other companies see patent law as the more convenient alternative, and hope they do not have to use such technology.<sup>366</sup> More fundamentally, this solution has the distinct disadvantage that unlike patents that expire after twenty years, the technology lock is perpetual.<sup>367</sup>

### 3. New Weeds

A third suggestion is for Monsanto to build another mousetrap. Over time, weeds may develop resistance to herbicide, as some already have towards Roundup. In 2012, twenty-three species of weeds have afflicted 16.8 million acres of farmland, up from 2.4 million acres four years earlier.<sup>368</sup> Similarly, crop-damaging insects are also evolving resistance. In 2011, the Environmental Protection Agency warned that Monsanto’s genetically engineered corn was losing effectiveness against corn rootworms.<sup>369</sup>

Just as stronger viruses generate a demand for stronger vaccines, there will be a continuous demand for new herbicides and genetically engineered seeds that can be grown effectively with these herbicides. Monsanto itself is introducing Roundup Ready 2 Yield soybeans, “a ‘stacked’ soybean variety to combat weed species that have developed resistance to glyphosate.”<sup>370</sup> Professor Rita S. Heimes argues that by severing Monsanto’s ability to charge for every generation of seed, it would be “encouraged to create new technologies that growers will want to buy each year.”<sup>371</sup>

The problem is that the biotech model functions more like the

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<sup>364</sup> *Id.*

<sup>365</sup> *Id.*

<sup>366</sup> *Id.* (“Monsanto says it is currently not researching the techniques, and other companies are hoping that they will not have to. ‘Perhaps these technologies could provide new ways to protect investments,’ says Brett Lund, former head of intellectual property for the biofuels group of Syngenta, an agri-giant headquartered in Basel, Switzerland. ‘But the easiest and best way is through our patent system.’”).

<sup>367</sup> *Id.*

<sup>368</sup> Shand, *supra* note 103, at 13.

<sup>369</sup> A.J. Gassmann et al., *Field-Evolved Resistance to Bt Maize by Western Corn Rootworm*, PLOS ONE (2011), <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0022629>. See also Claire Everett, *University Study Reveals Pest Now Resistant To Genetically Modified Corn*, THE DAILY ILLINI (Aug. 29, 2012), [http://www.dailyillini.com/article\\_53457935-8612-5bc7-9b85-8b46340b26dc.html](http://www.dailyillini.com/article_53457935-8612-5bc7-9b85-8b46340b26dc.html).

<sup>370</sup> See Brief of Am. Soybean Ass’n et al. as Amici Curiae in Support of Respondents, *supra* note 31, at 19–20.

<sup>371</sup> Heimes, *supra* note 56, at 134.

pharmaceutical model of innovation than like that of smartphones.<sup>372</sup> Product lifecycles must be longer in order to appropriate the huge sunk costs and lengthy periods of R&D involved in producing a commercially viable product. Accordingly, a short-run revenue model driven by meeting the latest industry fad is not sustainable.

#### 4. Compulsory Licensing

Fourth, one could conceive of a system of compulsory licensing similar to compulsory mechanical licenses under copyright law.<sup>373</sup> On January 4, 2013, Ohio Representative Marcy Kaptur introduced a bill designed to allow farmers to save patented seed from an earlier crop season in return for a royalty set by the Secretary of Agriculture.<sup>374</sup> Under this system, farmers can save their own crop for replanting even when covered by a utility patent. In return, farmers pay a license fee each season. This fee could be the difference in value of seed with the technology over an unpatented seed. This solution has the appeal of allowing patent owners to continue to rely on patent infringement to police access to their technology, while allowing farmers the option of paying a price which would be lower than the cost of a new bag of seeds, whether patented and unpatented. This reduces the consumer surplus that Monsanto appropriates while allowing Monsanto sufficient incentive to innovate.

One flaw with this system, however, is that farmers may cheat by under-declaring their seed. The cost of monitoring compliance may be substantial. Another problem is determining what a reasonable royalty would be. To the first objection, a possible solution to this may be to charge by acreage rather than seed declarations.<sup>375</sup> Since the number of seeds used each season depends on the size of the field, that number will in all likelihood remain constant. Monsanto's field inspectors can estimate the seeds needed by acreage. To the second objection, Monsanto currently charges a "Technology Fee" of \$6.50. The system used to calculate that fee does not change since the number of seeds subject to that royalty remains the same. One obvious change would be that seed companies, the intermediaries in the chain, would be rendered redundant. However, that sort of displacement has been seen with bookstores, travel agencies, and other intermediaries as the upstream

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<sup>372</sup> See, e.g., YAHONG LI, *IMITATION TO INNOVATION IN CHINA: THE ROLE OF PATENTS IN BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES* (2010).

<sup>373</sup> 17 U.S.C. § 115 (2010) (granting the rights to reproduce and distribute copyrighted musical compositions on phonorecords). The issue of compulsory licensing raises other important questions such as whether this would immunize cases of accidental cross-pollination.

<sup>374</sup> Seed Availability and Competition Act, H.R. 193, 113th Cong. (2013), available at <http://www.govtrack.us/congress/bills/113/hr193#summary/ourssummary>.

<sup>375</sup> I am grateful to Chris Seaman for this suggestion.

sellers transact directly with the downstream end-consumers.

The biggest obstacle may not be economic or legal, but political. Representative Kaptur previously introduced the bill three times before, but it has never made it out of committee.<sup>376</sup> However, Monsanto's win may provide the momentum needed to get the bill passed eventually. Patent attorney Kevin Noonan observed that patent holders have "resisted the political pressure to permit farmers to replant seed instead of purchasing seed for each planting. Although this has imposed legal and public relations costs on these patentees, the patent grant permits [patent holders] to impose these restrictions."<sup>377</sup> Professor Jerome Reichman likewise observed that "Congress has consistently and repeatedly declined to enact any such provision enabling the authorities, purely on grounds of public interest, to allow third parties to use a patented invention without the patentee's permission and thus to supply the market at more competitive prices."<sup>378</sup> Under these circumstances, it may be more realistic to turn to the \$20 billion the U.S. government gives to farmers annually, as agricultural subsidies to offset the cost of patent royalties, to agro-biotechnology companies, rather than attempt a compulsory licensing scheme.<sup>379</sup> To guard against creating a windfall for Monsanto, the government should exercise its market power as a monopsonist to push the market price close to one found at a competitive level. Professors Andrew Gavil, William Kovacic and Jonathan Baker have suggested that in markets where marginal costs are minimal, a competitive price would be "equated with entrant average cost."<sup>380</sup> At present, however, private ordering in U.S. agriculture seems entrenched and it will be unlikely that a compulsory licensing scheme will take root any time soon.

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<sup>376</sup> In 2011, 2009 and 2004. See Seed Availability and Competition Act, H.R. 193, 113th Cong. (2013).

<sup>377</sup> Kevin E. Noonan, *House Considers Alternative Patent Royalty Scheme for Genetically Engineered Seed*, PATENT DOCS (Jan. 14, 2013), <http://www.patentdocs.org/2013/01/house-considers-alternative-patent-royalty-scheme-for-genetically-engineered-seed.html> ("But regardless of which side has the better policy argument in that debate, Rep. Kaptur's bill is not a remedy required by the politics or economics of the situation. Indeed, it would just impose another government bureaucracy on U.S. agriculture that would not promote either agriculture or technological progress.").

<sup>378</sup> Jerome H. Reichman, *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options Under the TRIPS Agreement*, AALS MID-YEAR WORKSHOP ON INTELLECTUAL PROPERTY, (May 14, 2006), <http://www.aals.org/documents/2006intprop/JeromeReichmanOutline.pdf>.

<sup>379</sup> The United States currently pays around \$20 billion per year to farmers in direct subsidies as farm income stabilization via U.S. farm bills. See Daniel A. Sumner, *Agricultural Subsidy Programs*, in *The Concise Encyclopedia of Economics* (David R. Henderson ed., 2007), available at <http://www.econlib.org/library/Enc/AgriculturalSubsidyPrograms.html>.

<sup>380</sup> ANDREW GAVIL, ET AL., *ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY* 1155 (2008).

### 5. PVPA Protection Revisited

A fifth possibility is to rely on PVPA protection. It is possible that finding for Bowman would herd biotech companies back to relying on the PVPA. As Professor Mark Patterson noted, PVPA protection would still prevent farmers from selling saved seed to others for replanting.<sup>381</sup> Farmers like Bowman who buy grain as seed may be subject to prosecution under the PVPA.<sup>382</sup> The grain elevator may also be liable under the PVPA by selling to Bowman PVPA-protected Roundup Ready soybeans as seed.<sup>383</sup>

PVPA protection has the attraction of being more finely tailored to the agricultural sector than “one-size fits all” utility patents. As commentator observed, “the careful consideration Congress gave to the relationship between farmers, seed saving practices, and the property rights of seed manufacturers demonstrates the need for legislation tailored to this unique industry.”<sup>384</sup> In contrast, utility patents “simply do not permit the fine-tuned remedies and exemptions appropriate to the seed industry and judges should not try to force a fit.”<sup>385</sup>

The challenge as noted earlier in this Article is that utility patents are now the de facto method of protection for patent varieties. Unless the requirements for patentability are markedly different, there will be little reason for patent applicants to forgo the more robust protection patents afford in favor of PVPA certificates.

The discussion in the foregoing two sections begs this question: if Monsanto can sue for every new making and if the nature of the technology warrants that outcome, what implications does this have on those who inadvertently or unintentionally “make” a new patented article? The Court mentions that these two circumstances may warrant a finding of non-infringement. But that compromise represents a roughly hewn judicial exception for SRTs. Is there a better way to protect the rights of licensees, purchasers and other downstream users?

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<sup>381</sup> Mark Patterson, *Bowman v. Monsanto: A Primer and a Solution*, MADISONIAN.NET (Feb. 18, 2013), <http://madisonian.net/2013/02/18/bowman-v-monsanto-a-primer-and-a-solution/>. See also Hubbard, *supra* note 104, at 7 (“By establishing the PVPA as the sole means of intellectual property protection over plants, farmers could regain the right to save seed and the right to choice, as plant breeders would have better access to plant genetics that are currently off limits to innovation because of patents.”).

<sup>382</sup> 7 U.S.C. § 2541(a)(5) (2006) (“using seed which had been marked . . . to propagate the variety”); 7 U.S.C. § 2541(a)(10) (2006) (explaining infringement to “instigate or actively induce performance of any of the foregoing acts”).

<sup>383</sup> 7 U.S.C. §§ 2541(a)(1), (6), (8), (10) (2006) (providing for a variety of direct and indirect infringements). See Brief of Amicus Curiae Pioneer Hi-Bred International, Inc. in Support of Respondents Monsanto Company et al., *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013) (No. 11-796), 2013 WL 315224.

<sup>384</sup> Heimes *supra*, note 56, at 134, n.214.

<sup>385</sup> *Id.*



#### D. “Innocent” Infringers

As an initial matter, it is important to distinguish between three groups of potential defendants. The first two groups of inadvertent users were identified by the *Bowman v. Monsanto* Court are the inadvertent users—those who unintentionally or incidentally replicate the patented article. The third group is those who may have intentionally or unintentionally purchased the patent article, but who would at most be liable for contractual remedies had the Federal Circuit precedent in *Mallinckrodt* been clarified as not representing the law.

##### 1. Unintentional Users

The first group is unintentional users. Patented seed can be blown off trucks and farm equipment, through mixing of grains in grain elevators, and pollen drift.<sup>386</sup> On the spectrum of infringers, they are perhaps the least culpable. During oral arguments, the Justices seemed most concerned for them.<sup>387</sup> In the context of pollen drift, Federal Circuit Judge Gajarsa, in a concurring opinion, wrote that no liability should be found.<sup>388</sup>

In 2011, a coalition of organic growers, seed sellers and

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<sup>386</sup> Lynd, *supra* note 213, at 679 (“Pollen drift is the cross-pollination of agricultural commodities and can be caused by the movement of animals or shared equipment, by the wind carrying plants and seeds to other farms and contaminating the plants, or by planted, but dormant, seeds.”).

<sup>387</sup> Justice Kagan wondered about traited seeds contaminating organic crop fields and schoolchildren growing soybean seeds for science projects being sued for infringement. Transcript of Oral Arguments at 41, *Bowman v. Monsanto*, No. 11-796 (Feb. 19, 2013) (“[S]eeds can be blown onto a farmer’s farm by wind, and all of a sudden you have Roundup seeds there and the person—farmer is infringing, or there’s a 10-year-old who wants to do a science project of creating a soybean plant, and he goes to the supermarket and gets an edamame, and it turns out that it’s Roundup seeds. . . . And, you know, these Roundup seeds are everywhere, it seems to me. There’s, what, 90 percent of all the seeds that are around? So it seems as though—like pretty much everybody is an infringer at this point, aren’t they?”). Justice Scalia was worried about farmers unintentionally growing contaminated seeds bought from grain elevators. *Id.* at 27–28 (“[L]et me give you another horrible result, and that is if—if we agree with you, farmers will not be able to do a second planting by simply getting the undifferentiated seeds from—from a grain elevator because at least a few of those seeds will always be patented seeds, and no farmer could ever plant anything from a grain elevator, which means—I gather they use it for second plantings where the risks are so high that it doesn’t pay to buy expensive seed. Now they can’t do that anymore because there’s practically no grain elevator that doesn’t have at least one patented seed in it.”).

<sup>388</sup> See *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1360–61 (Fed. Cir. 2005) (Gajarsa, J., concurring) (“This [patented] compound raises a question similar to one that might arise when considering the invention of a fertile plant or a genetically engineered organism, capable of reproduction, released into the wild. Consider, for example, what might happen if the wind blew fertile, genetically modified blue corn protected by a patent, from the field of a single farmer into neighboring cornfields. The harvest from those fields would soon contain at least some patented blue corn mixed in with the traditional public domain yellow corn – thereby infringing the patent. The wind would continue to blow, and the patented crops would spread throughout the continent, thereby turning most (if not all) North American corn farmers into unintentional, yet inevitable, infringers.”).

agricultural organizations, cognizant of Monsanto's patent onslaught and fearing that they would be next in line, sought declaratory judgment against Monsanto for non-infringement and invalidity with respect to twenty-three of Monsanto's patents covering its Roundup Ready technology.<sup>389</sup> They did not want any of Monsanto's technology and were concerned that "if they do indeed become contaminated by transgenic seed, which may very well be inevitable given the proliferation of transgenic seed today, they could quite perversely also be accused of patent infringement by the company responsible for the transgenic seed that contaminates them."<sup>390</sup> The plaintiffs also sought a waiver from Monsanto not to sue them for infringement.<sup>391</sup> Monsanto refused, but issued a statement on its website that it would not sue farmers who had trace amounts of seeds with the patented trait in their fields "as a result of inadvertent means."<sup>392</sup> The Federal Circuit held that Monsanto's website disclaimer, together with its representations to the court, sufficiently eliminated standing for the farmers to sue because "Monsanto's representations unequivocally disclaim any intent to sue," and therefore create a judicial estoppel.<sup>393</sup>

The Federal Circuit concluded that one percent or less of seeds containing traited seed constitutes "trace" amounts.<sup>394</sup> However, it provided no guidance on whether there was a threshold of tolerance above that. Equally worrying is, as commentators have noted,

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<sup>389</sup> *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 851 F. Supp. 2d 544, 549 (S.D.N.Y. 2012) *aff'd*, 2012-1298, 2013 WL 2460949 (Fed. Cir. June 10, 2013). The Declaratory Judgment Act, 28 U.S.C. § 2201(a) (2010) (providing that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."). See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted) ("Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."). As one commentator pointed out, "Thus, the question in this case is not whether the appellants' subjective fear of suit by Monsanto is genuine, but whether they have demonstrated a "substantial risk' that the harm will occur, which may prompt [them] to reasonably incur costs to mitigate or avoid that harm." Courtenay C. Brinckerhoff, *Monsanto Avoids Declaratory Judgment Action Brought by Organic Farmers*, MONDAQ (June 13, 2013), <http://www.mondaq.com/unitedstates/x/246248/Patent/Monsanto+Avoids+Declaratory+Judgment+Action+Brought+By+Organic+Farmers>.

<sup>390</sup> First Amended Complaint ("Am. Compl.") at ¶ 2, *Organic Seed Growers and Trade Ass'n v. Monsanto Co.*, 851 F. Supp. 2d 544 (S.D.N.Y. 2012) (No. 11-CV-2163), ECF No. 3.

<sup>391</sup> *Organic Seed Growers*, 851 F. Supp. 2d at 549 (quoting Am. Compl. Ex. 3 (Apr. 18, 2011, letter from appellants' counsel to Monsanto's counsel)).

<sup>392</sup> *Monsanto's Commitment: Farmers and Patents*, MONSANTO, <http://www.monsanto.com/newsviews/pages/commitment-farmers-patents.aspx> (last visited Oct. 22, 2013).

<sup>393</sup> *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1358 (Fed. Cir. 2013).

<sup>394</sup> *Id.*

The statement that Monsanto made to the plaintiffs may not have been enough to prevent declaratory judgment jurisdiction if Monsanto had not relied on it in its efforts to dismiss this case for lack of jurisdiction! Thus, the Federal Circuit decision here seems to be as narrow as Monsanto's waiver—Monsanto may not be judicially estopped from asserting its patents against other organic farmers who inadvertently infringe the Monsanto patents in trace amounts.<sup>395</sup>

More fundamentally, the outcome in *Organic Seed Growers & Trade Ass'n v. Monsanto Co.* also does not address permutations of the same problem, and Monsanto's right to sue still hangs like the Sword of Damocles over the heads of farmers.<sup>396</sup> Farmers who do not want to use Monsanto's seed run the risk of infringement simply by purchasing seeds from a third party source, and it may be impossible for unwilling users to prevent the unauthorized making of patented seed.<sup>397</sup> This is particularly problematic since there is currently "no worldwide uniform standard about what constitutes an appropriate level of seed purity . . . [and] . . . [t]he assumption is that no seed [on the market] is 100 percent pure."<sup>398</sup> Further, "[e]ven if intent is considered when awarding damages and the accused farmer does not have to pay damages, the patent rights can still be costly because the farmer is not awarded legal fees and must still remove the contamination from his fields. Removal can leave the farmer without seed for the following years."<sup>399</sup> Risk-averse farmers may end up having to purchase a bundle of licenses to avoid inadvertent liability for infringement from multiple patentees.<sup>400</sup> As one commentator noted:

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<sup>395</sup> Brinckerhoff, *supra* note 389.

<sup>396</sup> Christina L. Nargolwala, *Renewable Agriculture: Contamination and Patent Enforcement Threats*, 26 NAT. RESOURCES & ENV'T 20, 20–21 (2012). *See also* Downing-Howk, *supra* note 95, at 66 ("The problem remains that without the appropriate equipment and training, those growing seed legally saved or obtained cannot tell if their crop has been pollinated or otherwise compromised by patented seed or pollen.").

<sup>397</sup> Downing-Howk, *supra* note 95, at 67 (2004) ("Because the gene introduced into the genetically modified (plant) expresses itself as a dominant gene, a 'non-genetically modified . . . plant can be transformed into a genetically-modified plant' simply by pollen drifting on the wind, insects transporting the pollen, or plants coming in contact with one another as well as the methods previously listed, resulting in the pollination of a non-genetically modified plant by pollen with the modified gene."); *Monsanto and DuPont Heat up Rivalry over Seeds*, NYTIMES.COM (Aug. 19, 2009), [http://www.nytimes.com/2009/08/20/business/global/20seeds.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2009/08/20/business/global/20seeds.html?pagewanted=all&_r=0).

<sup>398</sup> Gregory M. Lamb, *Are There Drugs in My Corn Flakes?*, THE CHRISTIAN SCI. MONITOR (Mar. 11, 2004), <http://www.csmonitor.com/2004/0311/p14s01-sten.html> (alteration in original) (internal quotation marks omitted).

<sup>399</sup> Lynd, *supra* note 213, at 679–80.

<sup>400</sup> *Id.* at 680 ("[P]ermittting infringement suits even when the court does not award damages creates a system through which the high risk of using conventional seeds and being sued due to unintended pollen drift incentivizes farmers to use GM seeds.").

[An] incentive farmers have for avoiding infringement and voluntarily choosing to pay the technology fee is the cost of patent infringement litigation. Not only would farmers have their own costs (attorneys' fees, expert witness fees, and lost time), but the Patent Act permits courts to award attorneys' fees to prevailing parties in "exceptional cases." Willful infringement is one factor courts consider in determining whether a case is exceptional. Patent litigation is notoriously expensive, which likely provides a strong incentive to avoid infringement.<sup>401</sup>

More broadly, because of the large number of patents in force and the non-public nature of licensing agreements, end users of SRTs will not be able to identify all patent licenses that are potentially implicated.<sup>402</sup> How then can unintentional infringers be better protected?

One approach is to require commodity seed sellers to distinguish between seeds that contain Roundup Ready traits and those that do not.<sup>403</sup> However *amicus* CHS, a grain elevator, warned that such measures were unfeasible. According to CHS, farmers deliver crops to a grain elevator as commodity grain rather than seed. Grain elevators "sort grain by kind, type and quality and nothing else in the ordinary course of its business."<sup>404</sup> CHS stated that grain elevators cannot "implement a cost-effective or manageable system for handling a billion bushels of grain per year as if some small portion of that grain were seed to be used for planting."<sup>405</sup>

The result, however uncomfortable, may be that growers and others like them must live under the grace of patent owners like Monsanto. As *amicus* Wisconsin Alumni Research Foundation also pointed out, "innocent" patent infringement is an "every day" occurrence as consumers use cell phones that may be infringing on another company's patents, yet no suits have been filed against end-

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<sup>401</sup> Ryan Vacca et al., *Food for Thought: Genetically Modified Seeds as De Facto Standard Essential Patents*, 85 U. COLO. L. REV. (forthcoming 2014).

<sup>402</sup> Brief of BSA | The Software Alliance as Amicus Curiae in Support of Respondents, *supra* note 167, at 22, (citing FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, EXECUTIVE SUMMARY 28 (2003)).

<sup>403</sup> The district court found this argument "compelling" in light of Monsanto's dominance of the soybean seed market, the regenerating nature of the Roundup Ready trait, and "the lack of any restriction against mixing of soybeans harvested from Roundup Ready crop from those that are harvested from a crop that was not grown from Roundup Ready seed." *Monsanto Co. v. Bowman*, 686 F. Supp. 2d 834, 836 (S.D. Ind. 2009), *aff'd*, 657 F.3d 1341 (Fed. Cir. 2011). However it noted that while it "may disagree with the decision to award unconditional patent protection to Monsanto," it "does not make policy; rather it interprets and enforces the law." *Id.* at 37.

<sup>404</sup> See Brief for Amicus Curiae CHS Inc. in Support of Respondents, *supra* note 134, at 8.

<sup>405</sup> *Id.* at 9.

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users.<sup>406</sup> Instead, it noted that “‘innocent infringement’ is a natural byproduct of a strict liability patent system.”<sup>407</sup> The relevant question for patent owners policing their rights is whether the value misappropriated as a result of the infringement is worth the lawsuit and the risk of negative publicity. This proved to be insufficient reassurance for the organic grower coalition, and it may not be in other instances as well.

A second approach is through state legislation. Monsanto’s patent enforcement policies prompted some states to enact legislation to protect their farmers. For example, California’s Seed Law protects farmers from contractual liability

based on the presence or possession of a patented genetically engineered plant on real property owned or occupied by the farmer when the farmer did not knowingly buy or otherwise knowingly acquire the genetically engineered plant, the farmer acted in good faith and without knowledge of the genetically engineered nature of the plant, and when the genetically engineered plant is detected at a *de minimis* level.<sup>408</sup>

State legislation of this sort raises the issue of federal preemption discussed earlier.<sup>409</sup> One related question is whether the “*de minimis level*” contemplated by the statute should be read in light of the one percent threshold articulated by the Federal Circuit in *Organic Seed Growers*. Whether laws like these will be challenged by Monsanto and other patent owners like it will depend on whether growers with a plausible argument for “*de minimis*” crop contamination raise them in defense to a patent infringement suit.

A third way is to limit remedies available to patentees. In *Monsanto v. Swann*, the court awarded damages for current planting, but refused to extend those damages to potential future damages resulting from planting seed produced from the current infringing incident.<sup>410</sup> In *Monsanto v. Scruggs*, the court only allowed injunctive relief and not monetary damages that were based on speculative

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<sup>406</sup> Brief of Amici Curiae Wisconsin Alumni Research Found. et al. in Support of Affirming the Federal Circuit, *supra* note 337, at 26–27. See, e.g., Mauro Whiteman, *Factbox: History of the mobile technology patent war*, REUTERS (July 5, 2012, 8:05 AM), <http://www.reuters.com/article/2012/07/05/us-apple-google-patents-idUSBRE8640IX20120705> (“Mobile technology has been a hotbed of patent litigation in recent years.”).

<sup>407</sup> Brief of Amici Curiae Wisconsin Alumni Research Found, *supra* note 337 at 26.

<sup>408</sup> Cal. Food & Agric. Code § 52305 (West 2009) (emphasis added). See also Me. Rev. Stat. Ann. tit. 7, § 1053(2) (2009) (emphasis added) (stating that if a farmer possesses on his property a genetically engineered product in either *de minimis* quantities or without his intent, “the farmer is not liable for breach of a seed contract nor for any damages claimed by the manufacturer.”).

<sup>409</sup> See *supra* Part II.C.1.

<sup>410</sup> *Monsanto v. Swann*, 308 F. Supp. 2d. 937 at 946 (E.D. Mo. 2001).

claims.<sup>411</sup> Following from the Court's decision in *eBay*, courts are now more willing to deny injunctive relief in appropriate cases, particularly where an injunction would impose substantial hardship on the defendant or the public interest.<sup>412</sup>

A fourth way is by raising the threshold of "making," so that while intent is not directly factored into the analysis, the circumstances as a whole could be sufficient to distinguish between conniving free-riders and victims of transgenic pollution. For example, under the facts of *Bowman v. Monsanto*, the concern is that given the amount of transgenic pollen "drifting in the wild," infringement would be nearly inevitable under the current threshold.<sup>413</sup> On the other hand, limiting infringement to the application of glyphosate would "raise the infringement bar high enough to exclude unintentional infringements."<sup>414</sup>

More recently, the tables have turned on Monsanto. In May 2013, it was reported that Monsanto's Roundup Ready wheat had contaminated wheat fields in Oregon.<sup>415</sup> Since genetically modified wheat is banned in many countries, U.S. farmers have not embraced it as they have with corn and soybean.<sup>416</sup> The recent discovery caused several countries, including Japan and South Korea, to ban U.S. wheat exports from Oregon and elsewhere.<sup>417</sup> A wheat farmer has sued Monsanto for negligence and claimed damages for cancelled orders and price erosion.<sup>418</sup> The same ease of contamination that struck fear into farmers across the country is now giving them the means to access Monsanto's coffers. Ironically, it may now be Monsanto who will be

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<sup>411</sup> See *Monsanto v. Scruggs*, 249 F. Supp. 2d 746, 758 (N.D. Miss. 2001) (stating that quantification of "other damages, including that resulting from previous and potential future unlicensed brown bag sales of Monsanto's patented Roundup Ready® and Bollgard® technology, are far less easily determined and computed. Equally difficult to discern are the resulting damages due to loss of consumer good will, the effect on Monsanto's efforts to control and steward its technology, and the corresponding dampening effect on Monsanto's research and development activities in the agricultural arena" and found that injunctive relief was appropriate rather than monetary relief.).

<sup>412</sup> *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2008). Server & Casey, *supra* note 232, at 640 (noting that "the distinction between a breach of contract remedy and a patent infringement remedy has diminished in the wake of the Supreme Court's eBay decision, blunting the impact of using contract-based remedies in lieu of patent remedies.").

<sup>413</sup> Robert Cook-Deegan, *Patenting Life: Genes and Generations*, IPBIO NETWORK (July 11, 2013), [ipbio.org/patenting-life-genes-generations.htm](http://ipbio.org/patenting-life-genes-generations.htm).

<sup>414</sup> *Id.*

<sup>415</sup> Nadia Arumugam, *Illegal Genetically Modified Wheat Found In Oregon Farm: Should We Be Worried?*, FORBES (May 31, 2013, 3:02 PM), <http://www.forbes.com/sites/nadiaarumugam/2013/05/31/illegal-genetically-modified-wheat-found-in-oregon-farm-should-we-be-worried/>.

<sup>416</sup> *Id.*

<sup>417</sup> *Id.*

<sup>418</sup> Daniel Fisher, *Monsanto Says GM Wheat 'Isolated Incident,' But Lawyers Bet There Will Be More*, FORBES (June 5, 2013, 2:18 PM), <http://www.forbes.com/sites/danielfisher/2013/06/05/monsanto-says-gm-wheat-isolated-incident-but-lawyers-bet-there-will-be-more/>.

pleading trace contamination and lack of intent.

## 2. Incidental Users

The second potential group of users liable for infringement is those whose uses were incidental. Justice Kagan noted, when writing for the Court in *Bowman v. Monsanto*, that incidental uses might not constitute infringement.<sup>419</sup> In the field of copyright law, Congress enacted an “essential step defense” for the operation of software on a computer system, which necessarily involves creating another copy.<sup>420</sup> As the United States argues, “[s]uch legislative action would have been unnecessary if the copyright exhaustion doctrine (codified at 17 U.S.C. 109(a)) already provided such a defense.”<sup>421</sup>

Patent attorneys Patrice P. Jean and Friedrich B. Laub have noted that courts may not find infringement for incidental users “independent of the precise scope of the claims covering the stem cells” because “self-replication would occur outside any human control, and because it would be incidental to the overall therapy and not the primary purpose.”<sup>422</sup> Since claims over stem cells are normally directed at isolated cells or cell cultures, “replication of patent protected stem cells in vivo (in the body), once they have been administered to the patient, will probably not constitute infringement because the resulting second-generation cells are not ‘isolated’ any longer.”<sup>423</sup> According to Jean and Laub, it is unlikely that incidental replication in stem cell-based therapeutic processes will harm the commercial interests of patent owners.<sup>424</sup> Where patent claims cover stem cells that are grown in vitro, the tissue culture is “outside of a living organism or patient” and may be

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<sup>419</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1769 (2013).

<sup>420</sup> *See, e.g., Vernor v. Autodesk, Inc.*, 621 F.3d 1102, 1109 (9th Cir. 2010) (“In order to use a software program, a user’s computer will automatically copy the software into the computer’s random access memory.”); *see* 17 U.S.C. § 117(a) (2013) (providing that “it is not an infringement for the owner of a copy of a computer program to make or authorize the making of another copy or adaption of that computer program” in the manner specified).

<sup>421</sup> Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 17.

<sup>422</sup> Patrice P. Jean & Friedrich B. Laub, *Protecting Self-Replicating Biotechnologies In View of Bowman v. Monsanto*, 86 Pat. Trademark & Copyright J. (BNA) 376 (2013) (“The term ‘stem cell’ refers to cells in multicellular organisms that can differentiate into a multitude of specialized cell types and that can divide to produce more stem cells. Adult stem cells, which are found in various tissues of the adult organism, are usually distinguished from embryonic stem cells, which are present in the inner cell mass of blastocysts. Stem cells are also distinguished based on their capacity to differentiate into any cell type or only into some cell types.”). *See also id.* (noting that “patent-protected stem cells are used for research purposes in animals” would likely be non-infringing.).

<sup>423</sup> *Id.*

<sup>424</sup> *Id.* Similarly, patent attorneys Chris Jeffers, Carl B. Massey, Jr. and Thomas F. Poché note the replication for the maintenance of culture cells during authorized use or in preparation for such use would be not be infringing if the law implies a license for multigenerational use. Jeffers et al., *supra* note 211.

infringing because replication is the primary purpose of the activity and the activity is done under human control.<sup>425</sup> While Jean and Laub acknowledge that there may be close cases between short and long-term cell cultures, they state that in practice the distinction is without practical relevance because new stem cell cultures are bought to ensure “optimal therapeutic capacity.”<sup>426</sup>

In contrast, a more serious threat is posed to patent owners who have claims over genetically engineered bacteria and eukaryotic cells, which better maintain their potency.<sup>427</sup> How might patent owners protect such inventions? One way, suggested by Jean and Laub, is through license restrictions on use.<sup>428</sup> Under such terms, buyers of genetically engineered bacteria and eukaryotic cells can use the cells, but cannot sell them to third parties. They note that such restrictions are “routine in the industry.”<sup>429</sup> Given that infringement will depend on how the invention works and its intended use, the context provided by the express grant of the license may be as important as its restrictions.<sup>430</sup> Reinforcing the loose assurance by the Court in *Bowman v. Monsanto* that a judicial exception might be available to them, the Federal Circuit decision in *Organic Farmers* suggests that like *de minimis* infringers, courts will exonerate these incidental users under the doctrine of implied licenses.

### 3. “*Mallinckrodt* Users” and the Unfinished Business of *Quanta*

The third group consists of licensees who fall within the ambit of the Federal Circuit’s *Mallinckrodt* case. The *Mallinckrodt* court held

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<sup>425</sup> Jean & Laub, *supra* note 422.

<sup>426</sup> *Id.* (“Stem cells are inherently prone to differentiation in culture and unnecessary culture is often avoided to maintain the cells’ capacity to differentiate into multiple cell types. Thus, similar to Vernon Bowman who purchased seeds from Monsanto for his first-crop but not his less economically important second-crop, customers might accept the cost of purchasing new stem cells each time they use them to assure that the cells have optimal therapeutic capacity and are not compromised.”); *see also id.* (noting that the foregoing also applies to plasmids, “small circular DNA molecules that were originally derived from bacteria and that encode, for example, resistance to certain antibiotics”).

<sup>427</sup> *Id.* (“Genetically engineered bacteria and eukaryotic cells are primarily useful as research tools or vehicles for the production of certain metabolites or proteins (e.g., antibodies). Additionally, engineered bacteria are also used for the degradation of certain waste products and the clean-up of oil spills, for example.”).

<sup>428</sup> *Id.* Similarly, Jeffers, Massey, and Poché note that the multifunctional nature of DNA vectors means that there are infringing purposes that do not specifically require replication. Jeffers et al., *supra* note 211 (“DNA vectors can be used for a variety of purposes, not all of which require replication. For example, vectors can be used as probes or markers, they can be used to transport sequences of interest for further manipulation, or they can be used as immunizing agents. . . . Of course, some vectors are used in contexts where replication is likely or assumed (e.g., transfection of cells or bacteria, generation of transgenic tissues or organisms).”).

<sup>429</sup> *Id.*

<sup>430</sup> *Id.*



that patentees could restrict the use and sale of patented articles, and that violation of the restriction amount to patent infringement.<sup>431</sup> But if the Court in *Bowman v. Monsanto* found every unauthorized new growing of Roundup Ready crops to be infringing, this would obviate the need in many cases for contractual restrictions. How then is *Mallinckrodt* still relevant?

Farmers may buy transgenic seed covered by method patents from authorized dealers. Under *Mallinckrodt*, the farmers would be liable for patent infringement if they used those seeds in a manner prohibited by the patentee, even though they were using the seeds bought (rather than new seeds grown), as long as the patentee had restricted the permissible uses through its license agreement. If the Court had held that *Quanta* overruled *Mallinckrodt*, the farmers would not be liable for infringement as the patent rights in those seeds would be exhausted. Farmers would be liable for contractual remedies, but not patent remedies. The same result would apply if farmers could buy transgenic seed cover by product patents but not grow new seeds. And farmers who had no contractual privity with Monsanto, for example, those who bought seed from grain elevators, would not even be contractually liable. The Court's express expunging of *Mallinckrodt* in *Bowman v. Monsanto* would have been helpful in clarifying the law. More importantly, it would have provided a critical avenue out for these farmers, whose rights must now be tested and defined by further litigation.

Exhaustion prevents a situation in which "a patentee could impose restrictions on the subsequent use and sale of patented articles," and "[t]he aggregation of such restrictions, through multiple downstream transactions, would create vast uncertainty and greatly impede the flow of commerce."<sup>432</sup> Consequently, if patent rights over an article can never be exhausted until patent expiration, *amicus* Business Software Alliance warns that patent holdups in the downstream market could occur if the defendant had incurred sunk costs in adopting the technology.<sup>433</sup>

Future cases taking up this issue should make a clear distinction between licenses and sales. A license is an agreement by the patentee not to sue the licensee for infringement of the patent, and is usually granted with certain restrictions in order for the patentee to divide its

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<sup>431</sup> *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (1992).

<sup>432</sup> Kyle M. Costello, *The State of the Patent Exhaustion Doctrine, Post-Quanta v. LG Electronics*, 18 TEX. INTELL. PROP. L.J. 237, 263–64 (2010).

<sup>433</sup> Herbert Hovenkamp, *Post-Sale Restraints and Competitive Harm: The First Sale Doctrine in Perspective*, 66 N.Y.U. ANN. SURV. AM. L. 487, 517 (2011) ("If the patentee can catch downstream violators by surprise it will be in a position to extract much higher royalty rates than it could if the infringement notification were more timely.").

rights between different licensees.<sup>434</sup> Importantly, patentees cannot use a license to cover up what was actually a sale.<sup>435</sup>

One obstacle to this initiative is that courts have been lax in making that distinction. In copyright law, software companies have successfully used licenses as an end run around exhaustion. In *Vernor v. Autodesk, Inc.*, the U.S. Court of Appeals for the Ninth Circuit held that a copyright owner retained title to the software despite the “significant transfer restrictions” it imposed on buyers of its software packages including that it was non-transferable, geographical use restrictions, and its termination upon authorized copying or failure to comply with license restrictions.<sup>436</sup> As a licensee rather than an owner of a copy of the software, the defendant was not allowed even to resell copies under the first sale doctrine.<sup>437</sup> The Ninth Circuit rejected the “economic realities” that customers possessed copies of their software indefinitely without recurring license payments as evidence that they were owners.<sup>438</sup> The operating system animating an iPhone, for instance, belongs to Apple Corp. and not to the device’s purchaser.

Similarly, under Monsanto’s business model farmers license their use and it may be the start of a trend where consumers no longer own what they buy.<sup>439</sup> Monsanto argued that farmers “are both purchasers and licensees” as they “purchase soybean seeds, which they then use to ‘make’ new patented articles under the authority of their license.”<sup>440</sup> It pointed out that it is paid a license fee with each purchase of seeds and that the soybean seeds were conveyed as “a qualified sale for less than value for limited use.”<sup>441</sup> The soybeans Bowman bought from the grain elevator were unauthorized because Monsanto had no contractual relationship with the grain elevator and “did not authorize elevators to do anything with its technology.”<sup>442</sup> Grain elevators, then too, are liable for infringing the right to sell seed with patented traits and for abetting farmers like Bowman who plant and grow the seeds.

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<sup>434</sup> Downing-Howk, *supra* note 95, at 52–53 (2004) (“[P]atentees, under some circumstances have maximized the exploitation of patent benefits by licensing another to make and vend the patented product.”).

<sup>435</sup> Richard H. Stern, *Post-Sale Patent Restrictions After Mallinckrodt—An Idea in Search of Definition*, 5 ALB. L.J. SCI. & TECH. 1, 4 (1994). *See also id.* at n.5 (transferring of possession of a patented product was a sale regardless of whether or not it was “accompanied by what purported to be a license.”).

<sup>436</sup> *Vernor v. Autodesk, Inc.*, 621 F.3d 1102, 1111–12 (9th Cir. 2010).

<sup>437</sup> *Id.* at 1112.

<sup>438</sup> *Id.*

<sup>439</sup> *See* Caleb Garling, *Monsanto Seed Suit and Software Patents*, SAN FRANCISCO CHRONICLE (Feb. 23, 2013, 3:54 PM), <http://www.sfgate.com/technology/article/Monsanto-seed-suit-and-software-patents-4303103.php>.

<sup>440</sup> Brief for Respondents, *supra* note 1, at 35, n.21.

<sup>441</sup> *Id.* at 35, n.21 (citing *Bauer & Cie v. O’Donnell*, 229 U.S. 1, 16 (1913)).

<sup>442</sup> *Id.* at 37, n.22.

Further, Monsanto argued that selling soybeans to farmers was “[t]he only practical way to license the Roundup Ready® trait commercially.”<sup>443</sup> In contrast with “more traditional technologies,” with which patentees can license uses transferring title, the seeds “delivering the patented technology to licensees are fully consumed when used; they cannot be leased or rented because Monsanto could not require return of those articles upon completion of the licensed use.”<sup>444</sup> Neither was a license appropriate, Monsanto asserted, because traited beans are produced “only through propagation and cross-breeding of a seed that already contains the patented invention.”<sup>445</sup>

In its brief, Monsanto argued that even if the sale was authorized, buyers remained subject to licensing restrictions between the patent owner and the manufacturer.<sup>446</sup> It was true that in *Quanta*, unlike in *Bowman v. Monsanto*, Intel’s authority to sell products embodying LG’s technology was unrestricted. However, what was relevant was the fact that an authorized sale was made.<sup>447</sup> If one could simply contract around exhaustion, this “would reduce the entire sale exhaustion doctrine to a default contract rule, easily avoided by proper drafting of a license agreement” and by “controlling the downstream uses of a patented item, the patent owner would be able to assert a right to seek additional royalties from subsequent purchasers of the product.”<sup>448</sup>

As a matter of precedent, Server and Casey argued that *Quanta*’s rejection of the implied license rationale for patent exhaustion “called into question [*Mallinckrodt*]’s treatment of a sale as a license,” and noted that the Federal Circuit itself had treated the license like a sale for exhaustion purposes.<sup>449</sup> Recently, the Federal Circuit reiterated that “‘lack of a sale’ was no barrier to the application of patent exhaustion.”<sup>450</sup> Instead, exhaustion “occur[s] when the patented product

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<sup>443</sup> *Id.* at 13.

<sup>444</sup> *Id.* at 45–48.

<sup>445</sup> Brief for Respondents, *supra* note 1, at 47 (“That Monsanto *must* accompany each license for a farmer to manufacture the patented technology with a sale of seeds that will be consumed when planted should not convert a limited license to use the technology to grow one commercial crop into a blanket authorization to become a direct competitor of Monsanto.”).

<sup>446</sup> *Id.*

<sup>447</sup> Brief of BSA | The Software Alliance as Amicus Curiae in Support of Respondents, *supra* note 167 at 21.

<sup>448</sup> *Id.* See also Shubha Ghosh, *Carte Blanche, Quanta, and Competition Policy*, 34 J. CORP. L. 1209, 1224 (2009) (“Once it is recognized that a patent owner can condition a transfer of patented technology and that this condition prevents the exhaustion of the patent owner’s rights, then the patent owner logically has the ability to bring patent infringement claims against anyone who obtains the technology from the first purchaser and violates the contractual condition.”).

<sup>449</sup> Server & Casey, *supra* note 232 at 594 (referring to *LG Elecs, Inc. v. Bizcom Elecs, Inc.*, 453 F.3d 1364 (Fed. Cir. 2006)).

<sup>450</sup> *LifeScan Scotland, Ltd. v. Shasta Technologies, LLC*, 2013-1271, 2013 WL 5878598 (Fed. Cir. Nov. 4, 2013)

‘passes to the hands’ of a transferee and when he ‘legally acquires a title’ to it.’<sup>451</sup>

Professors Thomas Cotter and John Golden have separately observed that the Court in recent years has been committed to reining in patentee rights and restoring primacy to its own jurisprudence in patent law.<sup>452</sup> The starting point of recalibrating patent rights must be in the Constitution, which authorizes Congress to “secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries” and requires that such grants “promote the Progress of Science and useful Arts.”<sup>453</sup> In agriculture as in other industries, patents fulfill this constitutional purpose.<sup>454</sup>

In interpreting the Patent Act, the Court has stated that the primary purpose of the patent system is not to reward individual inventors, but rather to promote technological advancement through disclosure and dissemination of inventions that meet the requirements for patentability.<sup>455</sup> The purpose of the Patent Act is not to ensure the greatest possible financial return, but to benefit the public. Once the initial sale is made, the inventor has received his financial incentive to invent and the purpose is fulfilled.<sup>456</sup> Thus, “[a] restriction which would

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<sup>451</sup> *Id.* See *Helferich Patent Licensing, LLC v. New York Times Co.*, 10-CV-4387, 2013 WL 4401378 (N.D. Ill. Aug. 14, 2013) (finding that patent exhaustion applied to patent licenses over mobile wireless technology).

<sup>452</sup> See, e.g., Thomas F. Cotter, *A Burkean Perspective on Patent Eligibility, Part II: Reflections on the (Counter) Revolution in Patent Law*, 11 MINN. J. L. SCI. & TECH. 365, 367, 371–72 (2010) (“In the four years since . . . the United States Supreme Court has scaled back some of the Federal Circuit’s more expansive readings of patent doctrine[,] . . . provided a necessary corrective to that ever-expanding system . . . and reaffirmed the vitality of the first-sale doctrine.”); John M. Golden, *The Supreme Court as “Prime Percolator”: A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. REV. 657, 658, 671 (2009) (“[T]he Supreme Court has, in the past six years, asserted its dominion over patent law with frequency and force. . . . [T]he increased frequency and substance of Supreme Court review has [sic] coincided with an increase in the rate and severity of adverse results for Federal Circuit decisions. In the last ten terms studied, the Supreme Court has affirmed the Federal Circuit’s decisions in only two patent cases, vacated the Circuit’s decisions in four, and reversed the Circuit’s decisions in six. All four of the most recently decided cases ended in a reversal.” (footnotes omitted)).

<sup>453</sup> U.S. CONST. art. I, § 8, cl. 8. It is the sole constitutional grant of power that “begins with a prescription of proper legislative purpose.” Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. ILL. L. REV. 1119, 1153.

<sup>454</sup> See *J.E.M. AgSupply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 534 U.S. 124, 130–31 (2001). See also *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (“The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts.”).

<sup>455</sup> *Chakrabarty*, 447 U.S. at 307 (quotations omitted) (noting that the legislative authority to enact patent laws “is exercised in the hope that ‘[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.’”) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974)).

<sup>456</sup> *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) (“[T]he primary purpose of our patent laws is not the creation of private fortunes for the owners of patents

give to the plaintiff such a potential power for evil over an industry . . . is plainly void, because wholly without the scope and purpose of our patent laws, and because, if sustained, it would be gravely injurious to that public interest, which we have seen is more a favorite of the law than is the promotion of private fortunes.”<sup>457</sup>

From a competition perspective, post-sale restrictions facilitate obtaining and maintaining monopoly power.<sup>458</sup> To hold that anyone who bought SRTs and used them for their intended purpose had violated patent rights would be to authorize patentees to extract tribute from an untold number of licenses for what was basically a single sale of the patented invention. As *amicus* Business Software Alliance points out, such licensing models will result in a “huge increase in litigation, with little benefit to anyone other than patent lawyers.”<sup>459</sup> Extending patent rights beyond the first sale through the stream of commerce disproportionately rewards patent owners and unduly interferes with the free movement of goods in the marketplace.

*Amicus* Automotive Aftermarket Industry Association (“AAIA”) confirms that “the threat of potentially devastating patent infringement liability chills competition by aftermarket businesses.”<sup>460</sup> The AAIA explains that “[p]atent suits involve technically complex issues of infringement, claim construction, and validity, and are extremely expensive to defend. Enhanced damages, attorney fees, and preliminary and permanent injunctive relief pose intolerable risks for small entrepreneurial companies.”<sup>461</sup> The AAIA argues:

Reaffirming the scope of patent exhaustion also will restore the proper balance between patent rights and antitrust law. Post-sale

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but is “to promote the progress of science and the useful arts”) (citation omitted).

<sup>457</sup> *Id.* at 519. *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942). (“[W]hilst the remuneration of genius and useful ingenuity is a duty incumbent upon the public, the rights and welfare of the community must be fairly dealt with and effectually guarded. Considerations of the individual emolument can never be permitted to operate to the injury of these.”).

<sup>458</sup> *Winston*, *supra* note 109, at 344 (“There has been a dramatic increase in private investment in agricultural research, based on the realization that contracts can be used to essentially monopolize the market.”).

<sup>459</sup> Brief of BSA | The Software Alliance as Amicus Curiae in Support of Respondents, *supra* note 167 at 24.

<sup>460</sup> Brief Amici Curiae of Automotive Aftermarket Indus. Ass’n, *supra* note 167 at 7 (“While repair and supplies businesses can rely on patent marking and published patents to evaluate whether their activities constitute repair and not reconstruction, they have no analogous public information to determine whether devices are subject to post-sale restrictions. Businesses that later upgrade or repair products (such as the computers at issue in *Quanta*) may be unaware of a purported downstream restriction. Aftermarket competitors likely never will see the outer container of the original vended item, and have no information to determine whether the outer container was slapped with a post-sale restriction or whether such a restriction legally could prevent repair.”).

<sup>461</sup> *Id.* at 7–8.

patent conditions and infringement lawsuits typically target manufacturers and sellers of competing supplies and repair services, not the purchasers that purportedly agreed to the post-sale restrictions. By allowing post-sale patent restrictions to limit exhaustion, the Federal Circuit necessarily proscribes lawful aftermarket competition and limits antitrust defenses—thereby restricting consumer choice, increasing consumer prices, and stifling aftermarket innovation.<sup>462</sup>

A careful reading of *Quanta* suggests that the position may be clearer than some might think. The Court quoted its earlier decision in *Keeler*.<sup>463</sup> The correct view seems to be that a post-sale condition cannot continue to haunt subsequent purchases as long as their use of the patented article does not involve a new “making.”<sup>464</sup> The court held that “regardless of the fact that Lexmark may not have received the full value of its Prebate cartridges, after *Quanta* Lexmark may not invoke patent law in order to enforce its Prebate terms” to limit post-sale use of its printer cartridges.<sup>465</sup>

Thus, once patentees part with their patented articles in a manner that does not constitute patent infringement by the seller, since it was authorized under the patent, exhaustion results. Failure by the buyer to adhere to any purported restrictions with respect to that article cannot trigger an infringement suit. As observed by the United States in its *Bowman v. Monsanto* brief, “the Federal Circuit had erred in fashioning a ‘conditional sale’ exception to patent-exhaustion principles.”<sup>466</sup> Servitude to the patent following an authorized sale is “the very thing the exhaustion doctrine is intended to prevent.”<sup>467</sup> Commentators such as Professor Herbert Hovenkamp agree that *Quanta* has “reinstated a strict patent ‘exhaustion’ (first-sale) rule against post-sale restraints.”<sup>468</sup>

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<sup>462</sup> *Id.* at 8.

<sup>463</sup> *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666 (1895) (“Whether a patentee may protect himself and his assignees by special contracts brought home to the purchasers is not a question before us, and upon which we express no opinion. It is, however, obvious that such a question would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws.” (quoting *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 637, n.7. (2008))).

<sup>464</sup> *Static Control Components, Inc. v. Lexmark Int’l, Inc.*, 615 F. Supp. 2d 575, 582–86 (E.D. Ky. 2009) (“*Quanta* . . . represents a change in the law . . . because the Court reasserted a broad understanding of patent exhaustion in the face of Federal Circuit case law that had narrowed the scope of the doctrine. That Federal Circuit case law had been followed as binding precedent by the district courts, including this one. . . . *Quanta* overruled *Mallinckrodt* sub silentio. The Supreme Court’s broad statement of the law of patent exhaustion simply cannot be squared with the position that the *Quanta* holding is limited to its specific facts.”).

<sup>465</sup> *Id.* at 586.

<sup>466</sup> Brief for the United States as Amicus Curiae Supporting Affirmance, *supra* note 1, at 7.

<sup>467</sup> *Id.* at 7.

<sup>468</sup> See Heimes, *supra* note 56, at 118 (“Since the *Scruggs* case was decided, the U.S. Supreme Court broadened the patent exhaustion doctrine in *Quanta Computer, Inc. v. LG Elecs., Inc.*,

Depending on the nature and scope of the SRT patents at issue, owners could still appropriate some returns on their investment even if contractual restrictions are not enforceable. In the context of genetically engineered bacteria and eukaryotic cells, Jean and Laub point out that owners could sell a companion product such as a growth medium that was independently patented, as Monsanto did with its Roundup-Roundup Ready pairing.<sup>469</sup> A second method, they suggest, is to “engineer cells that replicate slowly, or not at all, in culture” to prevent the creation of second-generation cells.<sup>470</sup> This is reminiscent of Monsanto’s Terminator gene technology discussed earlier.<sup>471</sup>

Extinguishing post-sale restrictions would provide a bright line rule preventing downstream purchasers from being caught unaware by a requirement to pay royalties, reducing the incentive of patentees to litigate against downstream purchasers, and increasing the incentive to bargain for a royalty *ex ante* that better reflects the value of that technology.<sup>472</sup> This is consistent with a plain reading of the Court’s observation in *Quanta* that “[t]he longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item.”<sup>473</sup> Apart from freeing up harvest seed for secondary market commerce, the seed will also be available for use in research in developing new stacked traits, thus enhancing competition in the upstream market for traits as well. Extinguishing post-sale restrictions would also be consistent with *Quanta*’s concern with “expectations of fairness and justice in the public interest” and not merely to the advancement of innovation.<sup>474</sup>

### III. MONSANTO AND THE IP-ANTITRUST INTERFACE

Antitrust and patent misuse claims were featured in Monsanto’s earlier suits against farmers and licensees in relation to its Roundup and Roundup Ready technologies, but none were successfully asserted.<sup>475</sup>

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reversing the Federal Circuit’s narrow application of the doctrine.”)

<sup>469</sup> Jean & Laub, *supra* note 422, at 4 (suggesting that plasmids could be “sold in conjunction with proprietary reagents (with separate IP protection) that enable, or at least enhance, their performance.” Giving an example of how “reporter” plasmids can be “marketed together with a proprietary reagent that allows them to properly be assayed or function.”).

<sup>470</sup> *Id.* (suggesting that plasmids could be prepared so that they self-replicate only after a DNA sequence has been inserted, citing the example of TA-vectors “which are linearized plasmids that become amplifiable only after they have been circularized with the help of an insert.”).

<sup>471</sup> See *supra* Part II.B.2.

<sup>472</sup> Amelia Smith Rinehart, *Contracting Patents: A Modern Patent Exhaustion Doctrine*, 23 HARV. J.L. & TECH. 483, 535 (2010).

<sup>473</sup> *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008).

<sup>474</sup> Rinehart, *supra* note 472, at 535.

<sup>475</sup> See, e.g., *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752 (1984) (distributor of agricultural herbicides brought antitrust suit against the manufacturer alleging Monsanto conspired with other distributors to fix resale prices and terminated plaintiff for price cutting);

Commentators reflecting on the *Bowman v. Monsanto* decision wrote that “[b]y holding that Monsanto’s restriction on replanting was within the scope of its patent rights, the Supreme Court effectively immunized that restriction from antitrust scrutiny.”<sup>476</sup> That view, which found currency with some judges in “pay-for-delay” cases, was recently dispelled by the Supreme Court in *Actavis*; the Court clarified that patent owners were not immune from antitrust scrutiny merely because they were acting within the scope of their patent rights.<sup>477</sup>

The Court emphasized that an antitrust inquiry into the appropriate scope of patent rights is not defined solely by “the length of the patent’s term or its earning potential[,]” but rather “by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances[.]”<sup>478</sup> Thus, “[w]hether a particular restraint lies ‘beyond the limits of the patent monopoly’ is a conclusion that flows from that analysis and not . . . its starting point.”<sup>479</sup> In that analysis, the Court noted that “patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”<sup>480</sup> Since patent misuse analysis typically starts with the analysis of patent scope, the doctrine will likely have to be rethought in light of *Actavis* as

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*Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1339 (Fed. Cir. 2006) (farmer accusing Monsanto of misuse and antitrust violations through its “seed grower incentive programs, its seed partner license agreements, its grower license agreements, and its alleged refusal to sell Roundup Ready® cotton seeds without the Bollgard trait.”); *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1342 (Fed. Cir. 2004) (farmer accusing Monsanto of misuse and antitrust violations by refusing to allow the “untying” of the seed and the trait “by permitting the farmer to save and replant ROUNDUP READY® seed each year, provided the farmer still pays directly to Monsanto the required technology fee, rather than requiring a farmer to purchase both the seed and the genetic technology together at the beginning of each growing season.”).

<sup>476</sup> Cynthia Chen et al., *Patent Exhaustion Rejected: Patented Seed Purchaser Has No Right to Make Copies*, MCDERMOTT WILL & EMERY, (May 16, 2013), <http://www.mwe.com/Patent-Exhaustion-Rejected-Patented-Seed-Purchaser-Has-No-Right-to-Make-Copies-05-16-2013/>. See 15 U.S.C. § 2 (2006) (declaring it unlawful for any person to “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.”); 15 U.S.C. § 1 (2006) (requiring, in section 1 of the Sherman Act, concert of action between two or more market participants and, therefore, foreclosing unilateral action by a firm from giving rise to an antitrust violation under that section).

<sup>477</sup> Fed. Trade Comm’n v. *Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013) (“Solvay’s patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement’s ‘anticompetitive effects fall within the scope of the exclusionary potential of the patent.’ But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.”) (quoting Fed. Trade Comm’n v. *Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012)).

<sup>478</sup> *Id.*

<sup>479</sup> *Id.* at 2231–32.

<sup>480</sup> *Id.* at 2231.



well.<sup>481</sup>

As antitrust cases involving Microsoft, Intel, Google and others have shown, widespread adoption of a particular technology by consumers does not mean that markets are functioning competitively.<sup>482</sup> A 2009 report by the AAI warned that the conditions in the seed industry create “an almost intractable situation for competition.”<sup>483</sup> It observed an absence of competition at an inter-platform level.<sup>484</sup> Growers are left with only one brand to choose from: Monsanto’s.<sup>485</sup> Roundup Ready is used on approximately 95% of soybean acres in America and Monsanto itself supplies 99.7% of the relevant market for herbicide-tolerant traits in the United States.<sup>486</sup> It is for all practical purposes a near monopolist and the 325% price increase between 1995 and 2011 is evidence of its market power.

Intra-platform competition—where biotech companies license popular patented traits from patentees to add new traits—has also been impaired according to a 2009 report by the AAI.<sup>487</sup> This lack of intra-platform competition stems from “high concentration, single-firm dominance, and strategic conduct [that] forecloses rivals from the access to technology that is critical for intra-platform competition.”<sup>488</sup> Judge Clevenger, dissenting in *Monsanto Co. v. McFarling* noted:

[T]he purchaser cannot reasonably obtain the necessary goods or services on alternative terms from any other source. Monsanto widely licenses its patents on glyphosate resistance technology, and over 200 seed companies offer Roundup Ready soybean seed. But each and every one of those licenses requires that the ultimate consumer (the farmer) sign Monsanto’s own Technology Agreement. While Monsanto’s monopoly on glyphosate resistance technology may be an entirely lawful one, Monsanto’s control of the market

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<sup>481</sup> See Daryl Lim, *Patent Misuse and Antitrust: Rebirth or False Dawn?*, 20 MICH. TELECOM. & TECH. L. REV. (forthcoming 2014).

<sup>482</sup> *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001); *in re Intel Corp. No. 9341*, F.T.C. (Oct. 29, 2010), available at <http://ftc.gov/os/adjpro/d9341/101102inteldo.pdf>; Consent Order, *In re Google, Inc.*, F.T.C. No. 102 3136 (Jan. 1, 2013), available at <http://www.ftc.gov/os/caselist/1023136/110330googlebuzzagreeorder.pdf>.

<sup>483</sup> MOSS, *supra* note 136, at 12.

<sup>484</sup> *Id.*

<sup>485</sup> *Id.* at 11 (“[R]ivalry is *between* transgenic seed platforms. Seed containing traits that are exclusive to a single firm are the product of such platforms.”); see Khan, *supra* note 7.

<sup>486</sup> Defendants’ Amended Answer and Counterclaims at 27, *Monsanto Co. v. E.I. DuPont De Nemours and Co.*, No. 409-686 (E.D. Mo. July 10, 2009), 2009 WL 2589331.

<sup>487</sup> MOSS, *supra* note 136, at 11–12 (“Intra-platform competition involves rivalry *within* platforms whereby firms develop new transgenic seed products, in part, by obtaining access to rivals’ patented traits.”).

<sup>488</sup> *Id.* at 14.

means that farmers have no place else to turn for glyphosate-resistant seed.<sup>489</sup>

The AAI Report characterized Monsanto's licensing model as a "closed" platform "designed to frustrate rivals' access to needed technology."<sup>490</sup> It noted that allowing Monsanto's seed-saving restrictions of patented seed could cause anticompetitive effects to "extend upstream to the market for genetic traits."<sup>491</sup> Rival genetic trait developers and seed companies would be incentivized to adopt Roundup Ready as an industry standard "because Monsanto's policing of its system ensures recurring annual sales."<sup>492</sup> Coupled with the ubiquity of the Monsanto Roundup Ready trait, rivals would lose incentive to compete vigorously to create rival soybean systems, which would enhance Monsanto's market power.<sup>493</sup>

DuPont's Pioneer division sought to introduce what it claimed were superior input and output traits that Monsanto did not offer.<sup>494</sup> DuPont alleged that because of the widespread adoption of Roundup Ready, the commercial viability of these next-generation output traits depends on the biotech company being able to stack these traits on Roundup Ready.<sup>495</sup> Monsanto's market share in seeds and seed traits has led commentators to liken Monsanto's business to "a classic platform monopoly" similar to "AT&T's telephone lines before the

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<sup>489</sup> *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1301 (Fed. Cir. 2002). See Burke Bindbeutel, *The Beans of Wrath: Genetic Patent Holders Reap Further Protection Monsanto Co. v. Bowman*, Note, 19 J. ENVTL. & SUSTAINABILITY L. 426, 449 (2013) ("An antitrust counterclaim against Monsanto becomes more persuasive as the availability of seeds that do not contain Monsanto's patented traits decreases, or even simply on the market realities that have compelled farmers to plant Monsanto's seeds.").

<sup>490</sup> In contrast, "open" platforms interoperate with rival technologies. See MOSS, *supra* note 136, at 12.

<sup>491</sup> Brief of Amici Curiae the Am. Antitrust Inst. et al., *supra* note 172, at 30.

<sup>492</sup> *Id.* at 30.

<sup>493</sup> *Id.* at 30–31 ("If Monsanto's share of the market for herbicide tolerant soybean traits allows it to dictate the terms of rivals' access to Monsanto traits for the purpose of developing plant varieties that combine or 'stack' various genetic traits, Monsanto's technology licensing practices are likely to have increasingly greater influence in shaping or controlling the evolution of competition in the market.").

<sup>494</sup> Pioneer sought to introduce Herculex, an insect resistant trait, in its corn, and offer Roundup Ready traited soybeans with low linolenic and high oleic traits, which according to DuPont have numerous practical and environmental benefits. See *E.I. DuPont de Nemours & Co., DuPont Asserts Anti-Trust, Patent Claims against Monsanto*, DUPONT (June 16, 2009) (characterizing Monsanto's lawsuit as "seek[ing] to block innovative new soybean lines from . . . Pioneer Hi-Bred" and asserting that "[w]e believe we have every right through our existing . . . license agreement to 'stack' our Optimum® GAT® trait Pioneer soybeans already containing a Roundup Ready® trait."). See also Defendants' Amended Answer and Counterclaims, *supra* note 486, at ¶ 162 ("To prevent competition from the introduction of the OGAT corn trait, Monsanto has used its monopoly power in the relevant markets to restrict Pioneer's ability to stack that trait with the Herculex® insect-resistant traits that Pioneer co-developed with Dow.").

<sup>495</sup> Defendants' Amended Answer and Counterclaims, *supra* note 486, at ¶ 47.

company's 1984 breakup or Microsoft Corp.'s Windows operating system in the 1990s."<sup>496</sup> That technology, they argue, is "a facility that competitors need access to, to compete against the monopolist."<sup>497</sup> Like Monsanto, Microsoft's market share in the PC operating system market exceeded 90%.<sup>498</sup> The tying of its Internet browser to its operating system foreclosed the secondary market for applications and hampered the ability of rivals to compete.<sup>499</sup> The technological tide in the years that followed, however, has eroded Microsoft's ability to leverage its market power. While the exact figures vary slightly, Internet Explorer is estimated to have slid from more than two-thirds of the Internet browser market in 2008 to under a third in 2013, due in part to the introduction of Google's more popular Chrome browser, which some market share estimates place as high as forty percent.<sup>500</sup> In the market for herbicide-resistant traits, however, it is a different story. Professor Bohannon points out that Monsanto possessed substantial market power since "no other competitors produced seed with the same herbicide-resistant qualities."<sup>501</sup>

Antitrust law equates neither the ownership of a patent with monopoly power, nor the mere possession of monopoly power as a violation.<sup>502</sup> However, the possession of monopoly power opens the conduct of Monsanto to scrutiny in extending or maintaining its monopoly in violation of the antitrust laws. With increased antitrust scrutiny, allegations of patent misuse, which require a lower, and in some cases, a different threshold, will likely follow.<sup>503</sup> Monsanto's victory against Bowman could fortify its market power against

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<sup>496</sup> Jack Kaskey & William McQuillen, *Monsanto's Seed Patents May Trump Antitrust Claims*, BLOOMBERG (Mar. 12, 2010), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aXnemqNlsotQ>.

<sup>497</sup> *Id.*

<sup>498</sup> *United States v. Microsoft Corp.*, 87 F. Supp. 2d 30, 51 & n.6 (D.D.C. 2000).

<sup>499</sup> Christina Bohannon, *IP Misuse As Foreclosure*, 96 IOWA L. REV. 475, 504 (2011) ("[F]irst, Windows was the only realistic choice for an operating system for most customers (there was market power in the tying product); and second, browsers have no viable uses except in conjunction with an operating system (there was no other incentive for rival firms to produce new browsers). As a result, the tie had the effect of foreclosing competition in the tied-product market.").

<sup>500</sup> *See Top 5 Browsers from July 2008 to Oct 2013*, STATCOUNTER GLOBAL STATS, <http://gs.statcounter.com/#browser-ww-monthly-200807-201310> (last visited Nov. 4, 2013).

<sup>501</sup> *Id.* at 503–04. *See also* Daryl Lim, *Beyond Microsoft: Intellectual Property, Peer Production and the Law's Concern with Market Dominance*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 291, 301 (2008) (arguing that "if there is an alternative system of innovation that creates more market players on a continuing basis, it should result in less dominance and, consequently, less need for intervention by competition authorities in IP markets").

<sup>502</sup> *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) ("[M]erely possessing monopoly power is not itself an antitrust violation . . .").

<sup>503</sup> *See, e.g., Kimble v. Marvel Enterprises Inc.*, 727 F.3d 856 (No. 11-15605), 2013 WL 3621763 (finding patent unenforceability for breach of royalty clause after the patent had expired). *See generally* LIM, *supra*, note 348.

consumers and competitors. Accordingly, it is useful to look ahead and consider the broader issues at the IP-Antitrust interface that have already arisen or will arise in light of Monsanto's market activities.

Part A examines the proposition advanced by some commentators that Roundup Ready is a standard essential patent, and considers how the controversial essential facilities doctrine could help foster competition in the market for genetically modified seeds and other SRT markets like embryonic stem cell research. Part B examines the Accord, an initiative by Monsanto and other agro-biotechnology companies to encourage the development and commercialization of their technology even after the patents covering those technologies expire, and how Monsanto's win may benefit Bowman and other farmers in the long run. Part C examines the charge of "evergreening" patents raised against Monsanto, and argues that a system similar to Paragraph IV challenges under the Hatch-Waxman Act could facilitate generic competition in agro-biotechnology and other markets.

#### A. *Roundup Ready: A Standard Essential Patent?*<sup>504</sup>

Even though the Roundup Ready patent expires in 2014, the Court's decision in *Bowman v. Monsanto* will still affect patents on Roundup Ready 2 Yield. As the AAI notes, "Monsanto would maintain its current ability to control access to the technology, agricultural biotechnology innovators may continue to experience difficulty in developing 'generic [Roundup Ready]' to generate competition."<sup>505</sup> Monsanto argues that such field-of-use restrictions are within the scope of its patents.<sup>506</sup> At the same time, Monsanto points out that competition will increase as the market for crops matures.<sup>507</sup> The fact that it is licensing, Monsanto asserts, shows that it is "encouraging, rather than hampering innovation."<sup>508</sup>

Monsanto is partially correct. Generally, there is no duty to license rivals under antitrust law.<sup>509</sup> Antitrust law also allows patentees to grant

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<sup>504</sup> The discussion in Parts III.A and III.C have been adapted from an earlier newsletter article. Daryl Lim, *Rebooting the Bean: Genetically Modified Seeds and the Antitrust-Patent Interface*, 3 A.B.A. SEC. OF ANTITRUST LAW, AGRIC. AND FOOD COMM. BULLETIN, at 2 (2012), available at [http://www.americanbar.org/content/dam/aba/publications/antitrust\\_law/at800006\\_newsletter\\_2012fall.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publications/antitrust_law/at800006_newsletter_2012fall.authcheckdam.pdf).

<sup>505</sup> Brief of Amici Curiae the Am. Antitrust Inst. et al., *supra* note 172, at 31 ("If Monsanto's existing contractual seed-saving restrictions, coupled with the Federal Circuit's new exception to the first sale doctrine for self-replicating technologies, simply migrate to [Roundup Ready 2], there is little evidence to suggest a meaningfully different competitive outcome.") (alteration in original).

<sup>506</sup> Brief for Respondents, *supra* note 1, at 13.

<sup>507</sup> William Neuman, *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, NYTIMES.COM (Mar. 11, 2010), <http://www.nytimes.com/2010/03/12/business/12seed.html?pagewanted=all>.

<sup>508</sup> *Id.*

<sup>509</sup> See *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). See also *Verizon Commc'ns*

licenses limited to use in a defined field.<sup>510</sup> Control over their technology is integral to encouraging patentees to license it and spur further investments in innovation. Supporters argue Monsanto represents “an IP success to be emulated,” rather than “an antitrust culprit to be eliminated.”<sup>511</sup>

At the same time, antitrust law prohibits patentees from creating or maintaining their monopoly, for example, through limiting access to intellectual property needed to compete in a secondary market.<sup>512</sup> The law is also clear that restrictions may be anticompetitive if used to prevent the emergence of a market for second-hand goods that compete with goods sold by the primary manufacturer.<sup>513</sup> The refusal to deal can be an actual refusal, or constructive—where the patent owner will only license on unreasonable terms and conditions.<sup>514</sup>

Since Roundup Ready is so popular, other biotech companies desiring to offer seeds with other traits need to offer Monsanto’s trait to farmers as well. DuPont argued that by refusing to license those traits for “stacking” within the seeds sold, Monsanto unlawfully excludes competition, allowing it to set the minimum prices for seed without significant impact on its market share.<sup>515</sup> Commentators also point out that the social waste of duplicating Monsanto’s effort makes it more efficient to encourage DuPont and others to invest in other types of traits.<sup>516</sup> Access to Roundup Ready trait stacking would allow DuPont and others to offer goods in the complementary output trait market. It

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Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) (“We have been very cautious in recognizing such exceptions [to the right of refusal to deal], because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm.”); 1 HERBERT HOVENKAMP, ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 13.3 (2d ed. 2010) (“[T]here is no general duty under either the intellectual property or antitrust laws to use or license an intellectual property right.”).

<sup>510</sup> Gen. Talking Pictures Corp. v. W. Elec. Co., 304 U.S. 175, 181 (1938). The joint IP licensing guidelines issued by the DOJ and FTC in 1995 are consistent with this position. See U.S. Dep’t of Justice & Fed. Trade Comm’n, *supra* note 334, at § 2.3 (noting that field-of-use licenses may increase the patentee’s incentive to license by “protecting the licensor from competition in the licensor’s own technology in a market niche that it wants to keep to itself”).

<sup>511</sup> Ronald A. Cass, *Monsanto’s Seeds of Growth*, FORBES (Feb. 11, 2010, 4:42 PM), [http://www.forbes.com/2010/02/11/antitrust-intellectual-property-monsanto-dupont-opinions-contributors-ronald-a-cass\\_print.html](http://www.forbes.com/2010/02/11/antitrust-intellectual-property-monsanto-dupont-opinions-contributors-ronald-a-cass_print.html).

<sup>512</sup> United States v. Paramount Pictures, Inc., 334 U.S. 131 (1948) (tying patented machines and copyrighted films); Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1219–20 (9th Cir. 1997) (holding that Kodak’s refusal to sell patented parts to ISOs constituted monopoly leveraging from parts to servicing). *But see in re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1329 (Fed. Cir. 2000) (holding that Xerox’s refusal to sell patented parts to ISOs did not violate the antitrust laws).

<sup>513</sup> See, e.g., United States v. United Shoe Mach. Corp., 110 F. Supp. 295, 346 (D. Mass. 1953).

<sup>514</sup> See, e.g., DocMagic, Inc. v. Ellie Mae, Inc., 745 F. Supp. 2d 1119 (N.D. Cal. 2010).

<sup>515</sup> Lim, *supra* note 504, at 2.

<sup>516</sup> Purcell, *supra* note 34, at 1252.

does not cannibalize on the Roundup Ready trait market, but instead fosters its growth in the same way that more apps written for a software platform would make that platform more attractive through network effects.<sup>517</sup>

The essential facilities doctrine (“EFD”), a related concept, prohibits actual or attempted monopolization of a single market by denying potential competitors access to a facility of which the owner has exclusive control.<sup>518</sup> As Professors Phillip Areeda and Herbert Hovenkamp explained:

It should be clear that the essential facility doctrine concerns vertical integration—in particular, the duty of a vertically integrated monopolist to share some input in a vertically related market, which we call market #1, with someone operating in an upstream or downstream market, which we shall call market #2. If the facility is truly “essential,” then the #1 monopoly facility also establishes a #2 monopoly . . . Understanding the “vertical” nature of essential facility claims helps to focus the analysis: the essential facility claim is about the duty to deal of a monopolist who is able to supply an input for itself in a fashion that is so superior to anything else available that others cannot succeed unless they can access this firm’s input as well.<sup>519</sup>

The Court of Appeals for the Seventh Circuit in *MCI Communications Corp. v. AT&T* held that where the owner denies access to competitors of an essential facility it controls that cannot be practically or reasonably duplicated, and that it can feasibly provide access to, antitrust law can require compulsory sharing of that facility.<sup>520</sup> Courts are divided on the threshold for access. Some require

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<sup>517</sup> See, e.g., *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001).

<sup>518</sup> Marina Lao, *Search, Essential Facilities, and the Antitrust Duty to Deal*, 11 NW. J. TECH. & INTEL. PROP. 275, 275–78, 304 (2013) (“The essential facilities doctrine is basically a subset of the general antitrust duty to deal. Even where no essential facility is involved, a monopolist’s unilateral ‘refusal to deal’ with a competitor can give rise to liability under section 2 of the Sherman Act in exceptional circumstances.”). Some decisions have confused the two, equating the essential facilities doctrine with monopoly leveraging. See, e.g., *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150 (4th Cir. 1990) (“As with monopoly leveraging claims, the central concern in an essential facilities claim is whether market power in one market is being used to create or further a monopoly in another market.”). The offense of monopolization is often said to require proof of the possession of monopoly power in a relevant market, and “the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966).

<sup>519</sup> PHILLIP E. AREEDA & HERBERT HOVENKAMP, *FUNDAMENTALS OF ANTITRUST LAW* 2012, 134–36 (4th ed. 2011).

<sup>520</sup> *MCI Commc’ns. Corp. v. American Tel. & Tel. Co.*, 708 F.2d 1081, 1132–33 (7th Cir. 1982) (condemning AT&T’s refusal to grant competing suppliers of long distance telephone services access to local telephone facilities that it controlled). See also *Hecht v. Pro-Football, Inc.*, 570

elimination of downstream competition, while for others it is sufficient that duplication is “economically infeasible” and denial inflicts a “severe handicap on potential market entrants.”<sup>521</sup>

One of the main criticisms directed to advocates of the EFD is that it has been invoked without proof that the owner actually intended to increase market power in a downstream market.<sup>522</sup> Denial by itself does not indicate anticompetitive intent. The antitrust plaintiff must prove that there was a “‘willful acquisition or maintenance’ of monopoly power” or attempt to monopolize.<sup>523</sup> Antitrust plaintiffs alleging essential facilities claims against Monsanto will face resistance from those claiming the Supreme Court’s equivocal stance on the EFD.<sup>524</sup>

Notwithstanding this potential resistance, some maintain that there is a clear role for the EFD. Ryan Vacca, Benjamin Cole and Brent Horton argue that “patents governing GM seeds should be deemed de facto standard essential patents (de facto SEP), when certain requirements are met” with the result that “[o]nce the GM seed has been labeled a de facto SEP, courts can find an implied license between Monsanto and farmers.”<sup>525</sup> They point to recent litigation involving patented technology adopted as industry standards by standard setting organizations being licensed on reasonable and non-discriminatory (RAND) terms.<sup>526</sup> This, they say, “changes the damages regime from one based in compensation, deterrence, and punishment to one based in

F.2d 982, 992 (D.C. Cir. 1977), *cert. denied*, 436 U.S. 956 (1978) (“To be ‘essential’ a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants.”).

<sup>521</sup> *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 992 (D.C. Cir. 1977). *Cf.* *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 544 (9th Cir. 1991).

<sup>522</sup> Allen Kezsbom & Alan V. Goldman, *No Shortcut to Antitrust Analysis: The Twisted Journey of the “Essential Facilities” Doctrine*, 1996 COLUM. BUS. L. REV. 1, 10-11. *See also* Philip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841 (1989); HERBERT HOVENKAMP, *FEDERAL ANTITRUST POLICY* §7.7 (3d ed. 2005) (“The so-called essential facility doctrine is one of the most troublesome, incoherent and unmanageable of bases for Sherman § 2 liability. The antitrust world would almost certainly be a better place if it were jettisoned.”).

<sup>523</sup> Kezsbom & Goldman, *supra* note 522, at 30; *see also* Amy Rachel Davis, *Patented Embryonic Stem Cells: The Quintessential “Essential Facility”?*, 94 GEO. L.J. 205, 225-26 (2005) (calling the foreclosure of a downstream market the “fifth criterion” of MCI).

<sup>524</sup> *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) (“[W]e find no need either to recognize it or to repudiate it here.”). *See* Spencer Weber Waller, *Areeda, Epithets, and Essential Facilities*, 2008 WIS. L. REV. 359, 363-64 (concluding that plaintiffs rarely won essential facility cases). *Cf.* Davis, *supra* note 523, at 230 (arguing that first, the Supreme Court decision in *Otter Tail* used the EFD’s underlying rationale and applied the elements in MCI, and second, that Verizon concerned a case where the industry had sector specific legislation obligating access).

<sup>525</sup> Vacca et al., *supra* note 401 (“Specifically, these requirements are that: (1) the patent holder has achieved dominance in a given field; (2) it is impracticable to expect that a farmer could operate without infringing the patent; and (3) the farmer is growing a crop used to meet a basic human need.”).

<sup>526</sup> *Id.*

compensation only.”<sup>527</sup> And they are not alone.

Applying the factors articulated by the *MCI* court, patent attorney Joseph M. Purcell, Jr. argued that “[p]roperly applied, the essential facilities doctrine would go no further than to ensure that no firm captured an entire agricultural market with one key trait and thereby used its monopoly power to garner market success for its other traits and suppress those of its competitors.”<sup>528</sup> Purcell’s analysis is as follows:

- Monsanto did not refuse to license Roundup Ready per se, but its licenses restricted trait stacking. Purcell notes that “[g]iven that the anti-stacking provisions in Monsanto’s licenses had the clear effect of restricting competition in stacked traits, it stands to reason that these licenses count as denial for the purposes of essential facility analysis.”<sup>529</sup>
- Monsanto’s patent over Roundup Ready confers monopoly power.<sup>530</sup> It has power over price and can exclude competition in the market for the herbicide-resistant trait for soybeans in the United States.<sup>531</sup> Purcell acknowledged that “[d]efining the relevant market as one that only incorporates the Roundup Ready trait may severely undermine the patent,” but the overwhelmingly widespread use of Roundup makes Roundup Ready a de facto standard, which justifies defining the relevant market around that standard as the Court of Appeals for the Third Circuit did in *Broadcom Corp. v. Qualcomm Inc.*<sup>532</sup>
- Monsanto’s refusal to grant access to Roundup Ready affects DuPont’s market for traits in oleic acid output. The two traits are not competing, but complementary. Therefore, “if Monsanto refused to license Roundup Ready for stacking with competitors’

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<sup>527</sup> *Id.*

<sup>528</sup> Purcell, *supra* note 34, at 1274.

<sup>529</sup> *Id.* at 1271.

<sup>530</sup> Vacca et al., *supra* note 401 (defining the product market as the crops that infringe the patent without distinction between GM and non-GM seed. They define the geographic market as where the community goes to buy seed, defined locally rather than regionally or nationally.). According to the authors, the Herfindahl-Hirschman Index (“HHI”) a measure of dominance, stands at 8100. *See id.* at 37, n.254. According to the guidelines used by the agencies, anything about 2500 is considered highly concentrated. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N., HORIZONTAL MERGER GUIDELINES § 5.3 (2010), available at <http://www.justice.gov/atr/public/guidelines/hmg-2010.html>.

<sup>531</sup> Vacca et al., *supra* note 401 (“[B]ecause alternatives are unavailable, it is not reasonably possible to exclude the GM crops from the alternative crops. In fact, it is impossible. Lack of access to non-GM alternatives forces farmers to purchase GM seeds (and thus, license the technology) even when the farmer may not desire to utilize the GM properties.”).

<sup>532</sup> *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 314, 316 (3d Cir. 2007). For a discussion of patent abuse in the standard setting context, see Daryl Lim, *Misconduct in Standard Setting: The Case for Patent Misuse*, 51 IDEA 559 (2011).



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output traits, that would resemble the leveraging theme present in most essential facility cases.”<sup>533</sup> Access would promote competition and innovation in complementary markets without harming incentives to innovate in traits that could become “essential.”

- Monsanto’s refusal to grant access to stack Optimum GAT with Roundup Ready constitutes a refusal to grant a competing product access. DuPont’s Optimum GAT was only commercially viable if offered together with Roundup Ready. Given that DuPont’s technology enabled it to offer seeds with stacked traits without Monsanto’s active assistance, by simply refraining from enforcing the restriction, Monsanto would provide access to the technology. The licensing would not require ongoing oversight by the courts.<sup>534</sup>

As to the last point, at least one court has refused to apply the EFD to intellectual property to deprive owners of a first mover advantage. The antitrust plaintiff in that case argued that they deserved the same timely and preferential access to interoperability information as the owner enjoyed in order to develop competing products.<sup>535</sup> Courts who have considered the EFD in the context of intellectual property cases have also rejected its application on grounds of non-essentiality rather than on the basis that the EFD cannot apply to IP.<sup>536</sup> At the same time, this objection should be properly contextualized. Antitrust law treats intellectual and real property alike.<sup>537</sup> Professor Marina Lao articulates

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<sup>533</sup> Purcell, *supra* note 34, at 1273.

<sup>534</sup> *Id.* at 1269–74. *See also id.* at 1268–69 (“Stacking, or the combination of traits within a single seed, allows for the possibility of crops containing multiple fruits of genetic research. The application of antitrust law and the essential facilities doctrine to stacking and its prohibition may therefore play a large role in the future of agricultural research, development, and consumer choice.”).

<sup>535</sup> *In re Microsoft Corp. Antitrust Litig.*, 274 F. Supp. 2d 743, 746 (D. Md. 2003). For a discussion of the essential facilities doctrine in the context of the Microsoft litigation, see Daryl Lim, *Copyright Under Siege: An Economic Analysis of the Essential Facilities Doctrine and the Compulsory Licensing of Copyrighted Works*, 17 ALB. L.J. SCI. & TECH. 481 (2007). *See also* Lim, *supra* note 501.

<sup>536</sup> *See* Davis, *supra* note 523, at 228–30 (citing *Montgomery Cnty. Ass’n of Realtors, Inc. v. Realty Photo Master Corp.*, 878 F. Supp. 804 (D. Md. 1995) (involving copyrighted “multiple listing service”), *aff’d*, 91 F.3d 132 (4th Cir. 1996); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 761 F. Supp. 185, 192 (D. Mass. 1991) (involving copyrighted computer diagnostic software), *aff’d in part*, 36 F.3d 1147 (1st Cir. 1994); *BellSouth Adver. & Publ’g Co. v. Donnelly Info. Publ’g, Inc.*, 719 F. Supp. 1551 (S.D. Fla. 1988) (involving copyrighted telephone listings), *rev’d on other grounds*, 999 F.2d 1436 (11th Cir. 1993).

<sup>537</sup> *See in re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000) (“Intellectual property rights do not confer a privilege to violate the antitrust laws.”). *See also* U.S. Dep’t of Justice & Fed. Trade Comm’n, *supra* note 334, at § 2 (“[F]or the purpose of antitrust analysis, the Agencies regard intellectual property as being essentially comparable to any other form of property.”); Robert Pitofsky et al., *The Essential Facilities Doctrine Under U.S.*

skepticism towards the incentive-based objections to requiring sharing:

These incentive concerns, though widely accepted, seem overstated. It is difficult to know the actual long-term economic effect of placing some limitations on a monopolist's reward through the imposition of a duty to deal in limited circumstances. While reducing returns on investment in innovation through compulsory sharing may reduce future investments at the margins, economic analysis cannot tell us how much less investment and whether it would actually decrease useful innovation. Moreover, mandatory sharing may unleash innovation and competition from *rivals* in the downstream market, which ought to be taken into account in the calculus of the total effects of compulsory access on innovation. Economic analysis, no matter how rigorous, is probably inadequate to make these assessments. Therefore, I am somewhat skeptical of incentive effects as a *macro* policy rationale against compulsory access.<sup>538</sup>

The Court has been increasingly concerned with patents preempting scientific advancement. In the context of another SRT—embryonic stem cell research, Amy Rachel Davis has argued that the EFD benefits consumers because it allows “many teams of researchers to be working toward inventing useful, marketable products incorporating embryonic stem cells—not just one—as competition in the innovation market for stem cell products is likely to yield a wider variety of consumer goods in a shorter amount of time.”<sup>539</sup>

With DuPont, it was not seeking to deprive Monsanto of a first mover advantage in a software market where products have commercial short shelf lives, but rather access in a market where product life cycles are long and more akin to patented drugs. This minimizes harm to Monsanto's appropriation to its investments in Roundup Ready.

Assuming the foregoing is correct, a court would still need to determine the appropriate royalty rate DuPont would pay Monsanto. Recent developments in standards involving smartphones and tablet PCs seem to suggest that where a patent owner owns a patent that forms a core component of a widely adopted standard, it can be subject to obligations to license its rivals.<sup>540</sup> Vacca, Cole, and Horton point to

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*Antitrust Law*, 70 ANTITRUST L.J. 443, 452 (2002) (“[T]he essential facilities doctrine applies to intellectual property no less than to tangible assets.”).

<sup>538</sup> Lao, *supra* note 518, at 314.

<sup>539</sup> Davis, *supra* note 523, at 213. *See also id.* at 232–33 (arguing first, that access to embryonic stem cells was essential to compete in the market for stem cell therapies, second that patents over purified stem cells create supply silos as no other firm can supply them without being liable for infringement, third, access to the cells would be both feasible and profitable and there would be no legitimate business justification in refusing access).

<sup>540</sup> *See generally* Dan O'Connor, *Standard-Essential Patents in Context: Just a Small Piece of the Smartphone War Puzzle*, PATENTPROGRESS (Mar. 5, 2013), <http://www.patentprogress.org/>

*Microsoft Corp. v. Motorola, Inc.*, as precedent for the court finding an established royalty rate of 2.25% based on prior license agreements, and argue that “[t]he case for using an established royalty in Monsanto’s GM seed litigation is even easier because the established rate is for the exact same product.”<sup>541</sup>

The European Union’s Directive on Protection of Biotechnological Inventions provides for compulsory cross-licensing, where breeders cannot acquire or exploit a plant variety right without infringing a prior patent.<sup>542</sup> A farmer or licensee can apply for a compulsory license for non-exclusive use of the patent, which will be granted “subject to payment of an appropriate royalty.”<sup>543</sup> Compulsory licenses also apply in situations where a patent holder cannot exploit an invention without infringing a plant variety right.<sup>544</sup> In addition, the Directive allows soybean farmers to save patented seed from their harvests for replanting.<sup>545</sup>

In March 2013, Monsanto and DuPont announced that they would be settling the patent infringement and antitrust disputes.<sup>546</sup> Under the terms of settlement, Monsanto agreed to license its Roundup Ready technology to DuPont for at least \$1.75 billion and drop its \$1 billion jury verdict against DuPont for patent infringement.<sup>547</sup> Under the terms of the settlement with Monsanto, DuPont will receive “regulatory data rights for the soybean and corn traits previously licensed from Monsanto, enabling it to create a wide array of stacked trait combinations using traits or genetics from DuPont Pioneer or others.”<sup>548</sup> According to DuPont Pioneer President Paul E. Schickler, this arrangement promises to help “both companies to expand the range of innovative solutions we can offer farmers, and to do so faster than either

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2013/03/05/standard-essential-patents-in-context-just-a-small-piece-of-the-smartphone-war-puzzle/.

<sup>541</sup> Vacca et al., *supra* note 401, at 47.

<sup>542</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 12, 1998 O.J. (L 213) 13, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> [hereinafter Directive 98/44/EC]. See generally Michael Blakeney, *Patenting of Plant Varieties and Plant Breeding Methods*, J. EXPERIMENTAL BOTANY (Jan. 2, 2012), <http://jxb.oxfordjournals.org/content/early/2012/01/02/jxb.err368.full>.

<sup>543</sup> Directive 98/44/EC, *supra* note 542, at art. 12.

<sup>544</sup> *Id.*

<sup>545</sup> *Id.* at art. 14 (confining protection to fodder plants, cereals, potatoes, oil and fiber plants). See also *id.* at art. 11(1).

<sup>546</sup> Carey Gillam, *Monsanto, DuPont Strike \$1.75 Billion Licensing Deal, End Lawsuits*, REUTERS (Mar. 26, 2013, 5:40 PM), <http://www.reuters.com/article/2013/03/26/us-monsanto-dupont-gmo-idUSBRE92P0IK20130326>.

<sup>547</sup> *Id.*

<sup>548</sup> *DuPont and Monsanto Reach Technology Licensing Agreements on Next-Generation Soybean Technologies*, MONSANTO (Mar. 26, 2013), <http://monsanto.mediaroom.com/index.php?s=27632&item=135196>.

of us could alone,” and provides “greater flexibility in developing combinations of genetics and traits[.]”<sup>549</sup>

The settlement between DuPont and Monsanto testifies to the importance of antitrust oversight in the biotechnology industries where SRTs are created. It should be recalled that the settlement comes after Monsanto had won a billion dollar victory against DuPont for patent infringement. Yet the specter of antitrust scrutiny from the DOJ and the threat of private enforcement from DuPont threatened to derail that victory. By committing to a license of its standard patents, Monsanto would have more control over the terms of access than a compulsory court mandated license, or worse, a divestiture as was initially ordered in the *Microsoft* litigation a decade earlier.<sup>550</sup> At the same time, the end result is that competitors benefit from increased access to patented trait technology and farmers benefit from a wider variety of seed traits at a lower cost.

Whether the DuPont settlement signals Monsanto’s willingness to allow trait stacking on a wider scale remains to be seen. Monsanto has every incentive to stay its course in opening up access to its technologies in a manner that it can control, rather than to do so under an antitrust decree. At present what is clear is that Monsanto and a few other seed companies have undertaken a remarkable new initiative called the Accord, whose success may depend on both the reassurance of robust patent rights as well as a continued reluctance to test the boundaries permitted under the antitrust laws.

#### B. *Enter The Accord: Aligning Disparate Interests?*

The Accord was presented as an invitation for members of the agricultural value chain to participate and guide its evolution. It counts among its signatories—BASF Plant Science, Bayer Crop Science, Dow Agro Sciences, DuPont Pioneer and Monsanto.<sup>551</sup> The Accord sets out the rights and duties involved in commercializing patented single-gene plant products and encourages patent holders to continue developing and commercializing their technology while ensuring international regulatory and stewardship responsibilities are maintained.<sup>552</sup> These goals are achieved via data access and compensation to the biotech companies.<sup>553</sup> Patent owners are required to notify interested parties to the Accord three years prior to relevant patents expiring.<sup>554</sup> Owners can

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<sup>549</sup> *Id.*

<sup>550</sup> *United States v. Microsoft Corp.*, 97 F. Supp. 2d 59 (D.D.C. 2000), *cert. denied*, 530 U.S. 1301 (2000), *aff’d in part, rev’d in part*, 253 F.3d 34 (D.C. Cir. 2001).

<sup>551</sup> *Generic Event Marketability and Access Agreement (GEMAA)*, *supra* note 19.

<sup>552</sup> *Factsheet*, *supra* note 18, at 1.

<sup>553</sup> *Id.* at 2.

<sup>554</sup> *Id.* at 3.

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choose to share or transition regulatory responsibilities through negotiation or arbitrations, if necessary.<sup>555</sup>

The Accord contains two agreements, the Data Use and Compensation Agreement (“DUCA”) and the Generic Event Marketability and Access Agreement (“GEMAA”).<sup>556</sup> DUCA promotes the range of crop options available to farmers through regulatory data sharing arrangements. Currently, more than twenty-four trait combinations are commercially available.<sup>557</sup> After patents expire, seed companies may want to use off-patent technology to develop and offer seeds stacked with expired traits. For example, as Roundup Ready expires in 2014, companies and universities with breeding programs using its patents can continue offering products containing the traits.

It is clear from *Bowman v. Monsanto* that farmers must continue to service their technology agreements with Monsanto and other seed companies as long as the relevant patents are in force. The certainty of reward over the life cycle of their products and potential for private and government antitrust enforcement may encourage greater support from patent owners, which will be crucial if farmers are to continue enjoying better seed varieties and access to foreign export markets.

The measure of control that DUCA provides patent owners encourages them to participate in the innovation and commercialization of products containing traits going off-patent. It also encourages licensing agreements without obliging farmers to pay post-expiration royalties, as well as destroy or return seed after licenses expire. Monsanto, for example, has committed not to exercise plant variety patent rights against farmers saving seeds for replanting on their own farms once the trait technology has expired.<sup>558</sup> At the same time, Monsanto has stated that it will continue to enforce variety patents and plant variety protection certificate rights against unauthorized commercialization and development.<sup>559</sup>

GEMAA allows patent owners or generic competitors willing to pay for the necessary data to obtain regulatory approval to do so without conducting its own health and environmental studies.<sup>560</sup> In this regard,

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<sup>555</sup> *Id.*

<sup>556</sup> *Id.* at 2.

<sup>557</sup> *Monsanto Company Statement on GEMAA*, THE HAGSTROM REPORT, [http://www.hagstromreport.com/assets/2012/2012\\_1109\\_MonsantaGEMAA.pdf](http://www.hagstromreport.com/assets/2012/2012_1109_MonsantaGEMAA.pdf) (last visited Oct. 22, 2013).

<sup>558</sup> *Greater Choices Are In The Hands Of Farmers*, MONSANTO, <http://sustainability.monsanto.com/commitments/greater-choices-are-in-the-hands-of-farmers> (last visited Oct. 22, 2013).

<sup>559</sup> *Roundup Ready Soybean Patent Expiration*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/roundup-ready-patent-expiration.aspx> (last visited Oct. 22, 2013).

<sup>560</sup> Thomas P. Redick & Norman W. Hawker, *Legal Issues Arising from Generic Biotech Crops*, AALA, AGRICULTURAL LAW UPDATE (Dec. 2010).

GEMAA bears similarities to an abbreviated process where generic drug companies can “fast-track” approval of their drugs at the Food and Drug Administration (“FDA”) by showing bioequivalence to patented drugs. The effect of GEMAA is to ensure that seed exports can continue to be sold and processed after patents covering the crops expire.

The United States is the largest producer and exporter of transgenic grain and crops.<sup>561</sup> About ninety percent of soybeans, cotton and corn grown the United States are transgenic.<sup>562</sup> Grain traded globally account for over \$40 billion in export revenue annually.<sup>563</sup> Unlike the United States, where the U.S. Department of Agriculture accepts indefinite use of patented seed, foreign governments approve use for a specific time period.<sup>564</sup> Transgenic grain exports thus require periodic renewals. Approvals in the European Union expire after ten years, and those in China expire after three.<sup>565</sup>

While Monsanto may have the incentive to maintain these approvals while its patents are in force, once those patents expire the technology becomes part of the public domain, free to be used by all. Predictably, that incentive is lost. Without someone to maintain regulatory approvals, governments in key markets such as Europe, China, and South America would become closed to U.S. transgenic grain exports. In the European Union and China alone, that would mean foregoing over \$10 billion in export revenue.<sup>566</sup>

GEMAA benefits seeds covered by at least one U.S. patent that are commercialized either by themselves or as stacked products in the United States at least four years prior to the expiration of the last U.S. patent. The events covered by GEMAA are fairly broad: patent term expiration, lapse in maintenance fees, invalidity or unenforceability of the relevant claims and a declaration of non-infringement by the patent holder. One significant limitation of GEMAA is that it may be nullified by a prior agreement to the contrary. Another limitation is that patent holders are only obligated to good faith negotiations for expired patents. While parties are to offer “reasonable and appropriate value,” neither is bound to accept the offer.

The smartphone and tablet industries have been grappling with the question of what constitutes a “reasonable” royalty for many years, and

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<sup>561</sup> *Factsheet*, *supra* note 18, at 1.

<sup>562</sup> *Id.*

<sup>563</sup> *Id.*

<sup>564</sup> Daniel Grushkin, *Threat to Global GM Soybean Access as Patents Nears Expiry*, 31 NATURE BIOTECHNOLOGY Vol. 10, 10–11 (Jan. 2013), available at <http://www.nature.com/nbt/journal/v31/n1/full/nbt0113-10c.html>.

<sup>565</sup> *Id.*

<sup>566</sup> Redick & Hawker, *supra* note 560, at 4.

the courts are only now beginning to define what that means.<sup>567</sup> These cases may help inform the outcome of GEMAA disputes. Another element in GEMAA that dilutes its efficacy is that even “joint responsibility” parties who are bound by the arbitral award are not obligated to execute it.<sup>568</sup>

Monsanto has chosen to independently maintain regulatory responsibilities.<sup>569</sup> It may refuse data access to companies seeking to develop new stacked seed products. At the same time, it must maintain global regulatory authorizations at no charge to users of its technology unless the companies choose to share those responsibilities or discontinue maintaining them. Choosing to discontinue starts a seven-year transition phase where other seed companies can access data necessary to continue seeking foreign regulatory approvals.<sup>570</sup> The Accord is an important private sector initiative and its impact on competition, innovation and consumer welfare as it unfurls in the coming years warrants further observation and study.

### C. Patent Evergreening and Paragraph IV Challenges

In its complaint, DuPont observed that Roundup Ready 2 Yield expresses the same enzyme that confers herbicide resistance in Roundup Ready, differing only in the use of different promoters, which function as “on switches.”<sup>571</sup> DuPont asserted that these promoters do not enhance either herbicide tolerance or yield. Rather, Roundup Ready 2 Yield’s enhancements result from non-patent-related factors, such as the different points on the genome at which the trait is incorporated and Monsanto’s requirement that farmers use its seed treatment.<sup>572</sup> DuPont also alleged that Monsanto forced Independent Seed Companies (“ISCs”) to switch from Roundup Ready to Roundup Ready 2 Yield to ensure that ISCs will offer seeds only with Monsanto’s patented Roundup Ready 2 Yield trait and not those with a competing generic

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<sup>567</sup> See, e.g., *Microsoft Corp. v. Motorola, Inc.*, No. C10-1823JLR, 2013 WL 2111217 (W.D. Wash. Apr. 25, 2013).

<sup>568</sup> *The Accord: Generic Event Marketability & Access Agreement (GEMAA)*, THE ACCORD, cl. 8(h) (May 9, 2013), [http://www.agaccord.org/include/gemaa\\_firstamendedMay9.pdf](http://www.agaccord.org/include/gemaa_firstamendedMay9.pdf).

<sup>569</sup> *The Accord: Generic Event Marketability & Access Agreement (GEMAA) Notice of Patent Expiration*, THE ACCORD (Jan. 15, 2013), <http://www.agaccord.org/include/NoticeofPatentExpirationMon810.pdf>.

<sup>570</sup> GEMAA, *supra* note 568, at cl. 2(i).

<sup>571</sup> *Id.* at ¶ 65.

<sup>572</sup> *Id.* at ¶ 66; Michael Stumo, *Anticompetitive Tactics in Ag Biotech Could Stifle Entrance of Generic Traits*, 15 DRAKE J. AGRIC. L. 137, 141 (2010) (“By using a different promoter, Monsanto can pursue additional patents only for that promoter, enabling it to claim longer patent protection for the identical RR gene. Furthermore, there appears to be no independent evidence, outside of Monsanto assertions, that RR2 offers farmers increased yields or improved tolerance to glyphosate over RR.”).

Roundup Ready trait, and in doing so foreclose generic entry.<sup>573</sup>

Michael Stumo argued that Monsanto's strategy resembles "product hopping," practiced by manufacturers of pioneer drugs to delay entry of their generic competitors. Trivial changes are made to the drugs, such as changing a capsule to a tablet. Pioneer drug companies then apply for patents over the new formulations that have marginal or no new benefits solely to delay the competition.<sup>574</sup>

In *Abbott Labs v. Teva Pharms. USA, Inc.*, for example, Abbott changed the drug Tricor from a capsule to a tablet and reduced the amount of the drug slightly.<sup>575</sup> Abbott also bought up its old products, destroyed them and listed them as obsolete in a national drug database. As a result, while Teva could sell its generic version of Tricor, it could not take advantage of state generic substitution laws, because Abbott's changes prevented Teva's drug from being equivalent and required Teva to start over in seeking FDA approval for the modified drug. The court concluded that the alleged manipulative and unjustifiable formulation changes that allegedly blocked generic substitution for Tricor barred cost-efficient distribution of generic versions of Tricor and prevented consumer choice were sufficient to support Teva's antitrust claims.<sup>576</sup> Generic entry would have facilitated inter-brand competition. Stumo argues that in the same way, generic entry in the seed trait market would result in "lower prices and more choice for farmers," as well as increased competition.<sup>577</sup>

Monsanto's CEO, Hugh Grant, acknowledged the need to convert users in order not to cannibalize profits for Roundup Ready 2 Yield, which would cost 40% more than Roundup Ready, but that this would be justified by a superior product that could increase yield by 7% to 11%.<sup>578</sup> In light of impending generic entry post-2014, such a steep

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<sup>573</sup> Defendants' Amended Answer and Counterclaims, *supra* note 486, at ¶ 2.

<sup>574</sup> 1 HOVENKAMP ET AL., *supra* note 509, at § 15.3.

<sup>575</sup> *Abbot Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408, 415, 418 (D. Del. 2006).

<sup>576</sup> *Id.* at 424.

<sup>577</sup> Stumo, *supra* note 572, at 148. Stumo also notes that Monsanto could protect its monopoly by obstructing the re-importation of generic RR soybeans. About 40% of soybeans produced in the U.S. are exported and grain elevators do not segregate them by destination. These exported soybeans thus represent an alternative source of seeds to farmers. By letting its foreign RR registrations expire or denying access to data required for foreign regulatory approvals for seeds containing RR-traits, Monsanto could cut off the exportation of those seeds, cutting off its supply at the source. *Id.* at 142. This concern has largely been addressed by Monsanto's recent commitment to maintain foreign import approvals during the transition to generic versions of RR through 2017. See Kaskey & McQuillen, *supra* note 496.

<sup>578</sup> *Monsanto Company F3Q09 (Qtr End 5/31/09) Earnings Call Transcript*, SEEKING ALPHA (June 24, 2009), available at <http://seekingalpha.com/article/152631-monsanto-company-f3q09-qtr-end-5-31-09-earnings-call-transcript?page=-1&find=crop%2Band%2Bseeds>; MONSANTO CO., MONSANTO ROUNDUP READY 2 YIELD INVESTOR PRESENTATION (2009), [http://www.monsanto.com/pdf/investors/2009/roundup\\_ready2\\_yield.pdf](http://www.monsanto.com/pdf/investors/2009/roundup_ready2_yield.pdf).



price increase, even with the increased yield, seems counterintuitive unless Monsanto was confident of being able to exclude that entry through its patents over Roundup Ready 2 Yield.

The question of whether Monsanto introduced Roundup Ready 2 Yield strategically to block lawful generic substitution for Roundup Ready would have been determined at the antitrust trial, but in 2004, Syngenta AG accused Monsanto of employing a similar switching strategy. Syngenta owned an herbicide-tolerant corn trait, GA21, originally licensed to Monsanto by GA21's previous owner.<sup>579</sup> Syngenta alleged that, perceiving Syngenta to be a competitive threat, Monsanto reacted by requiring its licensees then using the GA21 technology to switch to another herbicide-tolerant trait that Monsanto owned. Syngenta accused Monsanto of antitrust violations. Syngenta's lawsuit against Monsanto was eventually settled on undisclosed terms.<sup>580</sup>

Barriers to entry are high. An alternative to Roundup Ready could cost DuPont between \$100 million and \$150 million to develop and commercialize.<sup>581</sup> Moreover, before seeds can be commercialized, they need to receive approval from the Agriculture Department, Environmental Protection Agency and Food and Drug Administration. The process of developing new traits can span ten to fifteen years.<sup>582</sup> Because the process is long and costly, farmers cannot turn in the meantime to foreign suppliers that have not already been approved by these regulatory agencies.<sup>583</sup>

As with the pharmaceutical industry, rival agro-biotech companies need access to the patented technology before the patent expires in order to develop substitute products and navigate the regulatory channels and offer the generic substitutes when the patented version goes off-patent. Such a system could look like one established under the Hatch-Waxman

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<sup>579</sup> Defendants' Amended Answer and Counterclaims, *supra* note 486, at ¶ 159. *See also* Paul Christensen, *Roundup Ready Soybean Patent Infringement Suit Between Monsanto and DuPont: Part I Timeline*, INTLCORN (Aug. 6, 2012), <http://www.intlcom.com/seedsiteblog/?p=764> ("DEKALB/Monsanto sued Syngenta for use of GA21 patent infringement. Syngenta filed a countersuit against Monsanto alleging antitrust violations. Pattern is similar to the pattern of DuPont's response Monsanto infringement suit in 2009.")

<sup>580</sup> *See* *Monsanto Co. v. Syngenta Seeds, Inc.*, 431 F. Supp. 2d 482 (D. Del. 2006) (finding that DeKalb Genetics Corporation—which Monsanto acquired—had misappropriated the technology). The antitrust suit was settled on substantially undisclosed terms. *See Syngenta Settles with Monsanto*, THE BUSINESS JOURNAL (May 23, 2008, 10:39 AM), <http://www.bizjournals.com/triad/stories/2008/05/19/daily59.html>. For a full history of the litigation, see Paul Christensen, *GA21's Legal History*, INTLCORN (Dec. 21, 2011), <http://intlcom.com/seed%20site%202012/Intellectual%20Property/GA21.html>.

<sup>581</sup> Doug Cameron, *U.S. Regulators Speed Seed Oversight After Delays*, DOW JONES NEWswire (Sept. 2, 2009, 2:21 PM), [english.capital.gr/news.asp?ID=805738](http://english.capital.gr/news.asp?ID=805738).

<sup>582</sup> Jorge Fernandez-Cornejo, *The Seed Industry in U.S. Agriculture*, AGRICULTURE INFORMATION BULLETIN No. 786 (Jan. 2004), at 51.

<sup>583</sup> Defendants' Amended Answer and Counterclaims, *supra* note 486, at ¶ 51.

Act for pharmaceuticals that enables the promotion of generic pharmaceuticals before they go off-patent. Amanda Wellers argues that “[t]he Hatch-Waxman Act is a viable regulatory framework for the agricultural industry. The similarities between the pharmaceutical and agriculture industries, and the effectiveness of the Hatch-Waxman Act in the pharmaceutical industry, suggest that use of such a framework would be successful.”<sup>584</sup>

Manufacturers of new drugs are required to obtain the approval of a new drug application (“NDA”) from the FDA before marketing the drug.<sup>585</sup> A drug approved under the NDA process is often referred to as a “brand-name” drug. Congress enacted the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman Act”) in 1984.<sup>586</sup> The Hatch-Waxman Act was designed to speed the introduction of low-cost generic drugs to market while maintaining and refining the patent laws’ incentives for innovation.<sup>587</sup> After a brand-name drug’s NDA has been approved, another manufacturer can apply to market a generic version by filing an abbreviated new drug application (“ANDA”) with FDA.<sup>588</sup> This process does not require independent clinical evidence of safety and effectiveness, as long as the generic drug has the same active ingredient as the brand-name drug and is bioequivalent.<sup>589</sup>

The Hatch-Waxman Act creates a framework where brand-name drug makers identify to the FDA patents that can be asserted against someone making, using, or selling its drug.<sup>590</sup> Potential competitors submitting an ANDA must in turn explain how the generic drug can be marketed without infringing those patents by filing a “paragraph IV certification,” which states that a given patent identified by the patentee is invalid or will not be infringed by the making, use, or sale of the generic drug.<sup>591</sup>

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<sup>584</sup> Amanda Wellers, Note, *Striking A Balance: Revising USDA Regulations to Promote Competition Without Stifling Innovation*, 13 MINN. J.L. SCI. & TECH. 407, 423, 426 (2012) (“Due to current regulations, a generic manufacturer will need proprietary information from Monsanto to receive federal approval and the technical data needed to update licenses in areas like the European Union (EU) and China, where regulations tend to be stricter. If the agriculture industry adopted an act similar to the Hatch-Waxman Act, a generic manufacturer could develop a generic version based on the data provided in Monsanto’s patent and receive USDA approval through an abbreviated process.”).

<sup>585</sup> 21 U.S.C. §§ 355(a)–(b) (2013). The NDA contains information relating to the drug’s components, proposed labeling that describes the uses for which the new drug may be marketed, and scientific data and other information demonstrating that the drug is safe and effective as labeled. 21 U.S.C. 355(b)(1) (2013).

<sup>586</sup> Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

<sup>587</sup> See H.R. Rep. No. 98-857, pt. 1, at 14–17 (1984); *id.* pt. 2, at 5–6.

<sup>588</sup> See 21 U.S.C. § 355(j) (2013).

<sup>589</sup> 21 U.S.C. § 355(j)(2)(A)(ii), (iv) (2013).

<sup>590</sup> 21 U.S.C. § 355(b)(1) (2013).

<sup>591</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2013).

The framework incentivizes both patentees and potential competitors to engage in paragraph IV litigation. The first competitor to challenge the patent is rewarded with a promise of 180 days of exclusivity on the market if it is successful.<sup>592</sup> That exclusivity insulates the first filer from other entrants during the period of exclusivity and it gives that manufacturer a head start in reaching commercial arrangements with large purchasers, accounting for a “vast majority of [its] potential profits”<sup>593</sup> The Hatch-Waxman Act also encourage patentees to promptly sue for infringement, which triggers an automatic stay of FDA approval of the ANDA for thirty months.<sup>594</sup> That legislative injunction insulates against competition during the first thirty months of litigation.

A Federal Trade Commission study revealed that potential competitors have prevailed nearly three quarters of the time in paragraph IV litigation against patentees.<sup>595</sup> Paragraph IV litigation, therefore, provides an important means of market entry, particularly because, like patents over seeds, patents over drugs have grown in recent years with the addition of “secondary” patents, such as “patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.”<sup>596</sup> Those secondary patents may be particularly susceptible to being avoided, in whole or in part, by potential competitors.

The 2011 domestic market for drugs totaled approximately \$320 billion.<sup>597</sup> Brand-name drugs accounted for 18% of total prescriptions for drugs and biologics (which include products such as vaccines), but 73% of total spending.<sup>598</sup> This disparity reflects the monopoly reward the patent laws offer for brand name innovation. As competition sets in,

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<sup>592</sup> See 21 U.S.C. § 355(j)(5)(B)(iv) (2013) (providing that FDA will not approve a later filed ANDA to the same patent as an earlier-filed ANDA for 180 days after either a court decision finding the patent invalid or not infringed, or the first commercial marketing of the drug under the first ANDA, whichever is earlier).

<sup>593</sup> Comments on Generic Pharm. Ass’n to FTC on Authorized Generic Drug Study 2 (June 27, 2006) FED. TRADE COMM’N, available at <http://www.ftc.gov/os/comments/genericdrugstudy3/062806gpha.pdf>.

<sup>594</sup> 21 U.S.C. § 355(j)(5)(B)(iii) (2013).

<sup>595</sup> See FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 10, 19–20, (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (finding that generic competitors prevailed over brand-name manufacturers with respect to 73% of the drug products that were the subject of a court decision in paragraph IV litigation initiated between 1992 and 2000).

<sup>596</sup> C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 615, 619–23 (2011).

<sup>597</sup> See IMS INST. FOR HEALTHCARE INFORMATICS, THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2011 27 (2012), [http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII\\_Medicines\\_in\\_U.S\\_Report\\_2011.pdf](http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf).

<sup>598</sup> *Id.* at 16, 27.

prices for generic drugs fall, on average, to about 15% of what the branded manufacturer was charging.<sup>599</sup> At the same time, patentees lose about 90% of their market share to competitors.<sup>600</sup> In the context of traited seeds, companies such as DuPont seeking to offer generic genetically engineered traits could be allowed an abbreviated FDA approval process “if they can show generic equivalence to the name brand version of the crop.” Paragraph IV challenges could also make it less appealing for Monsanto to sue rival biotech developers who want to get their R&D programs going.<sup>601</sup>

#### CONCLUSION

The landscape of American agriculture has changed. Where independent farmers once characterized the industry, the work of today’s farmers is intertwined with the technology they use and those who sell such technologies. Limiting farmers to one growing season effectively means that they never own the seeds that they tend. Monsanto’s win against Bowman means that farmers must continue to honor their license agreements or risk being liable for patent infringement. Monsanto may also no longer need its restrictive agreements. The decision, therefore, may loosen its practices, giving seed companies more freedom to make their own choices.

The Article explained why alternative frameworks such as contract law have critical limitations, which make them unsuitable replacements for patent protection. Rather than fight the notion that every generation of SRTs will be laced with patent protection, it would be more constructive to focus on balancing consumer welfare and innovation concerns *ex post*. Courts will have an important role in shaping the contours of the legal landscape in SRT technology through interpretation of permissible uses, judicious use of antitrust doctrines, and drawing on experiences from the pharmaceutical industry in first finding, then refining the balance between owners, users and the public.

*Bowman v. Monsanto* reassures owners of seed patents that investment in their pipeline projects is secure. This reassurance should encourage seed companies to join the Accord, which will help stakeholders focus on bringing farmers the best products possible while working to advance innovation and long-term opportunity for

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<sup>599</sup> See FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8, (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

<sup>600</sup> *Id.*

<sup>601</sup> See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.); see generally 1 HOVENKAMP, ET AL., *supra* note 509 at § 15.3.

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agriculture. At least in theory, it opens the market to generic competition. However, this coalition of the willing few may not be enough. It will take an industry-wide adoption of the Accord, coupled with a commitment to speedy dispute resolution and a willingness to continually refine its terms to infuse it with the longevity, legitimacy and effectiveness it needs to ensure product stewardship into the foreseeable future.