

Bowman v. Monsanto and the protection of patented replicative biologic technologies

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An important US Supreme Court ruling means that prudent owners, end users and other courts will proceed with caution.

Replicative technologies have been, and synthetic replicative technologies are becoming, more and more ubiquitous. The varieties of materials capable of replication are numerous, and include biological materials such as DNA, proteins, larger macromolecular agents and entire organisms themselves¹⁻⁴. It is likely that plant genetic technologies, such as those applicable to transgenic plants or materials derived from them, for example, will continue to grow, as the number of varietal rights has generally increased over time. And because of their critical bearing on the US and global economy, it is not surprising that such technologies are protectable in the US under several different legal regimes, such as 35 U.S.C. 101 (refs. 5-6), The Plant Patent Act of 1930 (ref. 7), trade secret, and The Plant Variety Protection Act of 1970 (ref. 8), each having unique provisions and jurisprudence. For example, 42% of all such varietal rights were lodged between 2000 and 2008 alone⁹. Despite the prevalence of these technologies in society, the legal issues surrounding their patenting, including some natural and isolated synthetic DNAs, continues to be under intense debate¹⁰⁻¹². Even so, patents based on replicative technologies persist and are continuing to issue from the US Patent and Trademark Office (Table 1).

The US Supreme Court recently addressed, for the first time in its history, how the legal doctrine of patent exhaustion applies to transgenic, replicative technologies in the case of *Bowman v. Monsanto, et al.*¹³. The case came before the Court as the result of the activities of Vernon Hugh Bowman, an Indiana *Glycine*

max (that is, soybean) grower who repeatedly obtained, planted and harvested Monsanto's patented Roundup Ready soybean seed without the company's permission¹⁴. In 2011, the US Court of Appeals for the Federal Circuit decided that patent exhaustion does not bar patent infringement once a grower plants patented, genetically engineered seeds and the next generation of transgenic seed develops, thereby, in essence, creating a newly infringing article. On May 13, 2013, in a decision critical to the agbiotech industry, the Supreme Court unanimously affirmed the Federal Circuit's determination, holding that a grower of a transgenic seed, who once lawfully purchased the genetically engineered, patented seeds, was not permitted to replicate those seeds because the process used by the grower to replicate them essentially recreated the item of first purchase (that is, the transgenic seed itself, including certain patented genetic technologies). These activities, according to the Court, amounted to nothing more than the creation of a new seed that infringed the patent owner's rights. The decision was an unequivocal indication from the US Supreme Court that patented replicative seed inventions, like other nonreplicative inventions, can be adequately protected under US patent laws.

Monsanto's patented soybean technology

Generally speaking, wild-type soybeans and most transgenic soybeans are legumes that are noted for their protein-rich content and nitrogen-fixing properties¹⁵. Soybeans are relatively unique agricultural products in that subsequent-generation seed may be readily saved and replanted without suffering significant decreases in yield compared with the first-generation crop. Because soybeans are protein-rich they can be desiccated,

subsequently absorb water applied to them and survive to further replicate^{16,17}. There is essentially little comprehensive evidence of unwanted cross-pollination from transgenic soybeans to conventional or organic soybeans. Soybeans are self-pollinating and shed pollen relatively locally (that is, at a short distance). Soybean plant leaves are trifoliolate and fall off before the soybean seed fully matures. Soybean flowers are self-fertile and are formed in the axil of the leaf. The seed hull of a mature soybean is relatively hard and water-resistant, and protects the cotyledon and hypocotyl from trauma. However, they are vulnerable and if the seed coat is cracked, the seed typically will not germinate. Soybean seeds have a scar called a hilum, which is observable on the seed coat, which includes a micropyle that permits the absorption of water and subsequent sprouting¹³⁻¹⁵.

Monsanto created soybeans that are resistant to the effects of the compound glyphosate, the active ingredient in the herbicide Roundup as well as other commonly used agricultural herbicides. Although it is recognized that glyphosate can effectively eliminate weeds that contaminate crops and wild-type crops themselves, it is an attractive choice to growers because of its favorable environmental attributes (e.g., it is relatively otherwise nontoxic and can bind soil and break down rapidly). However, glyphosate-based herbicides are nonselective and will damage or completely destroy almost all varieties of wild-type plants they contact. The Roundup Ready soybean technology at issue in *Bowman v. Monsanto* is described in detail in US Patent Nos. 5,352,605 and RE 39,247 (ref. 18). Although the focus of the case has been the transgenic soybean seeds, the claims at issue describe much more than seeds, and include chimeric genes expressed

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Table 1 A sample of patented replicative technologies or those related to them

US patent no.	Title (e.g., type of replicative matter)	Assignee
8,431,767	Transgenic nonhuman animal and methods for stem cell engraftment	The Jackson Laboratory
8,329,443	Antibody composition-producing cell	Kyowa Hakko Kirin
8,202,703	Placental stem cell populations	Anthrogenesis
8,084,033	Composition comprising a cell expressing an AC133 cell surface antigen and an antibody or antigen-binding fragment	Amcell
8,283,161	Tumor cell lines and uses thereof	GlycoTope
8,450,106	Oncolytic virus	The Ohio State University Research Foundation
8,409,843	Multiplasmid system for the production of influenza virus	Medimmune
8,377,450	Clone of Newcastle disease virus, its manufacture and its application in the medical treatment of cancer	United Cancer Research Institute
6,512,161	Transgenic rabbit that expresses a functional human lipoprotein (a)	Aventis Pharmaceuticals
5,675,063	Immortalized rabbit hybridoma fusion partner	Loyola University of Chicago
7,645,925	Tobacco products with increased nicotine	North Carolina State University
8,450,561	Corn plant event MON87460 and compositions and methods for detection thereof	Monsanto Technology
8,344,209	Plant regulatory sequences	Syngenta Participations
8,435,781	Porous sheet-form material for cell culture, and bioreactor and culturing method using same	Kyushu Institute of Technology
8,133,481	Selectively replicating viral vectors	Canji
8,052,965	Viruses with enhanced lytic potency	Vereniging Voor Christelijk Hoger Onderwijs, Wetenschappelijk Onderzoek en Patientenzorg
7,780,962	Treatment of neoplasms with RNA viruses	Wellstat Biologics

in plant cells having a promoter from a cauliflower mosaic virus (that is, a CaMV (35S) promoter isolated from CaMV protein-encoding DNA sequences) and additional heterologous structural sequences, isolated DNA molecules encoding a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme having a specific amino acid sequence, glyphosate-tolerant plant cells, transgenic plant tissues and methods for selectively controlling weed growth in a field. Thus, at least two separate, published US patents set forth in detail the elements of the Roundup Ready soybean technology—one seeming to focus on the DNA molecules that encode an enzyme that allows Roundup Ready crops such as soybean to withstand the application of glyphosate and the glyphosate-tolerant plant cells, transgenic seeds and transgenic plants that have been transformed with those DNA molecules, and one said to describe the regulatory elements of chimeric genes (e.g., viral promoter DNA sequences for regulating the expression of engineered genes in plant cells). Thus, in *Bowman v. Monsanto*, far more than transgenic soybean seeds was at stake; fundamental, molecular biologic inventions were at risk of losing patent protection.

Perhaps due to the very nature of the technology, including its ability to replicate, the distribution of the Monsanto genetic technologies is tightly controlled. For example, when a purchaser wants to procure the technology described in the involved patents, he typically obtains a license from Monsanto by entering into a technology agreement, which is a contract between Monsanto and the

purchaser. Such agreements are not uncommon in the biotech industry. The agreement includes a description of the company's rights and the farmer's rights with regard to the patented technology embodied in the specifically licensed seeds, and authorizes the licensee (that is, a farmer) to use Roundup Ready seeds to grow a "single commercial crop"¹³. Because the technology is replicative, the single commercial crop that is subsequently grown from it will naturally contain the patented technologies^{14–17}. If a first-generation crop is grown under the terms of the licensee, the licensee may harvest and sell the crop he grows from Roundup Ready seeds to another party, such as an agricultural processor or a grain elevator. These third-party purchasers typically resell the harvested crops to additional parties, such as processors, and so on¹⁹. Importantly, under the explicit terms of the agreement and license, the licensee may not save seeds from harvested crops for planting in their own fields, nor may they sell saved seeds to others for the purpose of planting. Without having an agreement, Monsanto will typically refuse to license the planting of Roundup Ready seeds. This means that to act consistently with the terms of the agreement, a licensee who desires to lawfully replicate subsequent-generation seeds using Roundup Ready seeds must purchase new, first-generation seeds every planting season. According to Monsanto, the terms of this agreement are essential to their business under this model because, for example, any grower could potentially reproduce genetically identical soybeans at an exponential rate, with each soybean

having the DNA of a Roundup Ready seed and therefore having a highly desirable glyphosate-resistant phenotype.

Bowman's anomalous activities

According to court records from 1999 through 2007, Bowman planted Roundup Ready soybean seeds even though he had willfully executed a technology agreement that indicated that he would not plant and grow harvested Roundup Ready soybeans^{14–17}. He believed that he could obtain less-expensive commodity soybeans from a supplier, such as a grain elevator, and plant those soybeans which would allow him to harvest a new, subsequent-generation crop, without having to obtain Monsanto's permission. Bowman correctly anticipated that the soybeans he grew would inevitably contain Monsanto's patented technology¹⁴. Beginning in 1999, he grew several subsequent-generation soybean crops, most of which had the Roundup Ready desired trait and were therefore resistant to glyphosate, and repeatedly applied the herbicide in order to select for the desired, tolerant phenotype. Some of Bowman's resulting crops were sold to a grain elevator and some were saved to plant the following year. These types of activities have been described as being anomalous in the industry—soybean farmers typically sell harvested soybeans, transgenic or wild type, to a processor or to a grain elevator, which then offers the same soybeans for sale to processors²⁰. In other words, grain elevators do not themselves plant purchased seeds, nor do they offer for sale transgenic soybeans to farmers for the purposes of replanting. Typically,

Table 2 Selected amicus briefs and selected points raised for either Monsanto or Bowman

Selected amici	In support of	Selected points set forth
American Intellectual Property Law Association	Monsanto	Exhaustion of the right to control propagation of patented seed would disrupt the balance created by Congress between the Patent Act and the Plant Variety Protection Act Enforcement of innovators' rights in patented seed promotes the progress of useful arts Monsanto's rights are not exhausted under <i>Quanta</i> The scope of exhaustion of biotech patents could extend far beyond specific plants or seeds
American Antitrust Institute, National Farmers Union, Food & Water Watch, Organization for Competitive Markets, National Family Farm Coalition	Bowman	A patent exhaustion exception for self-replicating technologies is inconsistent with this Court's precedent and the competition policies reflected in the first-sale doctrine The Federal Circuit's holding unjustifiably departs from longstanding Congressional patent policy The Federal Circuit's discriminatory standard for self-replicating technologies ignores this Court's precedent on the patent misuse doctrine by expanding the scope of Monsanto's patent Contract law provides a balanced means of protecting the parties' interests and the public interest
Center for Food Safety, Save Our Seeds	Bowman	Applying the doctrine of patent exhaustion will curtail respondents' prosecution of US farmers Applying the doctrine of patent exhaustion will restore scientific research Applying the doctrine of patent exhaustion will benefit US agriculture by lowering farming costs and increasing crop choice and innovation Respondents' allegations of harm are grossly overstated Farming is not genetic engineering Considering farming "making" allows the absurd result that contaminated farmers are also infringers
BayDole25	Monsanto	Contractual limitations were violated by petitioner and implications for application of the exhaustion doctrine Petitioner's activities were in violation of the letter and spirit of the technology agreement
Knowledge Ecology International	Bowman	Creation of an inexhaustible monopoly right over self-replicating technology harms the public Contract law provides the more appropriate mechanism to protect investments in self-replicating technology while also safeguarding user rights Nonpatent mechanisms can and should encourage progress where patents are an inappropriate, unnecessary, insufficient or burdensome reward
Public Patent Foundation	Bowman	If progeny seed are excepted from exhaustion, then contaminated farmers are infringers The Circuit's theory indicates that Monsanto's customers routinely make and sell new infringing articles
United States	Monsanto	Under well-settled principles of patent exhaustion, the authorized sale of one article embodying a patented invention does not exhaust the patentee's exclusive right to control the creation of other articles embodying the same invention Congress's actions and this Court's decisions strongly reinforce the Court of Appeals' ruling Although prior Federal Circuit decisions applying a "conditional sale" doctrine are erroneous, those errors do not cast doubt on the court of appeals' decision in this case
New York Intellectual Property Law Association	Monsanto	The exhaustion doctrine should not be expanded beyond <i>Quanta</i> Each successive generation of a patented self-replicating biological material is a separate actionable "making" under 35 USC § 271(a)
BSA—The Software Alliance	Monsanto	The Federal Circuit properly concluded that sale of first-generation seeds does not exhaust a patent owner's rights in second-generation seeds There is no "self-replicating technology" exception to the standards governing patent exhaustion The Court should reaffirm <i>Quanta's</i> strict limits on the conditional sale doctrine
American Seed Trade Association	Monsanto	Patented seed technology benefits farmers, consumers and the environment Substantial time and resources are required to research, develop and obtain regulatory approval for patented seed Removing protection for each generation of patented seed would devastate the nation's seed industry, evaporate investment in patented seed technology and deprive the public of this technology's current and future benefits
Washington Legal Foundation	Monsanto	The patent exhaustion doctrine did not grant Bowman, by virtue of his commodity seed purchases, the right to make an unlimited number of new copies of the patented invention Roundup Ready seeds have been shown to provide numerous environmental benefits
CropLife America	Monsanto	The Federal Circuit's holding follows directly from this Court's precedents This Court's decisions in <i>Asgrow</i> and <i>J.E.M.</i> support the Federal Circuit's holding Congress has ratified this Court's and the Federal Circuit's decisions Neither <i>Quanta</i> nor <i>Univis</i> casts doubt on the Federal Circuit's holding Petitioner's proposed rule would dampen the incentive to develop new crop protection technologies, as well as readily replicable technologies in other industries
Wisconsin Alumni Research Foundation, <i>et al.</i> ^a	Monsanto	Reversing the Federal Circuit would deprive the public of the important benefits of artificial, progenitive technologies Bowman 'made' new generations of infringing seeds in violation of 35 USC § 271(a) The Court should not humor misplaced concerns about "innocent infringers"
American Soybean Association, <i>et al.</i> ^b	Monsanto	The Federal Circuit correctly held that the patent exhaustion doctrine was inapplicable to Bowman's creation of subsequent generations of soybean seeds Soybean farmers and society will substantially benefit from advances in plant biotech

^aIncluding, Association of Public and Land-grant Universities, Association of American Universities, The Regents of the University of California, The Board of Trustees of the University of Illinois, University of Florida, Duke University, Emory University, University of Georgia Research Foundation, Inc., Iowa State University of Science and Technology, NDSU Research Foundation, University of Iowa, University of Missouri-Columbia, South Dakota State University, Nutech Ventures, University of Nebraska-Lincoln, University of Kentucky, University of Kansas, Kansas State University, Montana State University, University of Delaware. ^bIncluding, Illinois Soybean Association, Indiana Soybean Alliance, Iowa Soybean Association, Kansas Soybean Association, Kentucky Soybean Association, Michigan Soybean Association, Minnesota Soybean Growers Association, Mississippi Soybean Association, Missouri Soybean Association, Nebraska Soybean Association, North Dakota Soybean Growers Association, Ohio Soybean Association, Tennessee Soybean Association, Virginia Soybean Association, Wisconsin Soybean Association, National Corn Growers Association, National Association of Wheat Growers, American Sugarbeet Growers Association, Growers for Biotechnology.



according to court records, grain elevators offer for sale soybeans to companies interested in using the seed as food for consumption by humans or livestock²⁰. Bowman's repeated activity, which was largely undisputed by him, incited Monsanto to defend their rights against infringement of the involved patents.

Although this case was *primaie impressionis*, that is, the first instance in which the Supreme Court applied the doctrine of patent exhaustion to a replicative genetic technology, the Court has previously decided cases having related issues pertaining to nonreplicative technologies, such as computer products and processes. Perhaps for this reason, stakeholders took the opportunity to extensively brief the Court on the issues. **Table 2** highlights some of the points raised by various amicus briefs. In fact, the Solicitor General of the United States encouraged the Court to refuse to hear the case and not take up the issues at all. One possible outcome was that the Court could have potentially banned infringement suits as to subsequent generations of a genetic replicative product, which may have enticed stakeholders to participate in the case. In reaching a decision in *Bowman v. Monsanto* the Court relied on, for example, its 2008 unanimous decision in *Quanta Computer, Inc. et al. v. LG Electronics, Inc.*, which involved the sale of computer components that substantially embodied a patented process.

In *Quanta*, LG Electronics (LGE) granted a license to Intel to, for example, make and use its patent-protected microprocessors, chipsets and processes²¹. The LGE-Intel licensing scheme required that a license agreement and a master agreement be entered into. The license agreement disclaimed acts by third parties that included combining licensed Intel microprocessors or chipsets with components or products that were not Intel or Quanta products, and the master agreement, a separate contract, required that Intel provide sufficient notice of this term, according to court records. Intel sent such notices to those who purchased the licensed microprocessors and chipsets, including Quanta, but Intel and Quanta ultimately combined the licensed microprocessors and chipsets with some non-Intel components. LGE subsequently sued Quanta and the involved computer manufacturers for infringement of LGE's related patents. Quanta argued that they did not infringe some of the asserted LGE patents because the technologies were licensed to Intel and/or Intel sold the licensed microprocessors and chipsets to the other defendants, acts which exhausted LGE's patent rights in the technologies. The Supreme Court ultimately found that Intel's authorized sale of chip components to Quanta exhausted LGE's patent rights because LGE authorized Intel's

sale of the licensed microprocessors and chipsets to the defendants (e.g., the license agreement) and broadly permitted "Intel to 'make, use, [or] sell' products free of LGE's patent claims"¹³. The Court reasoned that the only term limiting the party's relevant future activity was in the master agreement, which merely provided that Intel provide notice to its customers that LGE did not license to them a right to combine licensed Intel products with others' products. The Court held, "Intel's authority to sell its products embodying the LGE Patents was not conditioned on the notice or on Quanta's decision to abide by LGE's directions in that notice"¹³. Thus, according to the Supreme Court, because Intel was authorized to seemingly unconditionally sell the licensed products, LGE's patent rights were exhausted when Intel sold them outright to Quanta, for example. The Court reasoned that the authorized sale of microprocessors and chipsets (and the patented methods of using the products to organize read and write requests and to manage data traffic on a bus connecting computer components) by Intel exhausted LGE's ability to prevent subsequent purchasers of the products from using them in separately patented combinations with other components, where the products had no reasonable use except in combination with these other components¹³. According to the Court, the authorized sale of a patented product exhausted the patent owner's right to exclude subsequent purchasers from using the item that was previously sold, in certain other patented combinations or methods. Exhaustion of the right to use or sell an item, for example, extends only when the specific item is capable of use only in practicing the patent or does not have a reasonable use aside from its incorporation into the patented combination or use in the patented method.

In *Bowman v. Monsanto*, Bowman argued that the first authorized sale of Roundup Ready transgenic soybean seed exhausted Monsanto's patent rights in all subsequent progeny, and all of the technologies embodied in the progeny such as commodity soybeans produced by the original purchaser that were sold to grain elevators. The Supreme Court emphatically disagreed. According to the Court, although Bowman perhaps complied with the terms of the Monsanto agreement on his first planting, he then used significantly less-expensive commodity seed that contained patented transgenic seed, which he obtained from a grain elevator, in subsequent plantings, thereafter testing the subsequent generation crops for Roundup resistance. Through these activities the grower learned that substantial amounts of the patented transgenic seed were indeed present (e.g., plants were tolerant to glyphosate). Following

these activities, Bowman used Roundup herbicide composition to select and replant the seed. According to the Court, consistent and in line with the patent exhaustion doctrine as applied to nonreplicative technologies, and consistent with the terms of his willful agreements with Monsanto, Bowman could have resold the transgenic soybeans purchased from a grain elevator or used them as feed on his farm. The Court pointed out that Monsanto's patent rights were very limited, and would not reach so far as to extend to the various legitimate uses of Roundup Ready soybeans. However, the Court found that the exhaustion doctrine could not permit Bowman to make an unlimited number of additional transgenic soybeans without Monsanto's consent, which was clearly not consistent with the agreements that had been entered into. According to the Court, Bowman's admitted acts of purchasing transgenic seed, planting the seed, applying glyphosate to the transgenic plants and wild-type plants not having the Roundup Ready trait and harvesting more soybeans than he planted amounted to no more than a reproduction of Monsanto's patented invention, activities falling well outside of the scope of acts shielded by the exhaustion doctrine.

The Court carefully set forth the rationale for its decision. According to the Court, if Bowman were to prevail, Monsanto competitors, such as other seed companies, could readily reproduce the product without risk, thereby depriving Monsanto of all of the benefits of having obtained patents for its technology. The Justices agreed that consistent with this scenario, farmers could potentially purchase patented soybean seed once, "whether from Monsanto, a competitor, or (as here) a grain elevator" and unfairly multiply the initial purchase "*ad infinitum*." Such behavior (e.g., late-season plantings wherein after purchasing soybeans to be used for a single harvest the harvested soybeans are saved in order to eliminate the need for obtaining them in the future) was held to be inconsistent with the relevant law. The Court held that the exhaustion doctrine is limited to a "particular item" that was sold thereby avoiding a "mismatch between invention and reward." The Court thus rejected Bowman's request for an unprecedented replicative technology exception to the law¹³.

However, the Court cautioned that, "Our holding today is limited—addressing the situation before us, rather than every one involving a self-replicating product." The Court refused to make a broad rule in this case. Indeed, given the proliferation of patents covering replicative technologies, it is likely difficult for the courts to foresee how the doctrine of patent exhaustion will

be applied in various circumstances (e.g., a composition of matter that replicates without being induced to do so by a buyer but otherwise under the complete control of the buyer). Although not now creating law that is so broad as to encompass perhaps any of these hypothetical scenarios, the Court was clear that Bowman's planting of Monsanto's patented transgenic soybeans solely to make and sell identical copies of them undermined the *quid pro quo* of patent law—it unjustly deprives the company of a limited patent monopoly in return for the availability of the patented articles. Indeed, the record indicated that Roundup Ready soybeans were one of several genetically engineered crops planted in the United States and were desired owing to their phenotypic and ecologic benefits, for example. Due to the extremely limited scope of the Court's decision, more cases like this will probably be appealed to them as these technologies become more prevalent in society, which should provide courts

opportunities to clarify the scope of the narrow holding in this case.

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COMPETING FINANCIAL INTERESTS

The author declares no competing financial interests.

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