

No. 11-796

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In The  
Supreme Court of the United States

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VERNON HUGH BOWMAN,  
*Petitioner,*

v.

MONSANTO COMPANY, *ET AL.*,  
*Respondents.*

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*ON WRIT OF CERTIORARI  
TO THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT*

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**BRIEF OF THE BIOTECHNOLOGY INDUSTRY  
ORGANIZATION AS *AMICUS CURIAE* IN  
SUPPORT OF RESPONDENTS**

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Tom DiLenge  
Hans Sauer  
Biotechnology Industry  
Organization  
1201 Maryland Ave., SW  
Suite 900  
Washington, DC 20024  
(202) 962-9200

Matthew Pearson  
Akin, Gump, Strauss,  
Hauer & Feld LLP  
Two Commerce Square  
2001 Market St, Ste. 4100  
Philadelphia, PA 19103  
(215) 965-1200

Patricia A. Millett  
*Counsel of Record*  
Ruthanne M. Deutsch  
Akin, Gump, Strauss,  
Hauer & Feld LLP  
1333 New Hampshire  
Ave., NW  
Washington, DC 20036  
(202) 887-4000  
pmillett@akingump.com

## **QUESTION PRESENTED**

Whether an authorized sale subject to a technology license of one generation of patented plant seed exhausts the patentee's rights in all subsequently made generations of the patented seed.

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**INTEREST OF *AMICUS CURIAE*<sup>1</sup>**

The Biotechnology Industry Organization (“BIO”) is the principal trade association

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<sup>1</sup> This brief is filed with the written consent of all parties, who have filed universal consent letters with the Court. Pursuant to Rule 37.6, no counsel for either party authored this brief in whole or in part, nor did any party or other person make a monetary contribution to the preparation or submission of this brief.

representing the biotechnology industry domestically and abroad. BIO has more than 1100 members, which span the profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size businesses that have annual revenues under \$25 million.

Because modern biotechnological products commonly involve lengthy, expensive, and resource-intensive development periods, BIO's members depend critically on a strong, stable, and nationally uniform system of patent rights and protections. As this dispute involves the proper scope of patent protection for a biotechnological product—genetically engineered seed—BIO has a substantial interest in this Court's resolution of the case. In addition, the multifaceted experiences of BIO's members can provide the Court with unique insights on the essential role that patent rights play not only in agricultural advancements, but also in promoting medical, industrial, environmental, and scientific knowledge and discoveries.

## STATEMENT

### A. Biotechnology's Critical Innovations

The biotechnology industry is one of the most rapidly growing and innovative components of the United States economy. *See* Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (FTC Report)*

Ch. 3, p. 21 (2003) (noting the exceptionally “rapid” “pace of innovation in the biotechnology industry”).<sup>2</sup> Biotechnology companies are engaged daily in inventing, discovering, and developing new scientific testing processes, pharmaceuticals, environmental products, and treatment protocols for health problems. Those biotechnology innovations provide life-saving medicines and diagnostic procedures, disease- and drought-resistant crops, and a host of promising scientific solutions for modern environmental, medical, and agricultural challenges.

For example, biotechnology products have provided more than 250 new therapies and vaccines for once untreatable diseases, such as cancer, diabetes, HIV/AIDS, and autoimmune disorders like multiple sclerosis and rheumatoid arthritis. In addition, there are currently more than 400 biotechnology drugs in clinical trials targeting more than 200 different diseases. Those and other biologic therapies account for an increasing share of new drugs. In 2011, twenty percent of the new drugs approved by the FDA were biologic drugs.<sup>3</sup>

Biotechnology research has also resulted in new and improved vaccines, including those protecting children against pneumococcal meningitis and rotavirus. *See, e.g.,* Roger Glass & Umesh

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<sup>2</sup> *See* White House Office of Science and Technology Policy, NATIONAL BIOECONOMY BLUEPRINT 1, 7 (2012), [http://www.whitehouse.gov/sites/default/files/microsites/ostp/national\\_bioeconomy\\_blueprint\\_april\\_2012.pdf](http://www.whitehouse.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf).

<sup>3</sup> Asher Mullard, *2011 FDA Drug Approvals*, 11 NATURE REVIEWS DRUG DISCOVERY 91, 91 (2012).

Parashar, *The Promise of New Rotavirus Vaccines*, 354 NEW ENG. J. OF MED. 75, 75 (2006); Heather Hsu, *et al.*, *Effect of Pneumococcal Conjugate Vaccine on Pneumococcal Meningitis*, 360 NEW ENG. J. OF MED. 244, 244-256 (2009).

Diagnostic tools developed using biotechnology offer faster and more accurate diagnoses for illnesses ranging from strep throat to heart disease. In addition, specific genetic tests have been developed to identify cancers that will respond to treatment with specialized drugs. Biotech research tools also made it possible to discover the complete sequence of the human genome, an extraordinary feat accomplished within fifty years after the structure of DNA was first discovered. See Francis Collins, *et al.*, *A Vision for the Future of Genomics Research*, 422 NATURE 835, 835 (2003). Combining that knowledge of the human genetic makeup with specially adapted biotech research methods has led to the development of rapid and reliable diagnostic tests for a multitude of genetic diseases, as well as forensic DNA tests that help to free the innocent and jail the guilty. Nicholas Wade, *A Revolution At 50; DNA Changed the World. Now What?*, N.Y. TIMES, Feb. 25, 2003, at F1.

Biotechnology products have further achieved significantly enhanced agricultural production by creating crop seeds, like the seeds at issue here, that are more productive because they are resistant to insects and/or herbicides. In addition, crops are being developed that will grow under adverse conditions such as water or nitrogen deficiency—vital developments for combating famine around the world. Indeed, “[b]iotech foods could improve food

yields by up to 25 percent in the developing world and feed the more than three billion people to be born in the next three decades.”<sup>4</sup>

Finally, biotechnology research has provided new catalysts for improved industrial processes, such as paper manufacturing, renewable fuel sources, environmental clean-up technologies, and plastics. Those enhanced processes and products have led to dramatic energy savings, lower greenhouse gas emissions, reduced waste, and a more “bio-based economy.”<sup>5</sup>

### **B. The Importance Of Patent Protection**

Each of those products and discoveries, and countless others, resulted from years of investigation, research, and developmental efforts. That research and development process “is particularly lengthy for biotechnology firms, because biotechnology innovation is more uncertain than innovation in other industries.” *FTC Report*, Ch. 3, p. 16. It takes on average 98 months to move a drug from clinical

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<sup>4</sup> Tommy Thompson, Secretary of Health & Human Services, *Biotechnology: Its Promise and Challenge in the New Century*, <http://archive.hhs.gov/news/speech/2002/020211.html> (Feb. 11, 2002) (last visited Jan. 20, 2013); see U.S. Dep’t of Agric., *Frequently Asked Questions about Biotechnology* (2006), <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&navid=AGRICULTURE&contentid=BiotechnologyFAQs.xml>.

<sup>5</sup> See *About BIO*, Biotechnology Industry Organization, <http://www.bio.org/node/3089>; see also Organization for Economic Cooperation and Development, *The Application of Biotechnology to Industrial Sustainability—A Primer* (2001), [www.oecd.org/science/biotechnology/policies/1947629.pdf](http://www.oecd.org/science/biotechnology/policies/1947629.pdf).



development to regulatory approval, and for every successful biopharmaceutical, there are approximately 10,000 failed attempts.<sup>6</sup>

Furthermore, even when successful, the long and resource-intensive path from initial discovery of a biotechnology invention to the marketing of a useful product commonly involves multiple actors performing diverse developmental roles at different junctures. This is because “[t]he efforts required in bringing a therapy from discovery through development, regulatory approval, manufacturing and marketing are rarely the result of one company’s efforts.”<sup>7</sup> Congress, in fact, has recognized the importance of such collaborative efforts by passing the Bayh-Dole Act to, *inter alia*, “promote the commercialization and public availability of inventions” by establishing clear mechanisms for the allocation of distinct patent rights in a manner that ensures fair rewards at each step of the developmental process. 35 U.S.C. § 200.

Because biotechnology innovations require such a massive investment in research and development, “[t]he biotechnology industry is the most research and development intensive and capital-focused

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<sup>6</sup> Joseph DiMasi & Henry Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?* 28 *MANAGERIAL & DECISION ECON.* 469, 473 (2007).

<sup>7</sup> See Joseph Scholl, *WORKING TOGETHER IN THE PHARMACEUTICAL, BIOTECH AND MEDICAL DEVICE INDUSTRIES: CONTRACTUAL TERMS AND CONDITIONS* 3 (2004), *available at*: [http://www.kellogg.northwestern.edu/biotech/faculty/articles/working\\_together.pdf](http://www.kellogg.northwestern.edu/biotech/faculty/articles/working_together.pdf).

industry in the world.”<sup>8</sup> In 2010 alone, publicly traded biotechnology companies in the United States spent \$22.8 billion on research and development.<sup>9</sup>

For those reasons, “[b]iotechnology innovation is heavily dependent on the patent rights that have been available for biotechnology inventions since 1980.” *FTC Report*, Ch. 3, p. 29. Patent rights and protections make possible the stage-by-stage sharing and development of biotechnology inventions, as well as the collaborations and licensing agreements that are indispensable for small biotechnology start-ups and research universities to develop their products. In particular, patent protections “help firms to recover high, fixed R&D costs and are particularly useful in enabling biotechnology companies, which are generally small in size, to attract capital investment and to contract with other firms for commercial development of their inventions.” *FTC Report*, Ch. 3, p. 29.

### SUMMARY OF ARGUMENT

This case is about the unauthorized making of a product, not patent exhaustion. The right to make an invention is and always has been separate and distinct from the right to use or sell the invention. To accept petitioner’s proposition that the purchasers of

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<sup>8</sup> See 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., 1st Sess. 49 (2003) (Phylliss Gardner, M.D.).

<sup>9</sup> Ernst & Young, *Beyond Borders: Global Biotechnology Report 2011*, at 37 (2011).

a single patented article obtain not only that article, but also the separate right to freely and perpetually make new copies of the invention, would effectively eviscerate the government-conferred patent monopoly.

This Court's precedents foreclose that position. The Court has uniformly limited patent exhaustion principles to the right to use the specific item sold. And for good reason. Conflation of the right to use an invention with the entirely separate right to make more quantities of it would undermine the ability of a patent holder to capture any meaningful return on its investment in innovation and its sharing of new knowledge with the public.

Petitioner's patent exhaustion argument thus gets patent principles exactly backwards: The replicability of some innovations magnifies—it does not weaken—the need for adherence to established rules. To permit a purchaser to make unlimited copies of the product, simply because the blueprint for reproduction is within the product and it is relatively easy to do so would unravel the entire structure of patent rights and economic incentives that underpins innovation in the biotechnology industry and elsewhere. The right to use must end when the purchaser turns to unauthorized making.

To hold otherwise, and condone uncontrolled reproduction after the first purchase, would not only destroy the value of the patent, but would also make it impossible to commercialize a product at reasonable cost. Worse still, consumers would have no guarantee that the resulting product—whether a seed, a vaccine, or a cell-line—had been produced in

the same quality-controlled environment or was free from unintended (and unwanted) traits caused by contamination in the production-by-copying process.

Instead, patent law has made biotechnology and other high-tech innovation possible by protecting innovators' rights with a reinforcing web of foundational patent rules, field-of-use licenses, and use restrictions that has fostered collaborative investments and research partnerships and paved the way for unparalleled scientific advances in recent years, benefitting industry, agriculture, and medicine alike. Under this Court's precedents, purchasers of patented products may enjoy the full benefit of their bargain; but they may not hijack the patentee's exclusive right to make new copies of the invention or to control its field of use.

### **ARGUMENT**

Because the right to prohibit or control the reproduction of a discovery is vital to the promotion of innovation, the patent law invests those who hold a valid patent with, among other things, "the right to exclude others from making [or] using \*\*\* the invention." 35 U.S.C. § 154(a)(1). Petitioner's production of a new generation of seeds embodying respondents' patented invention through the application of specific cultivation techniques violated that fundamental patent protection. And the patent exhaustion rule does not shield petitioner's conduct because he made—not purchased or used—the infringing seeds. Furthermore, valid licensing restrictions forbade using the seeds for such unauthorized making.

**I. PATENT EXHAUSTION DOES NOT APPLY BECAUSE PETITIONER INFRINGED BY MAKING, NOT USING, SEEDS EMBODYING RESPONDENTS' PATENTED INVENTION.**

The act of infringement in this case was petitioner's repeated making of new generations of respondents' patented, glyphosate-resistant seed through the application of agricultural cultivation techniques. That act strikes at the core of patent law's most foundational protection—the patentee's right to exclude others from reproducing the patented product. Contrary to petitioner's entire argument, his infringing actions have nothing to do with patent exhaustion because the infringing seeds were made, not purchased; they were created by petitioner, not used after an authorized sale of those same patented seeds to petitioner. In other words, whatever patent rights were or were not retained by respondents in the commodity seed, petitioner's *use* of the commodity seed to plant a crop did not immunize his distinct patent-law violation of *making* a new generation of specifically glyphosate-resistant seeds that contained the Roundup Ready® trait. The biotechnology industry's ability to continue producing innovative products that save lives and promote economic growth hinges on the preservation of that critical distinction.

## **A. Patent Law Forbids the Unauthorized Making of a Patented Product**

### ***1. The Law's Distinct Prohibition on Making***

The right to exclude others from making a patented invention is a fundamental property right of a patent owner. The plain text of the patent law empowers the patentee to “exclude others from making \*\*\* the invention,” as well as “using, offering for sale, or selling” it. 35 U.S.C. § 154(a)(1). Indeed, that protection is an essential component of the quid that the patent law gives for the quo of disclosing the invention to the world and sharing new knowledge. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* 489 U.S. 141, 150-151 (1989) (patent law embodies “a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design”).

The Act’s disjunctive listing of the different patent rights, moreover, underscores that “[t]he 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.” *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964); *see Adams v. Burke*, 84 U.S. (17 Wall.) 453, 456 (1873) (similar); *see generally Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) (“[T]erms connected by a disjunctive” should “be given separate meanings, unless the context dictates otherwise.”).

The Patent Act reconfirms the disjunctive character of patent rights by providing that

infringement occurs when a person “makes \*\*\* any patented invention” “without authority,” just as much as when there is an unapproved “use[], offer[] to sell, or s[ale]” of the invention. 35 U.S.C. § 271(a). Accordingly, the patentee’s exhaustion of one of those rights—such as use—does not exhaust the others. See *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 549 (1852) (distinguishing between the right to make a machine and the right to use it); *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1573 (Fed. Cir. 1996) (the making of a patented product, even without a corresponding use or sale, constitutes infringement).

When Congress intends to depart from that traditional rule against the unauthorized making of protected intellectual property, it does so expressly. See, e.g., Plant Variety Protection Act, 7 U.S.C. §§ 2543, 2544 (expressly creating exceptions to infringement for limited seed-saving and research activities involving sexually reproduced plants). The Patent Act, however, contains no parallel “exemption[] for \*\*\* saving seed.” *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 143 (2001) (utility patents). Rather, the patent law “confer[s] a greater scope of protection” on ordinary patents. *Id.* at 138. Petitioner’s position, however, would erase that distinction and would engraft limitations on the patentee’s exclusive right to make that Congress has not enacted.

***2. An Authorized Sale Exhausts Only the Right to Use, Not to Make, the Sold Item***

It is a “longstanding principle” of patent law that, “when a patented item is ‘once lawfully made

and sold, there is no restriction on [its] *use* to be implied for the benefit of the patentee.” *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 630 (2008) (quoting *Adams*, 84 U.S. at 457). Under this rule of patent exhaustion, “the sale by a person who has the full right to make, sell, and use such a machine carries with it the right to the *use* of that machine to the full extent to which it can be *used*.” *Adams*, 84 U.S. at 455 (emphasis added).

But it is equally well established that exhaustion of the patentee’s right to regulate uses (including sales) of the vended item does not authorize the purchaser to *make* new versions of the patented product. “[T]he purchaser of the implement or machine for the purpose of using it in the ordinary pursuits of life \*\*\* does not acquire any right to construct another machine either for his own use or to be vended to another for any purpose.” *Mitchell v. Hawley*, 83 U.S. (16 Wall.) 544, 548 (1872). Indeed, the distinction between “the right to make and vend the machine \*\*\* [and] the right to use it” is “plain.” *Bloomer*, 55 U.S. at 549; see *United States v. Univis Lens Co.*, 316 U.S. 241, 249 (1942) (purchaser acquires the “right to use and sell”).

A purchased product accordingly cannot be used to make new copies. For example, when a buckle from a patented cotton-bale tie is used to “make” a new tie, the creation of that new object embodying the patented buckle-and-tie mechanism constitutes infringement. *American Cotton-Tie Co. v. Simmons*, 106 U.S. 89, 93-94 (1882). Likewise a purchaser’s unauthorized “reconstruction” (rather than routine repair) of a purchased product violates “the



patentee's right 'to exclude others from making' \*\*\* the article." *Wilbur-Ellis Co. v. Kuther*, 377 U.S. 422, 424 (1964); accord *Wilson v. Simpson*, 50 U.S. (9 How.) 109, 123-125 (1850).

The patent exhaustion doctrine, in short, is confined to a buyer's use of a purchased product; it does not in any way authorize the buyer to "make a new article." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 343 (1961). Quite the opposite, even after an authorized sale, "the prohibition that the product may not be the vehicle for a 'second creation of the patented entity' continues to apply, for such re-creation exceeds the rights that accompanied the initial sale." *Jazz Photo Corp. v. International Trade Comm'n*, 264 F.3d 1094, 1105 (Fed. Cir. 2001).

Indeed, patents would offer only ephemeral protection if the first sale of a patented product licensed the purchaser—and any downstream purchaser who could figure out how to construct the product from that template—to freely make and then sell new versions of the product fully embodying and exercising the patent. Furthermore, patentees could almost never recover the full value of their invention in that first, single sale.

This Court accordingly has confined the scope of patent exhaustion to the purchaser's right to use or sell only the specific article acquired. See *Quanta*, 553 U.S. at 625 ("The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to *that item*." (emphasis added)); *Quanta*, 553 U.S. at 631, 638 (exhaustion applies "with respect to the article

sold”); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 516 (1917) (“[T]he article sold” is “outside the monopoly of the patent law” after an unconditional sale.) (emphasis added); *Keeler v. Standard Folding-Bed Co.*, 157 U.S. 659, 666 (1895) (“[T]he purchase of *the article* from one authorized by the patentee to sell it, emancipates *such article* from any further subjection to the patent”) (emphasis added). That is because “the purpose of the patent law is fulfilled with respect to *any particular article* when the patentee has received his reward for the use of his invention by the sale of the article.” *Univis*, 316 U.S. at 251 (emphasis added).

However, the “purpose of the patent law[’s]” protection of the patentee’s exclusive right to *make* a biotechnological invention is decidedly “[un]fulfilled,” *see Univis*, 316 U.S. at 251, by the mere sale of the first seed, cell line, vaccine dose, DNA construct, or bacterium to the first purchaser. The types of biotechnology innovations that are changing the face of medicine, science, environmental research, and agricultural progress require a much more calibrated and sensitive approach to patent rights than petitioner’s incautious conflation of legitimate uses and illegitimate making would permit.

### **B. Petitioner Infringed By Making New Copies Of The Patented Product**

Petitioner concedes (Br. 37) that “the exhaustion doctrine does not extend to the right to ‘make’ a new product.” He also concedes that his “use” of commodity seeds “result[ed] in the creation of a new item.” Pet. Br. 38 (emphasis omitted). There also is

no dispute that the “new item” “creat[ed]” was glyphosate-resistant seeds containing the Roundup Ready® trait. *Id.* at 38, 42. That is straightforward infringement, and petitioner’s efforts to distinguish his “creation” of new glyphosate-resistant (actually, Roundup Ready® glyphosate-resistant seeds) from the infringing making of a patented article fail.

*First*, the plain meaning of the term “make” encompasses petitioner’s “creation” (Br. 38) of a patented item because a patent also forbids “independent creation.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 478 (1974). *See also Webster’s New International Dictionary* 1485 (2d ed. 1959) (defining “make” as, *inter alia*, “to create,” “to form or fashion physically,” “to cause to exist,” or to “bring about”); 9 *Oxford English Dictionary* 236 (2d ed. 1989) (“make” includes “to produce by action,” or to “bring about”); *see generally Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995) (ordinary meaning applies where common term is left undefined by Congress). Indeed, “[t]he right to make can scarcely be made plainer by definition,” and is certainly broad enough to “embrace[] the construction of the thing invented.” *Bauer & Cie v. O’Donnell*, 229 U.S. 1, 10 (1913).

*Second*, petitioner argues (Br. 42) that the seeds made themselves as the result of natural processes. That is both factually and legally wrong.

As a matter of fact, the seeds did not spontaneously “self-replicate” (Pet. Br. 42). Crops do not grow themselves—and certainly not in the commercial quantities petitioner has produced. *See* J.A.103a (602 acres grown). Petitioner’s creation of

considerable quantities of glyphosate-resistant soybeans resulted from his application of systematic and deliberative agronomic efforts to duplicate the specific Roundup Ready® patented trait, including systematic planting, cultivating, and harvesting techniques applied to the commodity seed. In particular, by planting and then applying a glyphosate herbicide, he eliminated all of the inferior, weed-susceptible seeds and transformed his “undifferentiated,” “impure,” and “dirty” mixture (Pet. Br. 5) into purely glyphosate-resistant seeds containing the Roundup Ready® trait to which herbicide could safely be applied.

For similar reasons, petitioner’s argument fails as a matter of law. The Patent Act holds petitioner accountable not for what the seeds did, but for what he did. Although infringement does not require intent, it does require human agency. The Patent Act provides that “*whoever*”—not “*whatever*”—“makes, uses, offers to sell, or sells” a patented invention is liable for infringement. 35 U.S.C. § 271(a) (emphasis added). The act of infringement, in other words, is not the biological capacity of seeds to reproduce. It is the efforts that petitioner applied repeatedly over nine planting seasons, Pet. App. 9a, to ensure that he did *not* harvest the natural “dirty,” and impure byproduct of his commodity seed, but instead made large quantities of uniformly herbicide-resistant seed that substantially embodied the patented trait. Petitioner’s actions, not nature, thus caused the

infringement, and that intervening human act of making is what the Patent Act polices.<sup>10</sup>

*Third*, for the same reason, petitioner's contention (Br. 42) that his creation of the patented seed inhered in its lawful use is wrong. The ordinary use of commodity soybeans is not planting, Resp. Br. 6 n.6, and the natural byproduct of planting commodity soybeans is *not* glyphosate-resistant seed. Petitioner's commercial quantities of cultivated, pure, glyphosate-resistant soybeans thus were not by themselves present or embodied in the commodity seed that petitioner purchased from the grain elevator (*see* Pet. Br. 5, 42). They were not even the raw progeny of the soybeans he bought. They were, instead, new and selectively cultivated seeds that survived the agronomic winnowing by which petitioner transformed impure commodity seed into uniformly herbicide-resistant seed fully embodying the patented Roundup Ready® trait.

*Finally*, this case is quite different from the computer method claims that were exhausted by an unconditional sale in *Quanta*, 553 U.S. 617. The specialized computer components at issue in *Quanta*

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<sup>10</sup> That petitioner used lawfully purchased soybeans as one step in his effort to create new, pure seeds carrying only the Roundup Ready® trait does nothing to insulate his behavior from liability. Infringers commonly use lawfully purchased, patented products—tools, chemicals, components—in the course of making a new infringing product. This case, moreover, does not involve accidental growth of seeds embodying the patented technology. *See* Resp. Br. 7-8, n.7 (“Monsanto has publicly committed not to assert its patent rights against persons who obtain its technology inadvertently.”).

were used in combination with standard parts to practice the patented methods. *Id.* at 624. But the sale that led to the application of patent exhaustion was of each individual, unpatented component, not the patented method. *Id.* at 635-636. Consistent with the purposes of the patent exhaustion doctrine, the patentee was foreclosed from controlling the purchaser's use of each of those individual components, *see id.* at 625 (exhaustion applies "to that item"), particularly because the product's "only reasonable and intended use was to practice the patent," *id.* at 631-632.

That made sense because the only reason to buy the components was to practice the patent; that was "the only object of the sale," as the purchaser was "destined" to use it for that purpose and no other. *Univis*, 316 U.S. at 249, 251; *see Quanta*, 553 U.S. at 632 ("A microprocessor or chipset cannot function until it is connected to buses and memory. And here, as in *Univis*, the only apparent object of Intel's sales to Quanta was to permit Quanta to incorporate the Intel Products into computers that would practice the patents."). The patentee thus collected his fair value by selling the unfinished objects that contained all of the "inventive features" and were lacking only an unimportant assembly step to complete the patented method.

This case is very different. *Univis* authorized buyers to use their purchased lens blanks to make patented lenses; it did not authorize purchasers to produce an endless stream of their own lens blanks, or to grind more patented, finished lenses than their purchases of blanks would permit. Nor did *Quanta*

authorize purchasers to make more memory buses than they had bought. Patent exhaustion is item-specific; it simply exhausts patent rights in the one item sold for its destined use without destroying other patent rights.

Here, the reasonable and commonly intended use of commodity soybeans is for purposes other than planting (*e.g.*, animal feed); it is not for culling out glyphosate-resistant traits. Resp. Br. 6 n.6. Petitioner's planting of the elevator soybeans to grow a crop was anomalous, not destined. More importantly, future production of multiple generations of pure, glyphosate-resistant seed was in no way "the only apparent object," *Quanta*, 553 U.S. at 632, of either respondents' initial licensed sales of seeds to farmers under the Technology Agreement, or of petitioner's purchase of impure, commodity seed. Petitioner neither bargained for, nor received, the distinct right to practice the patent and make Roundup Ready® seed.<sup>11</sup>

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<sup>11</sup> Just as 100 lens blanks could be said to "embody" 100 finished lenses, not millions, if a 50 pound bag of authorized patented soybean seed embodies anything other than the seed itself, it is at most the approximately one acre of soybean plants that can be grown from that quantity of seed by the farmer who purchased and consumed the seed for planting, *not* endless generations of future soybeans.

### **C. Continued Enforcement Of The Distinction Between “Making” and “Using” Is Vital For Biotechnology**

The patent law’s fundamental distinction between making a new patent-embodiment product and using a purchased product is vital to innovative development generally, and to biotechnological advancement in particular. In the biotech area, it commonly takes years of research, development, and investment to produce a new technology or product in usable form. But once it is available, that product’s patented biological feature may be susceptible to relatively easy, high-volume replication.

It is patent law’s longstanding prohibition against the unauthorized making of the patented product, and the law’s equally lengthy recognition that a sale does not exhaust that “substantive right[]” to make, *Adams*, 84 U.S. at 456, that has made biotechnological development possible. More specifically, preserving the patentee’s right to make the lifesaving vaccines, medical treatments, diagnostics, and other cutting-edge scientific products that are predicated on replicable forms of technology allows biotech innovations to be disclosed to the public without eviscerating the patent’s protections at the moment of the first sale. With the right to make their patented product or process protected, patent holders can undertake prolonged, stage-by-stage development in partnership with other researchers and developers confident that cooperative use of their inventions will not imperil their patent rights.



For example, safeguarding the patentee's control over the making of its product has made it possible to obtain the capital investment needed to develop new antibody-based therapeutics. *See FTC Report*, Ch. 3, p. 15 (biotechnology industry "relies primarily on patents to provide incentives to invest in innovation"). That, in turn, spurred further investment and development in the diagnosis of certain types of cancer and the production of biological drugs for distinctly targeted treatments. *See Martine Piccart-Gebhart et al., Trastuzumab after Adjuvant Chemotherapy in HER2-Positive Breast Cancer*, 353 *NEW ENG. J. OF MED.*, 1659, 1659-1672 (2005).

Preserving patent protections has also allowed biotechnology research to focus on the treatment of infectious diseases through the development of replicable cell lines that, for example, efficiently produce anti-malarial drugs to combat a disease that kills nearly 1 million people each year. World Health Organization, *GLOBAL BURDEN OF DISEASE: 2004 UPDATE* (2008); *see Victoria Hale, et al., Microbially Derived Artemisinin: A Biotechnology Solution to the Global Problem of Access to Affordable Antimalarial Drugs*, 77 (Supp. 6) *AM. J. OF TROPICAL MED. AND HYGIENE* 198, 198-202 (2007).

Petitioner's collapse of the right to use into the right to make, however, would effectively destroy the patent protection for those human-made living organisms—a patent right that this Court specifically recognized in *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980) ("human-made, genetically engineered bacterium" qualified as patentable subject matter).

Biotechnologies like Monsanto's Roundup Ready® seed, the *Diamond* bacterium, manufactured DNA molecules, newly developed cell lines, vaccines, and nanotechnologies all take years and millions of dollars to develop. But once commercialized, they could be readily reproduced in large quantities with significantly less investment—and, worse still, with attendant risks to the public of contamination and lack of quality control by unauthorized copy-cat makers. The continued success of this research-driven industry and the public benefits it provides thus depend critically on strong patent rights that prevent unauthorized reproduction.

## **II. SALES CONDITIONS THAT REGULATE MANUFACTURING WHILE ALLOWING REASONABLE USE FALL OUTSIDE THE PATENT EXHAUSTION DOCTRINE**

Patent exhaustion has no application to petitioner's conduct for a second, independent reason. Respondents' patent rights in the seeds that petitioner purchased were preserved because they were sold under a limited license that withheld any right to plant the harvested soybeans from any subsequent purchaser. JA27a. The price of the licensed sale, moreover, reflected the limited scope of the rights acquired, Resp. Br. 31-32, allowing growers to affordably obtain the technology to produce one commercial crop, without compensating respondent for the full value of its patented right to make future generations of the seed. That limited use-restriction, moreover, applied to third-party purchasers like petitioner who had no capacity to buy rights that respondents never conveyed.

Such restrictions are vital in the biotechnology industry, especially where the nature of a product's use renders it susceptible to readily making subsequent generations of the patented technology. For example, for inventions embodied in bacterial cells, the commercial product is often sold (and appropriately priced) for "research use only." Uses as research tools for further discovery have a very different value from uses in applied markets like medical diagnostics. Therefore field-of-use restrictions can foster arrangements by which purchasers can economically obtain the desired use of valuable technologies without jeopardizing the patent holder's exclusive right to control the making (and marketing) of the product for other, high-value commercial applications. That cooperative innovation by multiple actors is what allows valuable technology to be developed into useful products.

This Court has long recognized that a patentee may impose such reasonable restrictions as long as they fall fairly within the scope of the patent right, and the purchaser of the invention receives the full benefit of his or her bargain and obtains the "apparent object of [the] sale[]." *Quanta*, 553 U.S. at 632. Hewing to that precedent is of acute importance to biotechnological development.

**A. Patent Exhaustion Does Not Apply To Reasonable And Limited Use Restrictions.**

From its inception, patent exhaustion applied only to "a single *unconditional* sale" of a patented product. *Motion Picture Patents*, 243 U.S. at 516 (emphasis added). The sale had to be "absolute, and

without any conditions,” *Mitchell*, 83 U.S. at 548, because a sale only exhausts the patent rights actually sold in a particular item. Conditions on the ability to sell a patented product, moreover, may be enforced even against downstream purchasers that are unaware of the conditions. *Mitchell*, 83 U.S. at 550. “[N]o one can convey in such a case any better title than he owns.” *Id.* *General Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 181 (1938). (A purchaser who obtains only certain rights “could not convey \*\*\* what \*\*\* it was not authorized to sell.”

That principle accords with the longstanding recognition that patent rights are divisible, and enforcing such restrictions is a means that is “normally and reasonably adapted to secure pecuniary reward for the patentee’s monopoly” in all of its divisible aspects. *United States v. General Elec. Co.*, 272 U.S. 476, 490 (1926).

Similarly, product sales that are subject to single-use restrictions—like the single-season restrictions on respondents’ patented seeds—do not exhaust the patentee’s right to prevent the product from being used to make new, patented products outside the authorization. In *American Cotton-Tie*, the patented cotton ties were subject to a single-use restriction and were cut when the cotton bales reached the mill. 106 U.S. at 91. The Court upheld the patentee’s right to exclude downstream

purchasers from using the buckle of the cut cotton-tie to construct a new product. *Id.* at 93-94.<sup>12</sup>

For those reasons, patent law permits respondents to commercialize their invention subject to certain use rights—planting a single, commercial crop—while not empowering the purchaser to destroy the value of the patent by also making unlimited generations of new seeds fully embodying the patent. *See Mitchell*, 83 U.S. at 548 (Purchasers of exclusive privileges under the Patent Act “hold the whole or a portion of the franchise which the patent secures, depending upon the nature of the conveyance.”); *Keeler*, 157 U.S. at 663 (reaffirming *Mitchell v. Hawley*).

To be sure, there are important limitations on such use conditions, but none applies here.

*First*, the condition must preserve and enforce a legitimate component of the patent; the patentee cannot “extend the scope of its patent monopoly.” *Motion Picture Patents*, 243 U.S. at 516. Thus, if the patentee wields the patent right as a means of conjoining purchasers in anticompetitive behavior, like resale price restrictions, the conditions will be invalidated. *See Univis*, 316 U.S. at 250 (“[T]he patentee cannot control the resale price of patented articles which he has sold, either by resort to an infringement suit, or, consistently with the Sherman Act \*\*\* by stipulating for price maintenance by his

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<sup>12</sup> Transfers to licensees, moreover, generally are not subject to patent exhaustion. *See General Elec.*, 272 U.S. at 489-490; *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 93 (1902).

vendees.”); *Boston Store of Chicago v. American Graphophone Co.*, 246 U.S. 8, 25 (1918) (“alleged price-fixing contract disclosed in the certificate was contrary to the general law and \*\*\* was not within the monopoly conferred by the patent law”); *Straus v. Victor Talking Mach. Co.*, 243 U.S. 490, 500-501 (1917) (attempt to regulate the future price of the patented phonograph outside patent monopoly); *Bauer*, 229 U.S. at 16-17 (“[T]here is no grant of a privilege” in the patent law “to keep up prices and prevent competition by notices restricting the price at which the article may be resold.”).

Similarly, patent exhaustion precludes anticompetitive tying arrangements that unreasonably require the purchaser to use the patent with non-patented products because those conditions “have nothing to do with the invention which is patented.” *Motion Picture Patents*, 243 U.S. at 512-513; see *Leitch Mfg. Co. v. Barber Co.*, 302 U.S. 458, 461-463 (1938) (patent holder cannot forbid use of competitors’ inputs). Such an illegitimate attempt to impede competition was also implicated in *Quanta*, where Intel attempted (unsuccessfully) to prohibit subsequent purchasers of the components from combining them with anything other than Intel products. 553 U.S. at 624.

In each scenario, restrictions the patentee imposed on the purchaser’s use of the product sought to enforce requirements that “derive[d] no support from the patent.” *Univis*, 316 U.S. at 251. Respondents’ prohibition here on the making of subsequent generations of seed, however, properly preserved the recognized right of a patentee to

prohibit the re-creation of its product while licensing its use.

*Second*, use restrictions cannot deprive the purchaser of all reasonable use of the product. The “authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold.” *Quanta*, 553 U.S. at 631 (quoting *Univis*, 316 U.S. at 249). “The lens blanks in *Univis* met this standard because they were ‘without utility until [they were] ground and polished as the finished lens of the patent.’” *Id.* at 631-632 (quoting *Univis*, 316 at 249). As in *Univis*, the patent holder in *Quanta* had “suggested *no reasonable use*” other than an infringing use, and the Court could not “discern one.” *Id.* at 632 (emphasis added). To prohibit a sale of something for its only reasonable use, of course, would deprive the purchaser any meaningful ability to use what it bought, *id.* at 631-632, and thus the sale would exhaust *no* rights in the patentee.

But this Court has never held that a restriction on purchasers that is necessary to secure “the reward which the patentee by the grant of the patent is entitled to secure,” *General Talking Pictures*, 305 U.S. at 127, is subject to patent exhaustion. That is because such restrictions do not seek to extend a patentee’s authority beyond its ordinary scope or to amass rights and privileges that are not within the four corners of the patent right.

Rather, restrictions like those often imposed in the biotechnology area are archetypically legitimate exercises of the patent monopoly. They seek only to reserve for the patentee the right to control making

that the law has already granted, by imposing, for example, reasonable field-of-use restrictions to ensure a fair reward for inventions that require years of research, development, and investment while providing the purchaser the benefit of the bargain. The patent exhaustion doctrine was designed to police the efforts of patentees to expand their rights *beyond* what patent law grants them, not to hamstring legitimate efforts to enforce rights within the scope of patent protection. See *Boston Store*, 246 U.S. at 25 (patent law should not “deprive[] an inventor of any right coming within the patent monopoly”); *id.* at 26 (cases invalidating restrictions “alone concerned whether the monopoly of the patent law can be extended beyond the scope of that law”).

**B. Calibrated Restrictions That Permit Reasonable Use Are Vital To Innovation**

Petitioner’s position would require this Court to adopt a categorical hostility to use conditions that not only contradicts this Court’s decisions in *Mitchell* and *American Cotton-Tie*, but more fundamentally overlooks that not all conditions imposed by patentees are created equal. Of course over-reaching conditions that tread onto anti-competitive ground or deprive the purchaser of the only practical use of the item bought should not be permitted.

This case, however, is the polar opposite of a use restriction that impairs the purchaser’s proper enjoyment of the product. All that respondents’ restriction does is prohibit the one and only use that is aimed not at using the soybean *qua* soybean, but rather at arrogating to petitioner’s control the



patented technology within that bean itself—the making of a new glyphosate-resistant soybean. Respondents’ effort to protect against that unpaid-for, non-consensual appropriation of its core innovation sits at the very heart of patent law’s traditional protection. And petitioner’s effort to categorically prohibit such restrictions seeks to collapse the distinction between legitimate uses and illegitimate making in a way that will imperil innovation in many areas.

Indeed, in some of the most important areas of technological development in this Country—especially biotechnology—modern innovations can be susceptible to ready replication, making strong patent protections and reasonable licensing restrictions their lifeblood. In particular, the sale of many biotechnology products—whether genetically altered seeds, cell lines, nucleic acid preparations fermentation products, or live vaccines—inherently conveys not only the article itself, but also the means to readily reproduce the article. Accordingly, if a biotechnology patent holder cannot limit its licensee’s or purchaser’s use of the item either to prohibit replication or to contain the product to a specified field of use (like research rather than commercial exploitation), then every license and every sale becomes a de facto authorization to appropriate the inventor’s right to make the invention and compete directly with him or her.

Petitioner’s approach, moreover, would destroy all economic incentive to innovate. If the licensing of one seed or one DNA molecule necessarily conveys the means to readily produce countless replicas

without bearing any of the expense of invention, then the price the inventor would have to charge to capture the full value of the invention in that first-and-only sale or license would be prohibitively expensive. *See* Resp. Br. 34-35 & n.21 (value of license is “trivial” in comparison to full value of a never-ending supply of seed).

Furthermore, many new products commonly require lengthy and resource-intensive development periods involving multiple participants. Congress, in the context of federally funded research, has written into federal law the importance of clear patent rights reinforced by strong licensing mechanisms in fostering such collaborative research and development, *see generally* 35 U.S.C. §§ 200 *et seq.*, so that intellectual property can be licensed in a manner “that maximizes the potential for broad distribution \*\*\*,” Final Notice for Obtaining and Disseminating Biomedical Research Resources for NIH Research Grant and Contract Recipients, 64 Fed. Reg. 72090, 72091 (Dec. 23, 1999). Field-of-use restrictions, which are common in the biotechnology sector, facilitate collaboration between prime innovators and others. And they permit patent holders to charge reasonable fees each time downstream users use the invention in an authorized way, without running the risk of unlimited reproduction by third parties and the attendant loss of the underlying patent right.

At the same time, preserving the strength of patent protections is indispensable for the biotechnology industry to attract venture capital,” which “enables not-yet-profitable companies to sustain \*\*\* innovation through massive investments

in research and development.” *FTC Report*, Ch. 3, p. 18. Such mutually beneficial arrangements provide the licensee the exclusive rights needed to attract capital for research and development, while providing the university or biotechnology company that engaged in the original research with revenue needed to support their innovation. Meir Perez Pugatch, *et al.*, TAKING STOCK: HOW GLOBAL BIOTECHNOLOGY BENEFITS FROM INTELLECTUAL PROPERTY RIGHTS 35 (2012). The number of such collaborations in the biotechnology industry has steadily increased over the last two decades. *Id.* at 40.

Moreover, due to the speculative nature of early-stage biotechnology, initial licensing fees generally have to be low. It is only over time that further research and development in this symbiotic, cooperative process can add significant value to the patented technology. Thus, early-stage licensing fees not only do not, but cannot, capture the full value of a fully developed commercialized product, which can be realized only over the course of extended research and development into potential applications and final uses for drugs, diagnostics, biological organisms, and agricultural products.

To illustrate, an inventor might first develop a standardized cell-culture system that allows for the reliable production of a new protein, together with a novel antibody that binds to the protein and allows for its detection and quantification. Because such standardized technology is useful for research, the biotechnology company may make the cell-culture system widely available at low cost, but only for research applications through a field-of-use

limitation, thereby fostering dissemination of the technology while creating a small revenue stream to support further development efforts. If the technology becomes more widely adopted and scientifically validated, specialized biotechnology companies might join the research and development process, subject to bargained-for conditions that reflect the value of the licensed technology for the specific use (e.g., research or diagnostic) to which they will put the product. Should useful applications be further identified, larger companies with greater resources would enter the process to shoulder, at much greater cost, the scientific and regulatory burden of developing a new therapeutic product.

This synergetic relationship between a multitude of basic and applied research entities, large and small, with varying skill sets and resources, is crucial to ensuring the continued productivity of the biotechnology industry and maximizing the potential uses of an initial breakthrough. Strong patent rights, including reasonable use restrictions, underpin the effective functioning of this chain of cooperative innovation by allowing relative returns on investment to be fairly bargained for and distributed appropriately according to each player's relative contribution along the path from an initial breakthrough to its final marketable applications.

End users of biological products—including patients hoping for a cure, local governments looking for a cost-effective way to clean up a polluted river, or farmers seeking to grow drought-resistant crops in semi-arid zones—also critically depend upon the

strong enforceability of reasonable licensing and use restrictions, which assure that prices are contained and research can continue. The incentive to invest in innovation and research would be imperiled if the patent term for a vaccine was reduced from 20 years to the first sale of a single, readily replicated vial. Nothing in this Court's patent exhaustion precedent requires that patent-eviscerating and innovation-stultifying result.

### **C. Contract Law Offers Insufficient Protection**

Contrary to petitioner's argument, (Pet. Br. 55-57), the 50 States' variable and disuniform contract laws are incapable of adequately protecting an inventor against the multiplied replication of a biological product.

*First*, requiring the large number of individualized, elaborate licensing agreements that petitioner favors for every single sale of a cell line, DNA, bacteria, or gene sequence is economically infeasible. The early stage of research and development for biological products often involves university researchers and small biotechnology companies. Those entities have neither the expertise nor the leverage to negotiate individual, detailed contracts for every \$100 vial of cells or bacteria sold, much less the ability to calculate the appropriate pricing when the full value of the original innovation has yet to be established.

Furthermore, a patented product can have multiple functional uses—such as crop production versus seed manufacturing, or early-identified

research uses versus high-value therapeutic or diagnostic uses—that emerge only after years of research. Medical and scientific breakthroughs are predicated on a patent law system that ensures the inventor’s reward through lengthy and expensive cooperative research processes that early contractual terms simply cannot capture.

Nor can the market price adjust to reflect the additional rights that purchasers acquire and patentees lose. To begin with, the amount of cells or seeds needed for replication purposes is small, and it may take only one unrestricted purchase of a handful of seeds or a single cell line to unravel completely the patentee’s rights. As a result, the patentee’s entire compensation—the single royalty that the patent exhaustion doctrine promises, see *Univis*, 316 U.S. at 251; *Bloomer v. Millinger*, 68 U.S. (1 Wall.) 340, 350 (1863)—would have to be captured in the first sale of a vial of cells, a sample of recombinant DNA, or a packet of seeds. But that cost would be so exorbitant that few if any researchers or farmers could afford the product.

Beyond that, the public interest would be better served by a patent system that permits biotechnology research decisions to be made based not upon the highest bid, but upon which entity has the best capacity to investigate and develop a particular product and to promote scientific advancement.

*Second*, as this case well illustrates, contract law cannot effectively protect the patentee when a third party acquires a copy of a biological product and uses that copy as the genesis for continuous, unlimited production. That is because that third

party may not be in privity of contract with the patentee (or a licensee), making it next to impossible to enforce any contractual restrictions. And when the patented product contains within itself the capacity for ready replication, the patentee has no realistic capacity to enter into a contractual agreement with every party that could potentially make new copies of the technology.

In addition, privity may be broken deliberately by the sale and repurchase of a subsequent generation of a patented biological product. A licensee, for example, could sell his commercial crop of seeds to a grain elevator, an intermediary (like petitioner) could use the seed to undertake the very planting prohibited by the license, and then the farmer could purchase that newly made seed containing the patented technology from the intermediary. Thus, it would take only one \$100 cell line diverted from research use or one farmer commercially exploiting second-generation seed to prove, that an “article can be unfettered from the claim of his monopoly without paying its tribute.” *Keeler*, 157 U.S. at 666-667.<sup>13</sup> Moreover, as the product continuously replicates and penetrates the market, the value of the product declines, taking with it the scope of damages the patentee can recover.

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<sup>13</sup> See Pet. App. 179a (district court inquires: “[D]oes [petitioner] contend that he could simply take his Roundup Ready® crop to a grain elevator, sell it, and then buy some of it right back that same day without violating the Monsanto patents?”).

*Third*, consigning patentees, particularly small biotech companies, to the vagaries of 50 States' contract laws will deny innovators the stability and consistency that the federal government itself has acknowledged is critical to the industry's survival and continued growth. *FTC Report* at Ch. 3, p. 29. That would undermine the "fundamental purpose" behind the Patent Clause of the Constitution, which "was to promote national uniformity in the realm of intellectual property." *Bonito Boats*, 489 U.S. at 162 (citing 43 THE FEDERALIST 309 (B. Wright ed. 1961)). And those uncertainties, in turn, would deprive early-stage technologies of the ability to attract the necessary investment for further development.

*Fourth*, contract law cannot adequately remediate the harm to the patentee arising from the release of the biological product to make unlimited new copies. Free use of only one patented product to make a potentially unlimited supply of new products is the equivalent of a complete loss of control of the patent right, making it all but impossible to determine an adequate damages amount. Patent law provides for injunctive relief precisely because of the "difficulty of protecting a right to exclude through monetary remedies that allow an infringer to use an invention against the patentee's wishes." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 395 (2006) (Roberts, C.J., concurring). The remedies afforded by contract law, however, generally do not include enjoining the unauthorized purchaser or user from distributing a replicable product or combining it with other products.



In short, the profound advances that the biotechnology industry has given the American public in the last two decades, not to mention billions of dollars in current and ongoing capital investment decisions, rest critically upon stable and vigorous patent law protections. It is the patent law's distinctive ability to reach third parties, to enforce uniform protections, to preserve the exclusive right to make a patented product, and to allow reasonable use conditions that has established a safe and predictable legal environment for biotechnology innovation. The patent exhaustion doctrine was designed to protect against patentees who overreach the proper boundaries of patent law, not to unravel the fundamental protections that have proven critical to modern innovation and that have played a singularly important role in the development of new medicines, diagnostics, research tools, and agricultural products.

### CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

Tom DiLenge  
Hans Sauer  
Biotechnology Industry  
Organization

Patricia A. Millett  
*Counsel of Record*  
Ruthanne M. Deutsch  
Matthew Pearson  
Akin, Gump, Strauss,  
Hauer & Feld LLP

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