No. 06-937

In The

Supreme Court of the United States

Quanta Computer, Inc., Et Al.
Petitioners,

v.

LG Electronics, Inc., Et Al.
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Federal Circuit

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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QUESTION PRESENTED

Whether patent rights are exhausted by a licensee's authorized sale of a patented product to an authorized purchaser, where that product has no reasonable use other than in practicing the patented invention.

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BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

INTEREST OF *AMICUS CURIAE*[1]

The Biotechnology Industry Organization (BIO) is the principal trade association representing the biotechnology industry both domestically and abroad. BIO has more than eleven hundred members, including businesses, biotechnology centers, and academic institutions. BIO's members range from Fortune 500 companies to research universities and small start-up companies. Approximately 90% of BIO's corporate members have annual revenues under $25 million. In developing

[1] This brief is filed with the written consent of all parties. Pursuant to Rule 37.6, no counsel for either party authored this brief in whole or in part, nor did any party make a monetary contribution to the preparation or submission of this brief.

modern biotechnological products, BIO's members depend on generating, developing, patenting, licensing, and selling scientific innovations. As a result, the maintenance of a stable commercial system that, consistent with the patent system's goal of promoting science, permits the imposition of valid conditions on the sale and licensing of patented products is critical to the industry. BIO thus has a substantial interest in this Court's resolution of the patent exhaustion question, and BIO can provide unique insights on the operation of the patent exhaustion doctrine in practice and its impact on the rapidly growing biotechnology industry.

STATEMENT

Biotechnology innovations provide life-saving medical treatments and diagnostic procedures, disease- and herbicide-resistant crops, and a host of promising scientific solutions for modern environmental, medical, and agricultural challenges. For example, biotechnology products have provided more than 200 new therapies and vaccines for once untreatable diseases, such as cancer, diabetes, HIV/AIDS, and autoimmune disorders. 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 S. Collins, *et al.*, *A Vision for the Future of Genomics Research*, NATURE, Apr. 24, 2003, at 835-847. Combining that knowledge of the human genetic makeup with specially-adapted biotech research methods has made it possible to develop rapid and reliable diagnostic tests for a multitude of genetic diseases, as well as forensic DNA tests that

help free the innocent and jail the guilty. Nicholas Wade, *A Revolution At 50; DNA Changed the World. Now What?*, New York Times, Feb. 25, 2003, at F1. Biotechnology research also holds the promise of developing "personalized medicine," in which specialized biotech research tools will permit the affordable sequencing of an individual's own unique genetic code to enable customized medical treatments that are cheaper and more effective than the current "one-size-fits-all" approach. See Mayo Clinic Staff, *Personalized Medicine: Tailoring Treatment To Your Genetic Profile*, http://www.mayoclinic.com/health/personalized-medicine/CA00078 (Jun. 30, 2006) (as visited Nov. 12, 2007).

Biotechnology products have also achieved significantly enhanced agricultural production by creating crop seeds that are more productive because they are resistant to insects and/or herbicides. In their first nine years, biotech foods increased farm income in the United States by $10.7 billion and, at the same time, significantly reduced the need for herbicides and thus the environmental impact of food production by as much as 32% for some crops.[2] In addition, crops are being developed that will grow under adverse conditions such as water or nitrogen deficiency. 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."[3]

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[2] See PG Economics, Graham Brookes & Peter Barfoot, *Plant Biotechnology Proven Promising* at 1 (Oct. 11, 2005).

[3] Tommy Thompson (Secretary of Health & Human Services), *Biotechnology: Its Promise and Challenge in the New*

Every day, biotechnology companies are engaged in inventing, discovering, and developing new tests, new drugs, new cures, and new products. See Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (FTC Report)*, Ch. 3, p. 21 (Oct. 2003), available at http://www.ftc.gov/os/2003/10/innovation rpt.pdf (as visited Nov. 12, 2007) (noting the exceptionally "rapid" "pace of innovation in the biotechnology industry"). Those innovations require a massive investment in research and development. "The biotechnology industry is the most research and development-intensive and capital-focused industry in the world."[4] Biotechnology research and development expenditures are more than double the average of the pharmaceutical industry, which itself is several times more intensive than any other industry. See *id*. at pp. 15-16. In 2005 alone, the industry spent approximately $20 billion in research and development efforts.[5]

The 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

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Century, http://www.hhs.gov/news/speech/2002/020211.html (Feb. 11, 2002) (as visited Nov. 12, 2007).

[4] See National Institute of Health: *Moving Research from the Bench to the Bedside: Hearings Before the Subcomm. On Health of the House Comm. on Energy and Commerce*, 108th Cong., 1st Sess. 47 (2003) (testimony of Phylliss Gardner, M.D.).

[5] See *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing*, Hearing Before the Comm. on the Judiciary Subcomm. on Courts, the Internet and Intellectual Property, at 3 (Oct. 30, 2007) (testimony of Jeffrey P. Kushan).

16. For every successful biopharmaceutical, there are approximately 10,000 failed attempts. Furthermore, the time required to move a drug from clinical development through regulatory approval and into the market averages 98 months.[6]

Bringing biotechnological advancements to market for use by doctors, patients, scientists, and farmers, often requires extensive and long-term collaboration between large and small biotechnology companies and research universities. For example, a university scientist might discover a new protein linked to certain cancers. After patenting the relevant technology, the university might then license a biotech business or university spin-off company to begin the time-intensive process of developing standardized tools for further research, as well as diagnostic methods, therapeutic treatments, and other real-world applications for the discovery.

Such licensing arrangements are mutually beneficial. They provide the licensee the exclusive rights needed to attract capital for research and development, while providing the university with revenue to support further academic research. Due to the speculative nature of early-stage biotechnology, such licensing fees are generally low. Over time, however, research and development can add significant value to the patented technology. The licensee, for example, may decide first to develop a standardized cell-culture system that allows for the

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[6] See Joseph A DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, MANAGERIAL & DECISION ECONOMICS 473 (2007).

reliable production of the new protein under laboratory conditions, 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 decide to make the cell-culture system and detection method widely available at low cost only to researchers, thus fostering dissemination of the technology, while creating a small revenue stream to support further development efforts. As 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 (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 staggering cost, the burden of developing a new therapeutic product.

That symbiotic relationship between different entities engaged in biotechnological research and development is crucial both to ensuring the continued viability of small and publicly funded biotechnology research entities, which cannot afford expensive licensing fees or sale prices, and to making it possible for inventors to navigate successfully the long and resource-intensive road to the commercial use of their products. For example, the identification and isolation of a gene associated with a particularly aggressive and common type of breast cancer, and the development of a patented drug to treat it, cost more than $200 million and took nearly two decades

of cooperative research by companies and a university.[7]

In addition, the products that biotechnology companies often patent – many of which involve live organisms or living matter, rather than the inanimate products traditionally patented – require sensitive application of the patent laws. For example, many of the important advances in medical and agricultural biotechnology, such as cell lines, DNA sequences, or transgenic seed, involve DNA, which self-replicates through the ordinary process of cell division, but is also routinely capable of artificial replication. As a result, the manufacture and further transfer of self-replicating products are often prohibited and restricted to use in research. Absent such a restriction, the first sale – which is often for a reduced price to permit universities and small companies to participate in research – would effectively extinguish the patentee's rights, because the purchaser would obtain, in effect, a never-ending supply of the product that it could use, sell, and market in competition with the patentee.

Likewise, transgenic seed is produced when a genetic sequence is artificially introduced into a naturally occurring seed to create a particular trait, such as drought-, disease-, or insect-resistance. See generally *Mycogen Plant Sci., Inc.* v. *Monsanto Co.*, 61 F. Supp. 2d 199, 207-209 (D. Del. 1999), aff'd, 243 F.3d 1316 (Fed. Cir. 2001). Such seeds create more bountiful crops, which increase food supply, while

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[7] See Robert Bazell, *Her-2: The Making of Herceptin, A Revolutionary Treatment for Breast Cancer* xvii, 33, 38, 48, 54, 88 (1998).

often reducing the environmental impact of production (by, for example, reducing the need for insecticides). Like DNA, however, transgenic seeds self-replicate during the crop cycle. Restrictions on the use or production of those second-generation seeds are indispensable to continued research and development in the agricultural area.[8]

The linchpin of biotechnology development has been the legal protections afforded to intellectual property under United States law. Patents have become the primary asset – often the lifeblood – of biotechnology companies. *FTC Report*, Ch. 3, p. 29 ("Biotechnology innovation is heavily dependent on the patent rights that have been available for biotechnology inventions since 1980."). In addition, billions of dollars in business decisionmaking and investment have been made predicated on patent law protection for the biotechnology products that are developed. See *id.* at p. 15. "[P]atentability of biotech inventions enables the biotechnology industry to attract venture capital," and that capital "enables not-yet-profitable companies to sustain * * * innovation through massive investments in research and development." *Id.* at p. 18. The promise of enforceable patent rights that are not undermined by the involvement of multiple entities in the research process is critical to ensuring that discoveries and

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[8] In 2004, 85% of the soybeans, 76% of the cotton, and 46% of the corn that was planted involved biotechnologically improved seed. Department of Agriculture, *Frequently Asked Questions on Biotechnology*, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&navid=AGRICULTURE&contentid=BiotechnologyFAQs.xml (Oct. 6, 2005) (as visited Nov. 12, 2007).

innovations can financially survive the lengthy development, testing, approval, and marketing process. See *id.* at p. 15 ("Biotechnology companies seek patent protection to appropriate the value of their inventions, to attract investment from capital markets, which funds their costly research, and to facilitate inter-firm relationships necessary for commercial development of their inventions.").

SUMMARY OF ARGUMENT

Because the licensing and sales practices within the biotechnology industry involve distinctive considerations, the Biotechnology Industry Organization does not take a position on the proper disposition of this case. Instead, the purpose of this brief is (i) to advise the Court about one particularly important and complex context in which patent exhaustion arguments arise, (ii) to highlight the legal distinctions between the biotechnology industry's practices and those at issue here, (iii) to suggest that, should the Court hold that patent exhaustion applies, the decision should be limited to the type of practice before the Court and should not address different legal arrangements, and (iv) to explain the adverse implications of a sweeping patent exhaustion rule for an industry that works cooperatively with public universities and other research entities (many of which have limited financial resources) to develop cutting edge technology to treat diseases and to feed a hungry world.

First, unlike respondent LG Electronics (LGE), one central concern of the biotechnology industry is not restricting "use" of the patented product per se, but prohibiting purchasers from "making" the

patented product by, for example, exploiting an item's self-replicating character. The patent exhaustion doctrine has never extended to the manufacturing of a patented product, and this Court's decision should reinforce that distinction.

Second, the biotechnology industry commonly restricts the authority of licensees to sell their products and may also require purchasers themselves to be licensed. Nothing in this case should call into question the patent law's longstanding distinction between the patentee's authority to restrict licensees and its authority to restrict eligible purchasers.

Third, when restrictions are imposed on purchasers, such as "for research use only" or to constrain the use of second-generation products, the biotechnology industry does not attempt to restrict a buyer's only reasonable use of a product. The restrictions only proscribe alternative uses, such as commercial uses that the buyer "does not purchase or pay for," *Bloomer* v. *McQuewan*, 55 U.S. (14 How.) 539, 549 (1853). Restrictions on usage that do nothing more than enforce rights in the property that were not sold, while affording the purchaser the full benefit of its bargain, should be sustained.

Fourth, because biotechnology products often require years of research and development, early licenses and sales often do not reflect the ultimate value of the invention, but instead are a cooperative nominal exchange designed to promote further research. Likewise, with self-replicating products, the sale price of the first item sold – a single vial of genetically modified cells or a single packet of seeds – cannot capture the patentee's fair reward for

painstakingly developing the product. The patent law's current level of protection for such inventions has made enormous innovation possible in the last two decades, and the patent exhaustion doctrine should accommodate the unique demands of modern technological development.

ARGUMENT

Under the patent exhaustion doctrine, the general rule is that the purchaser of a patented product obtains "the right to use and sell it, and upon familiar principles 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." *United States* v. *Univis Lens Co.*, 316 U.S. 241, 249 (1942); see *Bloomer* v. *Millinger*, 68 U.S. (1 Wall.) 340, 352 (1864). 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," and "once that purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold." *Id*. at 251.

While the patent exhaustion rule can be stated simply, care must be taken in its application to the complex and diverse arrangements that pervade patent law and that make modern technological advancement possible. The doctrine's limits must be respected and enforced as much as its core. The central purpose of patent exhaustion is to prevent overreaching by patentees who attempt to cling to rights they have already surrendered or to assume authority that the patent law never granted to them.

However, controls put in place by patentees that do nothing more than give effect to the patentee's retained rights, while giving the purchaser fair use of the product, should be permitted.

THE PATENT EXHAUSTION DOCTRINE DOES NOT APPLY TO RESTRICTIONS THAT PREVENT THE MAKING OF REPLICABLE BIOLOGICAL PRODUCTS OR THAT PERMIT RESEARCH USE ONLY

I. The Patent Exhaustion Doctrine Does Not Authorize Purchasers To Make A Self-Replicating Product

The Patent Act protects the patentee's exclusive right not only to "us[e]" the invention, but also to "mak[e]" it. 35 U.S.C. 154(a). Consistent with that distinction, patent law has long established that the authorized *use* of a patented product does not authorize the *making* of the 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 (1873).[9] Rather, "[t]he right to

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[9] See *American Cotton-Tie Co.* v. *Simmons*, 106 U.S. (16 Otto) 89, 94 (1882) (reconstruction infringes patent); *Adams* v. *Burke*, 84 U.S. (17 Wall.) 453, 456 (1873) (the right to "make" and the right to "use" "may be granted or conferred separately by the patentee"); *Nachman Spring-Filled Corp.* v. *Kay Mfg. Corp.*, 78 F.2d 653, 657 (2d Cir. 1935) ("The sale by a patentee of an element of the patented combination capable of noninfringing use does not carry the right to make an infringing structure.")

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). The patent exhaustion doctrine tracks that distinction. Exhaustion is limited to the purchaser's right to use and sell the product, and does not extend to the patentee's right to "make a new article." *Aro Mfg. Co.* v. *Convertible Top Replacement Co. (Aro I)*, 365 U.S. 336, 343 (1961).[10]

Preserving the rule that patent exhaustion law does not extend to the making of patented products is of critical importance to the biotechnology industry. When DNA, cell lines, gene sequences, and crop seeds are licensed or sold, they have the capacity to self-replicate in the hands of the licensee or purchaser. With respect to seeds, while the patent exhaustion doctrine may give the purchaser full rights to *use* the seeds actually purchased, the patentee's rights are not exhausted with respect to the second-, third-, fourth-, or nth-generation of seeds that might be *made* by the purchaser. Where exhaustion applies, the patent monopoly is relinquished only "with respect to the article sold," *Univis*, 316 U.S. at 249, and not with respect to copies of it that the purchaser might make.

Similarly, with respect to cell lines, bacteria, or DNA preparations, the patentee may grant the

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[10] See also *Univis*, 316 U.S. at 249 (purchaser acquires the "right to use and sell"); *Bloomer* v. *McQuewan*, 55 U.S. (14 How.) 539, 549 (1853) (explaining the "distinction" between "the right to make and vend the machine * * * [and] the right to use it").

researcher the right to use the biological material for research purposes, which will often necessitate its replication in the laboratory for a number of cycles. While the patentee may permit such uses for research purposes, the patentee retains the right to preclude licensees and purchasers from replicating – making – such material for different purposes, such as diagnostic, therapeutic, or prophylactic applications, or to engage in commercial competition. Thus, even where a purchase has exhausted the patentee's right to research uses of a particular cell line, the purchaser's replication or "second creation of the patented entity" will "call the monopoly conferred by the patent grant[] into play for a second time," *Aro I*, 365 U.S. at 346, thereby permitting the imposition of "research use only" restrictions on the replicated product.

That distinction makes sense, and is not disputed by petitioners (Pet. Br. 28-29, 43 n.13). The patentee only sold the first generation of seeds or the research uses of its replicating cell lines, and that is all that was paid for by the purchaser. The patentee could not have sold and the purchaser could not have acquired unrestricted title over the subsequent generations because those were not part of the bill of sale and, in fact, did not even exist at the time of the purchase. See *Monsanto Co.* v. *McFarling*, 302 F.3d 1291, 1299 (Fed. Cir. 2002) ("The original sale of the seeds did not confer a license to construct new seeds."), cert. denied, 537 U.S. 1232 (2003).[11]

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[11] See *McFarling*, 302 F.3d at 1299 ("The 'first sale' doctrine of exhaustion of the patent right is not implicated, as the new seeds grown from the original batch had never been

Likewise, because the patentee retains the right to preclude the unauthorized making of its product, the patentee can reasonably proscribe the manufacture (through replication) and sale of its cell lines for commercial purposes while permitting publicly beneficial, non-commercial research to go forward. "The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology," and "[w]ithout the actual sale of the second generation * * *, there can be no patent exhaustion." *Monsanto Co.* v. *Scruggs*, 459 F.3d 1328, 1336 (Fed. Cir. 2006), cert. denied, 127 S. Ct. 2062 (2007).

The line between using and making can be a fine one in the case of self-replicating products, and one that could be undermined by adoption of an unnecessarily expansive patent exhaustion rule. Petitioners, for their part, acknowledge that the patent exhaustion issue could have implications for self-replicating products like computer software, see Pet. Br. 43 n.13, and do not dispute the validity of restrictions designed to protect the patentee's rights. Pet. 8, 26. Indeed, to argue otherwise "would eviscerate the rights of the patent holder," while giving an unjustifiable windfall to purchasers. *Scruggs*, 459 F.3d at 1336. Because the potential for replication inheres in these unique products, the patentee cannot sell the product for its ordinary use – medical testing and research or production of a crop –

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sold. The price paid by the purchaser 'reflects only the value of the "use" rights conferred by the patentee.'"); see also *Monsanto Co.* v. *McFarling*, 488 F.3d 973, 977 (Fed. Cir. 2007), pet. for cert. pending, No. 07-241 (filed Aug. 22, 2007).

without simultaneously arming the purchaser with the ability to take over independent production of the cells or seeds – a privilege for which the purchaser did not pay and to which *purchasers* are not entitled. Accordingly, this Court's decision should leave undisturbed the longstanding rule that patent exhaustion does not preclude restrictions on the making or re-creation of a patented product.

II. The Patent Exhaustion Doctrine Does Not Apply To Validly Restricted Sales And Purchases

Patent exhaustion has two prerequisites: the sale must be authorized, and the purchaser must be authorized to buy. If either the sale or purchase was "without authority," then using or vending the patented product will constitute infringement of the patent. 35 U.S.C. 271(a). There thus are three scenarios that preclude application of the patent exhaustion doctrine: (1) the sale was not authorized, (2) the purchaser lacked authority to buy, or (3) the buyer violated a restriction on alternative uses of the product that was reasonably imposed and necessary to enforce rights within the scope of the patent.

A. Unauthorized Sales Do Not Exhaust Patent Rights

There is no dispute in this case that an unauthorized sale does not deprive the patentee of its rights (see Pet. Br. 18), nor could there be. If the sale is made without authority, it cannot confer any rights on the purchaser, because a seller cannot transfer rights that it does not possess. See *Aro Mfg. Co.* v. *Convertible Top Replacement Co. (Aro II)*, 377 U.S. 476, 484 (1964); *General Talking Pictures Corp.* v.

Western Elec. Co., 305 U.S. 124, 127 (1938); *Mitchell*, 83 U.S. at 549 ("[N]o one can convey in such a case any better title than he owns.").

In the biotechnology industry (and industry generally), patentees often license others to sell a patented product for them. In so doing, the patentee can restrict the licensee's authority to sell the product generally or for particular uses, and products sold in violation of those agreed-upon terms will not trigger patent exhaustion. In that respect, patent law has long distinguished between licensees and purchasers. See, *e.g.*, *United Shoe Mach. Corp.* v. *United States*, 258 U.S. 451, 463 (1922) ("Undoubtedly the patentee has the right to grant the use of the rights or privileges conferred by his patent to others by making licenses and agreements with them which are not in themselves unlawful."); *Millinger*, 68 U.S. at 351. As against a licensee, the patentee may continue to exercise its exclusive rights by reasonably restricting up front the licensee's ability to use, make, or sell the product. See *General Talking Pictures*, 305 U.S. at 127 ("That a restrictive license is legal seems clear."). A patentee also "may legally restrict a licensee to a particular field and exclude him from others." *Id*. at 126.[12]

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[12] See also *General Talking Pictures*, 305 U.S. at 127 ("The practice of granting licenses for a restricted use is an old one.") (citing *Providence Rubber Co.* v. *Goodyear*, 76 U.S. (9 Wall.) 788, 799-800 (1869)); *E. Bement & Sons* v. *National Harrow Co.*, 186 U.S. 70, 93 (1902); *Hobbie* v. *Jennison*, 149 U.S. 355, 363 (1893); cf. *Illinois Tool Works, Inc.* v. *Independent Ink, Inc.*, 547 U.S. 28 (2006) (tying arrangements imposed on licensees are not presumptively impermissible).

In the case at hand, Intel had the unrestricted authority to sell components embodying the essential elements of LGE's patent. Pet. App. 33a. The biotechnology industry, by contrast, typically imposes restrictions on the ability of a licensee to sell the patented product. For example, a university may license one biotechnology company to sell a patented antibody only to research scientists, and another biotechnology company to sell the same antibody only to diagnostic test laboratories. In addition, a biotechnology company that has developed a chemical process for improving the blight resistance of crop seed may license a seed company to produce and sell the enhanced seed to farmers. Such licenses frequently contain field of use restrictions that limit the uses for which the licensee may sell the patented article. Common restrictions include requirements that the product be used only for non-commercial research, not be used for human use, or be used for planting only a single generation of crops.

Such licensing restrictions fully comport with patent law. "[W]here a patented invention is applicable to different uses, the owner of the patent may legally restrict a licensee to a particular field and exclude him from others." *General Talking Pictures*, 305 U.S. at 126. Likewise, restrictions on licensee sales that protect the patentee's interest in second-generation seeds, or in commercial, as opposed to non-commercial research-based exploitation of patented biotechnology products are permissible. That is because such restrictions "are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly." *United States* v. *General Elec. Co.*, 272 U.S. 476, 490 (1926). Sales

made in violation of such restrictions on the licensee's authority infringe the patent, and relief may be obtained against both the licensee and the purchaser. *General Talking Pictures*, 305 U.S. at 127; see *General Elec.*, 272 U.S. at 490; *Hobbie* v. *Jennison*, 149 U.S. 355, 363 (1893). Purchasers, "however innocent they may be, obtain no property whatever in the goods." *Mitchell*, 83 U.S. at 550.

Neither petitioner nor the government disputes that the patent exhaustion doctrine applies only to authorized sales, Pet. Br. 16-17, 29; U.S. Cert. Amicus Br. 7-8, 13, and this Court's cases have endorsed the doctrine's inapplicability in that context for over two centuries. See, *e.g.*, *General Elec.*, *supra*; *Mitchell*, *supra.*; *McQuewan*, *supra.* Maintaining stability in that body of law is important to the biotechnology industry because business arrangements and investments have been made in reliance on that legal principle for decades. See *FTC Report*, Ch. 3, p. 17 (the biotechnology industry involves "a tremendous amount of licensing").

B. Unauthorized Purchases Do Not Exhaust Patent Rights

For many of those same reasons, the patent exhaustion doctrine applies only to the use of a product by a person who was authorized to acquire it. Indeed, the restrictions on sales by licensees that this Court upheld in *General Electric* and *Mitchell* would be meaningless unless those conditions could be enforced against purchasers who buy without authority to do so. See *Aro II*, 377 U.S. at 484-485 (infringement by car purchasers who bought automobiles embodying a patent without authority).

Thus, restrictions on who may purchase a product that are "normally and reasonably adapted" to protecting the patentee's legitimate interest in fair compensation are permissible, and violators of those restrictions cannot seek refuge in the patent exhaustion doctrine.[13]

In the present case, there was no express restriction on who could purchase the computer parts. Pet. Br. 41. Instead, LGE simply required Intel to notify customers of its view that its patent rights continued in the product. Pet. App. 3a. Regardless of whether such a notice constitutes a valid restriction on authorized purchasers, the types of limitations on authorized purchasers imposed by the biotechnology industry are consistent with this Court's precedent and are not subject to the patent exhaustion doctrine.

Like the computer software industry, which requires that its purchasers become licensees to protect against the threat of replication, see Pet. 26, the biotechnology industry sometimes permits the sale of its patented products only to individuals or entities that have a license with the patentee. For example, to protect against unauthorized replication, only farmers directly licensed by the patentee are permitted to purchase transgenic grains and seeds. See *McFarling*, 302 F.3d at 1293.

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[13] See *General Elec.*, 272 U.S. at 490; *Mitchell*, 83 U.S. at 550; *Harshberger* v. *Tarrson*, 184 F.2d 628, 629 (7th Cir. 1950); see also *Union Tool Co.* v. *Wilson*, 259 U.S. 107, 113 (1922).

Those sales to licensees do not trigger patent exhaustion, as petitioners acknowledge (Br. 51). First, transfers to licensees 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). Indeed, the very purpose of a license is to maintain the patentee's core rights, not to exhaust them. There is no sound basis for distinguishing, in that regard, between licenses to vend and licenses to acquire.

Second, exchanges of a patented product between a patentee and a licensee, between two licensees for the same product, or between a licensee and a sublicensee (where the patentee is the third-party beneficiary) bear no resemblance to the type of arms-length sales with independent purchasers that give rise to the patent exhaustion doctrine, see, *e.g.*, *Chaffee* v. *Boston Belting Co.*, 63 U.S. (22 How.) 217 (1859); *McQuewan*, 55 U.S. at 549-550. Such inter-licensee exchanges are more accurately characterized as transfers subject to established patent-law rules for licenses, than "sales" for purposes of the patent exhaustion doctrine.

C. Restrictions on Purchasers that Reasonably Protect the Patentee's Retained Rights While Permitting Reasonable Use of the Product Are Not Subject to the Patent Exhaustion Doctrine

Where the purchaser is not a licensee, the parties have taken diametrically opposed positions concerning a patentee's ability to restrict usage. Petitioners would permit virtually no restrictions on

purchasers, Pet. Br. 20, 30-35, while respondents would forbid only those restrictions that amount to illicit anti-competitive behavior or patent misuse, Br. in Opp. 15-20. The position of the biotechnology industry lies in the middle. Restrictions that (i) are reasonably necessary to protect the patentee's legitimately reserved patent right, and (ii) do not deny the purchaser reasonable use of the product, may be imposed, consistent with this Court's precedent and the purposes of patent exhaustion.

1. Use restrictions may be necessary to protect basic patent rights

This Court has not held that *all* restrictions on purchasers are invalid under the patent exhaustion doctrine. Of course, where the sale is unconditional, patent exhaustion applies. See *Mitchell*, 83 U.S. at 548 (exhaustion applies "where the sale is absolute, and without any conditions"); *Millinger*, 68 U.S. at 350 (1863); *McQuewan*, 55 U.S. at 539 (machines had "been purchased and paid for without any limitation").

Likewise, where the restriction that the patentee imposed reaches beyond the legitimate scope of the patent right, patent exhaustion has been applied. This Court has applied the patent exhaustion doctrine to invalidate the anticompetitive regulation of downstream prices.[14] The Court has

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[14] See *Univis*, 316 U.S. at 252 (noting that "[t]he price fixing features of appellees' licensing system * * * violate the Sherman Act"); *Boston Store of Chicago* v. *American Graphophone Co.*, 246 U.S. 8, 25 (1918); *Bauer & Cie* v. *O'Donnell*, 229 U.S. 1, 16-17 (1913); *Straus* v. *Victor Talking Mach. Co.*, 243 U.S. 490, 500-510 (1917).

also freed buyers from restrictions unreasonably requiring the exclusive use of non-patented materials that "have nothing to do with the invention which is patented," *Motion Picture Patents Co.* v. *Universal Film Mfg. Co.*, 243 U.S. 502, 512 (1917),[15] and has further held that patentees may not geographically restrict where a patented product may be used after it is bought, *Adams* v. *Burke*, 84 U.S. (17 Wall.) 453, 456-457 (1873).

Such restrictions are invalid because they "cannot with any regard to propriety in the use of language be termed a restriction upon the use of the machine itself," *Motion Picture Patents*, 243 U.S. at 512-513, and to permit them would "in effect, extend the scope of [the] patent monopoly," *id.* at 516. See *Univis*, 316 U.S. at 251 (stipulation regarding resale prices "derives no support from the patent"). Thus, the common flaw in restrictions that this Court has struck down has been the patentee's effort "to control conduct * * * not embraced in the patent monopoly," and to control the use of property "outside of the monopoly." *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 456 (1940).

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 unenforceable and subject to patent exhaustion. Petitioners themselves acknowledge (Pet. Br. 26) that "patent exhaustion

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[15] See *Leitch Mfg. Co.* v. *Barber Co.*, 302 U.S. 458, 461-463 (1938).

stems from inherent limits on the grant of the patent right." Accordingly, limited restrictions on use that fall within the scope of the patent right – such as restrictions limiting the replanting of subsequent generations of transgenic seed, or the use of biotechnology research products for commercial purposes – should not be subject to 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. Nor do they seek to regulate downstream prices, to collect repeated and unearned royalties, to compel the purchase of unpatented products through unlawful tying arrangements, or to delimit uses geographically.

Rather, restrictions like those imposed in the biotechnology area – restrictions that simply enforce legitimate rights to prohibit the unauthorized making (as opposed to the use) of the product, or that limit the field of use to research – reflect archetypically legitimate exercises of the patent power. They seek only to reserve for the patentee rights that the law has already granted it and to ensure a fair reward for inventions that require years of research, development, and investment.[16] 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

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[16] See 2 Jay Dratler, *Licensing of Intellectual Property*, at 7-50 (2007) ("[F]ield-of-use restraints are attempts by the patentee to extract the full value of the patented invention from its various market applications; they often have little or no adverse effect on competition.").

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").

Furthermore, the imposition of reasonable restrictions on purchases is a practical, unavoidable, and "genuine necessity" for the biotechnology industry. 2 Jay Dratler, *Licensing of Intellectual Property,* at 7-60 (2007). Due to the capacity for self-replication, the only alternative to regulating how new cycles of cells or generations of seeds are used would be to charge exorbitantly high prices for the sale of a single vial of cells or packet of seeds. But the market simply will not bear that price and, absent the ability to recoup the lengthy and resource-intensive costs incurred in bringing biotechnology products to market, the industry will lose all reasonable incentive to continue the rapid technological development that has occurred in this area.[17]

Similarly, reasonable field-of-use restrictions on research tools, such as cell lines, nucleic acid preparations, and antibodies, provide research institutions with low-cost access to patented technology, thus spurring more research and

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[17] See *FTC Report*, Ch. 3, p. 29 ("Patents 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.").

fostering the adoption, validation, and acceptance of the patented technology in the research community. In short, the practical realities of biotechnology constitute "a case of use control by necessity" because, without those restrictions, the patentee is "unlikely to recoup its development costs – let alone make the open-ended profit that serves as an incentive for innovation." 2 Dratler, *supra*, at 7-54.

Moreover, even if the market could, in some respect, adjust to a new economic framework, publicly funded research entities and small biotechnology companies – which have been central players in the biotechnology boom, *FTC Report*, Ch. 3, p. 29 – will be pushed out of the market, with immeasurable and irreparable loss to future biotechnological development and innovation. Thus, reasonable restrictions are indispensable because that is the only option that protects the patentee's interest in a fair reward for its product, while respecting the operational needs of purchasers and avoiding practical and transactional costs that could otherwise strangle (both financially and functionally) the biotechnology industry. As this Court has "more than once cautioned," courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." *Diamond* v. *Diehr*, 450 U.S. 175, 182 (1981). There thus is no sound basis for applying the extra-statutory patent exhaustion doctrine so inflexibly that biotechnology companies cannot undertake necessary research or sell the first generation of seeds or vial of cells without "withdraw[ing] [the product] indefinitely from the operation of the franchise secured by the patent." *Mitchell*, 83 U.S. at 551.

2. Legitimate restrictions preserve reasonable uses of the product

Of central concern to petitioners and the Solicitor General are use restrictions that allegedly deprive the purchaser of the only reasonable use of the purchased product. Pet. Br. 33-34, 39; contrast *id*. at 33; Pet. App. 46a; U.S. Cert. Amicus Br. i, 19. This Court's patent exhaustion cases too have stressed the inappropriateness of restrictions that deprive the purchaser of any permissible use of the purchased product.[18]

But the restrictions imposed by the biotechnology industry on the buyer's field of use – that is, limiting the purchaser to non-commercial research rather than commercial exploitation of the patented article – or on the use of second-generation products do not deny the purchaser the opportunity to use the product acquired. The scientist may still conduct her research, and the farmer may still plant and harvest his crop. In so doing, the researcher and farmer enjoy all the ordinary attributes of the patented product that they acquired and are able to put it to the use for which they obtained it.

Channeling uses in that manner simply limits purchasers to using the product that they bought – a first generation seed, a cell line for research – and not a product that they did not buy. Cf. *Andrus* v. *Allard*, 444 U.S. 51, 66 (1979) (noting that property

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[18] See *Univis*, 316 U.S. at 249 (lens blank "is capable of use only in practicing the patent"); *Adams*, 84 U.S. at 456 (exhaustion where item's "sole value is in its use"); *McQuewan*, 55 U.S. at 553 ("Their only value consists in their use.").

owners possess a "full 'bundle' of property rights," and that loss of one "'strand' of the bundle" does not mean that others have been lost). The restrictions thus do not deprive purchasers of the basic utility of the product, as occurred in *Univis*. They simply protect the patentee against deprivation of its reserved, unsold, and unrewarded rights.

Petitioners themselves acknowledge (Br. 33) – and rightly so – that the patent exhaustion doctrine cannot be extended automatically to products with multiple functional uses. Having notice of the restrictions on its right, the price the purchaser is willing to pay will reflect the limited rights obtained. To permit purchasers to obtain full and unrestricted patent rights after paying for only partial rights would result in an unjustified windfall to the buyer and commensurate loss of the true value of the patent to the patentee.

Moreover, patent law must seek a balance between the need to reward inventors appropriately, as a means to the constitutional end of promoting the progress of science, and the interest of purchasers in exercising the property rights they acquire free from unwarranted control. See *United States* v. *Masonite Corp.*, 316 U.S. 265, 278 (1942). The purpose of the patent exhaustion doctrine has never been to provide bonanzas for purchasers and, in fact, this Court has held that patent exhaustion should not apply unless "it may fairly be said that the patentee has received his reward for the use of the article." *Ibid*. While a patentee is "entitled to but one royalty for a patented machine," he is entitled to obtain that one royalty,

and the patent exhaustion doctrine should not be applied so woodenly as to defeat that right.[19]

3. Contract law offers insufficient protection

Petitioners contend (Pet. Br. 28-29, 41-42, 46) that valid restrictions should be imposed through licenses. But, if by licensing, petitioners mean elaborate and individually negotiated, detailed agreements (as they seem to suggest, see Pet. 42-44), such licensing is not feasible for every $100 vial of cells or bacteria. Small companies – which predominate in the biotechnology area – do not have the resources to implement elaborate licensing arrangements and would have to rely on so-called "shrink-wrap" licenses, where the recipient's acceptance and use of the product gives rise to a limited use license.[20] Petitioners, for their part, are of two minds about whether such licenses should defeat patent exhaustion. Compare *ibid.*, with *id.* at 43 n.13 (noting the "unique exhaustion" issues that

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[19] See *Union Tool*, 259 U.S. at 113 (no implied license granted for unauthorized sale where patentee did not receive compensation for infringement); cf. *Straus*, 243 U.S. at 500 (invalidating restriction despite its form as a "license notice," because it was "clear" that the patentee had already received his full royalty); *Bauer*, 229 U.S. at 16 (patent exhaustion applied where "[t]here is no showing of a qualified sale for less than value for limited use").

[20] See, *e.g.*, *ProCD, Inc.* v. *Zeidenberg*, 86 F.3d 1447, 1448, 1450-1451 (7th Cir. 1996); *M.A. Mortenson Co.* v. *Timberline Software Corp.*, 998 P.2d 305, 313 (Wash. 2000); *Brower* v. *Gateway 2000, Inc.*, 246 A.D.2d 246, 251 (N.Y. App. Div. 1998).

arise with respect to biotechnology products and computer software).

Reality also belies petitioners' assertion (Br. 49) that the "genius" of a sweeping exhaustion doctrine "is that it greatly reduces transaction costs *without* reducing the patentee's award." With respect to the biotechnology industry, the opposite is true. Biotechnology is critically dependent on a patent law system that protects patentee's rights in subsequent generations of seeds and cycles of biological material, and that can reward the patentee's investment in the lengthy and expensive research and development process. Requiring the elaborate licensing agreements that petitioners favor for every single sale of a cell line, DNA, bacteria, or gene sequence would profoundly increase transaction costs in the industry. And, contrary to petitioners' argument, 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." Pet. Br. 49 (quoting *Keeler* v. *Standard Folding Bed Co.*, 157 U.S 659, 666-667 (1895)) (emphasis added).

Furthermore, petitioners are just wrong to argue (Br. 50) that a patentee can have no distinctive need to "parcel its royalty out." In the biotechnology industry, 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.

Finally, contrary to petitioners' view (Br. 46), contract law cannot adequately defend the biotechnology patentee's legitimate interests. As the Constitution itself recognizes, where patentees are enforcing their "exclusive Right to their respective * * * Discoveries," a uniform federal law is needed.[21] Consigning patentees, particularly small biotech companies, to the vagaries of 50 States' contract laws will deny the biotechnology industry 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.

In addition, contract law cannot adequately protect a patentee's exclusive rights when a third party improperly acquires the second-generation of a self-replicating product. That third party may not be in privity of contract with the patentee or licensee, and thus further (and potentially limitless) reproduction and distribution of the self-replicating product will be difficult to halt. Patent law, by contrast, permits the patentee to enjoin anyone who infringes the patent when irreparable harm is shown (as it would be with self-replication). See 35 U.S.C.

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[21] See *Florida Prepaid Postsecondary Educ. Expense Bd.* v. *College Sav. Bank*, 527 U.S. 627, 644-645 (1999) ("The need for uniformity in the construction of patent law is undoubtedly important."); *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) ("One of the fundamental purposes behind the Patent and Copyright Clauses of the Constitution was to promote national uniformity in the realm of intellectual property.").

281, 283-285; *eBay Inc.* v. *MercExchange, L.L.C.*, 126 S. Ct. 1837, 1840 (2006).

Even were the third party in privity of contact with the patentee or licensee, the ability to undo the damage wrought by infringing conduct under contract law is extremely limited. The remedies afforded by contract law generally do not include enjoining the unauthorized purchaser or user from distributing a self-replicating product or incorporating or combining it with other products. Unlike many traditional products, once self-replicating gene sequences are combined, they cannot be uncombined. It is virtually impossible "to 'unscramble the egg.'" *Federal Trade Comm'n* v. *University Health, Inc.*, 938 F.2d 1206, 1217 n.23 (11th Cir. 1991). 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.

Nor is it any answer to assert – as petitioners suggest, Pet. Br. 49-50 – that the market price will simply 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 to unravel completely the patentee's rights, given the products' capacity to replicate indefinitely. As a result, the patentee's entire compensation – the single royalty that the patent exhaustion doctrine promises, see *Univis*, 316 U.S. at 251; *Millinger*, 68 U.S. at 350 – 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. And with respect to products like cell lines, the patentee rarely has any realistic capacity to predict, at the time the first cells are sold or licensed for research purposes, what the ultimate cost and value of the product will be. 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 advances in health and agricultural sciences.

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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, as the federal government has acknowledged, see *FTC Report*, Ch. 3, p. 1-29; see *id*. at Ch. 1, pp. 1-2. Whatever the proper resolution of the dispute between petitioners and LGE, this Court should not erode (i) the long-established distinction between the right to use and the right to make a patented product; (ii) the legitimacy of licensing restrictions on both venders and purchasers; or (iii) the propriety of restrictions on purchasers that are necessary to the exercise of a patentee's properly reserved rights and that leave the purchaser a reasonable use of the product. The patent exhaustion doctrine was designed to protect against patentees who overreach the proper boundaries of patent law, not to unravel the fundamental protections in patent law that have

proven critical to the development of biotechnology and that have played a singularly important role in spurring the dramatic improvements in medical treatment, health care diagnostics, and agricultural expansion that the last two decades have witnessed.

CONCLUSION

For the foregoing reasons, the Court's decision should preserve the right of patentees to impose restrictions that prevent the unauthorized making of the patented product, that regulate purchases and sales by licensees, or that restrict a buyer's use of a product only as reasonably necessary to enforce the patentee's reserved rights in the patented product's replication or use in alternative fields, while reserving the reasonable and expected use of the product for the purchaser.

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