No. 06-937

In The
Supreme Court of the United States

QUANTA COMPUTER, INC., *et al.*,

Petitioners

v.

LG ELECTRONICS, INC.

**On Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

BRIEF FOR GEN-PROBE INCORPORATED AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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MISCELLANEOUS

INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Gen-Probe Incorporated is a global leader in the biotechnology industry. It has developed, manufactured, and marketed rapid, accurate, and cost-effective nucleic acid probe-based products that are used for the clinical diagnosis of human diseases and to screen donated human blood. For a quarter of a century, Gen-Probe also has developed and manufactured nucleic acid probe-based products for the detection of harmful organisms in the environment and in industrial processes. Gen-Probe's products are based on its patented technology for nucleic acid testing. Such products are used daily in clinical laboratories and blood collection centers in countries throughout the world. Gen-Probe holds more than 200 patents in these vital fields.

Much of Gen-Probe's success is achieved through strategic alliances, collaborations, and other commercial relationships with other companies in the biotechnology industry. These commercial relationships help to develop products that, among other things, will assist in blood screening, diagnosing prostate cancer, detecting human papillomavirus, and improving food safety. Gen-Probe has a significant interest in the

[1] Letters from all parties indicating that they have provided a blanket consent to the filing of *amicus curiae* briefs in this case have been filed with the Clerk of this Court pursuant to Supreme Court Rule 37.3(a). No counsel for a party authored this brief in whole or in part and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief. No person other than *amicus curiae*, their members, or their counsel made a monetary contribution to the preparation or submission of this brief.

instant case because many of Gen-Probe's research and development projects depend upon the purchase of patented articles and the licensing of patented technologies. Like other biotechnology firms, Gen-Probe relies on the expectation that a sale by a patent holder, or an authorized sale by a licensee, of products that incorporate those patented articles and technologies cannot give rise to patent liability on the part of the purchasers.

The decision below creates doubt where there must be none. The Federal Circuit's ruling permits a patent holder to resurrect patent rights on articles already sold in commerce. This creates uncertainty as to when, and under what circumstances, a patent holder has retained or forfeited its patent rights following its licensing of a patented technology or its sale of patented products, and it exposes those who purchase articles from the patent holder or its authorized licensee to potential patent infringement liability in circumstances never before contemplated by this Court.

This uncertainty has grave implications for the Nation's economy, which is increasingly dependent on scientific progress, as encouraged and protected by our patent system. In the area of biotechnology, the decision below will have a particularly profound effect because it often takes years, and millions of dollars of capital investment, before the commercial products that incorporate the patented articles (which include *amicus curiae*'s life-saving diagnoses and detection devices) become marketable. If companies, or their investors, fear that marketable biotechnology products will be prone to patent infringement suits by patent

holders, even though patented components have been purchased from a licensed seller and even after the company's products have been sold to their customers or their customers' customers, then biotechnology innovation will suffer.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case can be distilled down to two basic principles.

First, if a patent holder *sells* a patented article but wants to restrict what the purchaser does with that article after the sale, *e.g.,* to prohibit resale or to restrict the manner of use, the patent holder must make and enforce any such restrictions pursuant to a *contract*. The patent holder cannot enforce such restrictions under *patent* law, because the patent monopoly terminates upon the sale of the patented product to the purchaser, who obtains title to the property through the sale and passes such title on to any subsequent purchasers. This is known as "patent exhaustion" or the "first sale" doctrine.

Second, the result is no different if the seller is a *licensee* of the patent holder because a patent licensee acting within the scope of its license stands in the shoes of the patent holder when selling patented products. As such, when a licensee acting within the scope of its license sells an article that incorporates patented technology, it, too, cannot impose restrictions upon purchasers that are enforceable under *patent* law regarding the use or resale of that article.

The ruling of the Federal Circuit ignores these basic principles. It permits a patent holder (respondent,

here) to maintain a patent infringement action against the purchasers (petitioners) of an article containing patented technology from a licensee acting within the scope of its license (Intel), thereby allowing the patent holder to evade patent exhaustion. It confers onto a patent holder the right to impose, through its licensee, restrictions on purchasers of articles incorporating patented technology that are enforceable under patent law and that will follow that article whenever it is used or resold.

A. The ruling below threatens innovation in technology dependent industries such as biotechnology. This is because the products typically each incorporate numerous patented technologies, and biotechnology companies and their customers must rely upon patent exhaustion to preclude patent infringement actions after they have bought, through an authorized sale, an article containing a patented technology. Knowledge that a final commercial product will not be subject after sale to subsequent patent infringement suits by patent holders supports the incentive for biotechnology companies to make the enormous investments of time and capital necessary to the development of new drug therapies and products.

The Federal Circuit's exhaustion ruling ignores the purposes of the Patent Act. It departs from this Court's firmly established precedent and authorizes a result that is in many ways unimaginable: that a patent holder who voluntarily sells (or authorizes the sale of) a patented article can resurrect its patent rights with respect to that article and extract

additional sums from far-removed subsequent purchasers by invoking patent law.

B. For more than a century, the Court has held that a purchaser of a patented article sold by a patent holder (or by its licensee) receives complete title to that article and the patent holder's right to exclude others from using that particular article is "exhausted." The Court has recognized that the property interest of the purchaser outweighs the patent holder's right to exclusive use. And because such an article has passed outside "the limits of the monopoly," *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 549 (1852), the Court has rejected attempts by the patent holder to enforce against purchasers any restrictions on the use of the patented article through infringement suits under *patent* law (such patent holder may nonetheless have a right to sue under a contract).

This is as it should be. By preventing patent holders from pursuing infringement actions against downstream purchasers, but also allowing patent holders to recover damages under contract law if such purchasers fail to proceed in accordance with a contractual restriction on use of the article after sale, the law reflects the realities of the marketplace. Patent exhaustion also promotes fairness in transactions involving patented goods and fosters stability, growth and development in technological industries.

C. The Federal Circuit's ruling casts doubt upon and undermines this well-settled patent exhaustion doctrine. Rather than acknowledging that an authorized sale creates a property right in the purchaser that, of necessity, trumps the patent holder's

right to exclude under patent law, the court below held that a patent holder can sell patented technology and also retain its monopoly rights with respect to the article sold simply by imposing use restrictions at the time of sale. This conclusion demonstrates a fundamental misperception of the patent exhaustion rule and the property-based and contract-based interests that it protects.

The Federal Circuit's "conditional sale" (*non*exhaustion) rule muddies the waters regarding the circumstances under which a company can acquire or confer "freedom to operate," *i.e.*, the ability to research, develop, and bring to market life-saving products without concerns about patent infringement. In order to function effectively, the biotechnology industry needs clear legal rules and guidance to ensure that a patent holder receives from its licensees its full royalty for their right to manufacture, use, and sell the patented article (which often costs hundreds of millions of dollars to create), and also that purchasers of the products sold by the patent holder or its authorized licensee can use those products (and invest hundreds of millions of dollars to create other products incorporating them) without being subject to patent infringement suits.

Without patent peace, the operation of the biotechnology sector would be profoundly disrupted. The funds needed to support the research and development of marketable products in this industry are substantial, and the instability caused by the Federal Circuit's application of distorted exhaustion principles could affect innovation and investment for years to come. Moreover, under a legal system in

which a patent holder can seek to extract additional royalties under patent law from a company or its customers for a product that took many years, and hundreds of millions of dollars, to develop, patent holders would have extraordinary, market-distorting power. Research and development ventures could also become so risky that production of biotechnology products would be jeopardized. At the very least, this Court should avoid the untenable result of a patent system in which a patent holder is free to bring an infringement suit against downstream purchasers even if those purchasers are complying with the patent holder's use restrictions.

ARGUMENT

THE FEDERAL CIRCUIT'S DISREGARD OF THIS COURT'S WELL-ESTABLISHED PATENT EXHAUSTION DOCTRINE STIFLES INNOVATION, DISTORTS SETTLED PATENT PRINCIPLES THAT UNDERGIRD THE BIOTECHNOLOGY SECTOR, AND LEADS TO UNTENABLE RESULTS

The "patent exhaustion" doctrine, also known as the "first sale" doctrine, provides a defense against a claim of patent infringement where the patent holder sold the patented article in question, or the patented product was sold with the patent holder's authorization, for example, by a licensee. *Adams v. Burke*, 84 U.S. (17 Wall.) 453, 456 (1873) ("[W]hen the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use."); Donald S. Chisum, *Chisum on Patents* § 16.03[2][a] ("[A]n

authorized sale of a patented product exhausts the patent monopoly as to that product."). This bedrock principle of patent law strikes an important balance between, on the one hand, the interest of a patent holder in recouping his investment and generating profits through sales, and on the other hand, the interests of the public in the free use and movement in the marketplace of products after a patent holder has reaped its economic benefit through its sale (or its licensee's authorized sale) of the patented product.

The Federal Circuit has upset this equilibrium. In the instant case, respondent LG Electronics, Inc. owns several patents related to microprocessors and chipsets, which it licensed to the Intel Corporation. That license gave Intel the right to make, use, and sell, without infringement liability, certain microprocessors and chipsets that incorporate LG Electronics's patented technology. Pet. App. 33a. Pursuant to this license, Intel sold to petitioners (and others) chipsets that incorporated that patented technology, Pet. App. 29a-30a, and those chipsets were then installed in desktop and laptop computers sold throughout the United States and the world, Pet. Br. 3. Although Intel's license with LG Electronics did not limit or otherwise affect patent exhaustion, it purported to disclaim conferring any express or implied license in its patents to any computer manufacturers, *e.g.*, petitioner Quanta Computers, who might purchase Intel products and then manufacture computers by combining those products (which incorporated LG Electronics's patented technology) with non-Intel products.

Under a straightforward application of this Court's patent exhaustion doctrine, however, LG Electronics could not retain any patent rights to bring infringement actions against manufacturers that had purchased Intel's chipsets. That is because the authorized sale to the manufacturers by Intel, as a licensee of LG Electronics, of the products that incorporated LG Electronics's patented technology transferred title in the products to the purchasers who could then use the products as they liked. The sale thereby exhausted LG Electronics's *patent* rights to exclude the customers' use of the patented technology in the products sold; in order to restrict the use by such purchasers, the patent holder must rely on a contractual agreement.

But the Federal Circuit disagreed, holding that LG Electronics's license to Intel and Intel's sales to petitioners were "conditional," and therefore LG Electronics's patent rights were not exhausted, so that LG Electronics could bring an infringement action against those who had bought chipsets from Intel that incorporated the patented technology. That incorrect ruling has far-reaching consequences because it resurrects respondent's patent rights and allows it to recover again for patent rights for which it has already been fully compensated.

A. The Biotechnology Industry Relies Upon Strategic Alliances And Commercial Relationships That Will Be Disrupted If The Ruling Below Is Not Reversed

Patents are vital to biotechnology companies such as *amicus curiae*. Few sectors of the United States economy are as dependent upon patents as the biotechnology industry. Companies such as *amicus* Gen-Probe frequently expend hundreds of millions of dollars, over the course of a decade or more, for development of medical devices *before* the first dollar of revenue is realized. *See NIH: Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 108th Cong. 47 (2003) (testimony of Phylliss Gardner, M.D.). ("The biotechnology industry is the most research and development-intensive and capital-focused industry in the world.").

The enormous capital investments that support this development are attracted only by clear evidence of patent protection so that biotechnology companies can ensure that the investment, and their corresponding advancements, is not for naught during the lengthy development, approval, and marketing process for their inventions. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) (patent laws "promote * * * progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development").

The days of a single patent covering a world-altering invention are over, however, even in the biotechnology industry. Commercial products in the biotechnology

industry such as new screening methods, drugs, and therapies for life threatening disease often embody *multiple* patented inventions. This is so because no single biotechnology company holds patents to all of the necessary components that are used to comprise or create the final commercially available product. As such, those companies, including *amicus* Gen-Probe, must negotiate appropriate arrangements with those who hold patents for various components or intermediate products. *See, e.g.*, Gen-Probe, Corporate Collaborations and Strategic Alliances, *available at* http://www.gen-probe.com/corp_overview/collab.htm (last visited Nov. 11, 2007) (describing collaborations and strategic alliances to help diagnose and detect cancers and other serious diseases). Gen-Probe must either obtain a license or purchase such components from a licensed seller in order to have "freedom to operate," which enables it to research, develop, and bring to market life-saving products without infringement fears.

The decision below will have significant, adverse ramifications in such circumstances. The ability to use properly patented technology as the building blocks for the next test, therapy, or cure for debilitating or life-threatening diseases would be compromised if companies face threats of patent infringement suits long after the purchase of patented articles and the investment of hundreds of millions of dollars into products based on those articles.

B. This Court's Patent Exhaustion Doctrine Reflects Well-Settled Legal Rules Regarding The Transfer Of Property Interests, And It Reaffirms That Limits On Patent Monopolies Are Essential To Fairness And Advancements In Technological Markets

1. The authorized sale of a patented item transfers title and exhausts any patent rights with regard to that item

The patent exhaustion principle that an authorized sale of a patented article prevents the patent holder from suing that purchaser, or any subsequent purchasers, for patent infringement has long guided this Court's patent jurisprudence. *See Adams*, 84 U.S. (17 Wall.) at 456 (limiting patent rights when a patented invention is sold is "[i]n the essential nature of things"); *accord United States v. Univis Lens Co.*, 316 U.S. 241, 250-51 (1942); *see also United States v. General Elec. Co.*, 272 U.S. 476, 489 (1926) (after an authorized sale a patent holder "can exercise no future control over what the purchaser may wish to do with the article after his purchase" because "[i]t has passed beyond the scope of the patentee's rights."); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 516 (1917) (when a patent holder sells or authorizes the sale of a patented invention, "the article sold [is] thereby carried outside the monopoly of the patent law and rendered free of every restriction" on use that the patent holder might otherwise have sought to enforce as a matter of patent law). It finds roots in a fundamental legal principle that this Court first articulated in *Bloomer v. McQuewan*, 55 U.S. (14

How.) 539 (1852); namely, that the conveyance of a patented invention itself (through sale) for use by the purchaser, as opposed to the mere license to make, use, or sell the patented invention, allows the purchaser to use the property it bought as it sees fit.

In *Bloomer*, this Court explained that the bundle of rights belonging to a patent holder under patent law "consists altogether in the right to exclude every one from making, using, or vending the thing patented." *Id.* at 549; *accord Univis Lens*, 316 U.S. at 250. In a license agreement, the patent holder sells only the "privilege of making or vending" the invention, *i.e.*, the licensee "obtains a share in the [patent] monopoly, and that monopoly is derived from, and exercised under, the protection of the United States." *Bloomer*, 55 U.S. (14 How.) at 549; *see also Mitchell v. Hawley*, 83 U.S. (16 Wall.) 544, 548 (1872) (licensees "hold the whole or a portion of the franchise which the patent secures").

But one who *buys* the patented invention itself "stands on different ground" from a licensee. A purchaser of a patented item does not exercise "rights created by the act of Congress, nor does he derive title to [the invention] by virtue of the franchise or exclusive privilege granted to the patentee." *Bloomer*, 55 U.S. (14 How.) at 549. Rather, the invention that he purchased "becomes his private, individual property" to do with as he wishes (or as he may have contracted to do) without regard to the limitations on use that patent law imposed before the sale. *Id.* at 550. In other words, "when the machine passes to the hands of the purchaser, it is no longer within the limits of the monopoly" but "passes outside of it, and

is no longer under the protection of the act of Congress." *Id.* at 549; *see also Mitchell*, 83 U.S. (16 Wall.) at 548 (in contrast to a licensee, a purchaser "acquires no portion of the franchise" and "the machine, which rightfully passes from the patentee to the purchaser, ceases to be within the limits of the monopoly").[2]

2. Conditions on the use of a patented article after sale are a matter of contract and have no bearing on whether a patent is exhausted

In the instant dispute, the Federal Circuit concluded that patent exhaustion "'does not apply to an expressly conditional sale or license.'" Pet. App. 6a (quoting *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997)). It thereby erroneously conflated a sale with a license. *See* Pet. App. 5a ("There are two sales at issue here. First, * * * LGE granted Intel a license * * *. Second, with LGE's authorization, Intel sold its microprocessors and chipsets * * * .").

But this Court has clearly distinguished between sales and licenses. In contrast to licenses, sales create *ownership* rights in the thing transferred, *Univis Lens*, 316 U.S. at 252 (a sale is "the vehicle for transferring to the buyer ownership of the invention with respect to that article"), and a necessary concomitant of that ownership is the right to use

[2] This is so even if the sale was not by the patent holder himself, so long as the seller is authorized to sell the patented invention. *Adams*, 84 U.S. (17 Wall.) at 456.

what has been purchased in whatever manner the owner wishes, *Adams*, 84 U.S. (17 Wall.) at 455 ("[T]he 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"); *see also Univis Lens*, 316 U.S. at 249 ("[a]n incident to the purchase of any article * * * is the right to use and sell it").

This Court has repeatedly held that the transfer of a patented invention by a sale *creates property interests in the purchaser*—including the right to freely use the invention—and that it simultaneously extinguishes the patent holder's right to exclusivity under patent law with respect to the use of that particular item sold. *See ibid.*; *Keeler v. Standard Folding-Bed Co.*, 157 U.S. 659, 666 (1895) ("[O]ne who buys patented articles of manufacture from one authorized to sell them becomes possessed of an absolute property in such articles, unrestricted in time or place."); *Mitchell*, 83 U.S. (16 Wall.) at 548 ("Complete title to the implement or machine purchased becomes vested in the vendee by the sale and purchase.").

This Court's decisions thus balance the rights and interests conveyed under the common law of property and those that are protected by the statutory right of patent. These decisions recognize a straightforward legal principle: that a purchaser's right to use a purchased invention in whatever manner it pleases and a patentee's right to prevent such use are, by necessity, mutually exclusive. Consequently, the authorized sale of a patented invention *necessarily* divests the patent holder of

his monopoly with respect to use of the article sold. *See* Richard H. Stern, *The Unobserved Demise of the Exhaustion Doctrine in US Patent Law*, 15 EUR. INTEL. PROP. REV. 460, 462 (1993) (the patent exhaustion doctrine is "based on property law, which the Court considered to supervene over patent law once the patentee sold the patented article to the customer-owner").

Significantly, because one who purchases a patented article receives the right to use that article "to the full extent to which it can be used" as a result of possessing its title, *Adams*, 84 U.S. (17 Wall.) at 455, any restrictions that the seller wishes to impose on a purchaser's use of the article can be obtained by the seller *only through a contract* that is evaluated and enforced as a matter of *contract* law. It is for that reason that this Court in *Motion Picture Patents* refused to authorize the enforcement under patent law of use restrictions against purchasers and expressly distinguished between "the rights which are given to the inventor by the patent law and which he may assert against all the world through an infringement proceeding," and the "rights which [the inventor] may create for himself by private contract." 243 U.S. at 514. In *Keeler*, too, this Court found that the sale exhausted the patent holder's *patent* rights, while expressing no opinion as to "[w]hether a patentee may protect himself and his assignees by special contracts brought home to purchasers," which, it noted, was an issue that "would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws." 157 U.S. at 666; *see also Bloomer*, 55 U.S. (14 How.) at 550

(contracts in relation to sold goods "are regulated by the laws of the State," not patent law).

3. The ruling below would lead to outcomes that are contrary to well-established market norms

The Federal Circuit's view that the patent exhaustion doctrine does not apply to a sale where the seller intends to restrict use of the patented article after sale not only ignores this Court's precedents but would lead to nonsensical and economically disadvantageous results.

For example, the decision below could be misinterpreted to leave the purchaser of a patented product that is subject to use restrictions open to a suit for patent infringement *without regard* to whether such purchaser complies with the restrictions. For if the exhaustion doctrine truly "does not apply to an expressly conditional sale,"[3] then *no one* who purchases a restricted item is immune from liability for patent infringement, even by complying with the restriction.

Under this Court's precedents, however, patent exhaustion does, in fact, occur upon a restricted sale, leaving the purchaser who violates the restriction exposed only to contract liability. *Keeler*, 157 U.S. at 661. Indeed, this Court's consistent recognition that

[3] The Federal Circuit interprets the term "conditional sale" to be synonymous with a restricted sale. But petitioners have shown that that interpretation of "conditional sale" finds no support in this Court's patent exhaustion precedents. Pet. Br. 19-20.

an authorized sale extinguishes the monopoly of patent is crucial if patented articles are to be marketed, and the marketing of such articles is, in turn, a prerequisite for technological advancement. When a product that is patented (or that is comprised of patented components) is sold, it is released into the stream of commerce just like any other good. For the market to react properly—*i.e.*, for that product to retain its value—the patent holder's right to exclude others from using the patented product or component cannot persist.

Respondent suggests that a patent holder may somehow sell a patented article so that the sale merely reallocates to the purchaser some portion of the patent holder's exclusive authority under the patent laws with respect to that article, depending upon the amount that is paid. Resp. Br. in Opp. at 25 ("whether the authorizations are partial or complete" affects the price). But one who *sells* a patented item is not "parceling out" his exclusivity rights in a manner that preserves his rights under the Patent Act or his entitlement to extract usage fees from successive downstream purchasers under free market principles. Resp. Br. in Opp. at 25. With respect to such purchasers, the right to use derives from purchase of the title itself, not from any authority granted to, or by, the patent holder; consequently, the price paid is not "partial" in any respect. *See Bloomer*, 55 U.S. (14 How.) at 550 (what a buyer is willing to pay for a product is based on "the usefulness of the thing he buys, and the advantages he will derive from its use"); *see also Univis Lens*, 316 U.S. at 252 (the purchase price reflects "every benefit of th[e]

monopoly which the patent law secures" with respect to the item sold); *Adams*, 84 U.S. (17 Wall.) at 456 (in "the act of sale" the patentee or assignee "receive[s] all the royalty or consideration which he claims for the use of his invention in that particular machine or instrument").

Of course, if a patent holder markets an invention that is saddled with restrictions on the use to which the invention can be put after sale, the sales price will reflect that restriction. But neither free market principles nor this Court's patent precedents permit what the Federal Circuit authorized here: the potential recovery of the "full" value of that restricted item through an action for infringement brought under patent law. *See Motion Picture Patents*, 243 U.S. at 420-421 ("[I]t is not competent for the owner of the patent * * * to send its machines forth into the channels of trade of the country subject to conditions as to use or royalty to be paid, to be imposed thereafter at the discretion of such patent owner. The patent law furnishes no warrant for such a practice, and the cost, inconvenience, and annoyance to the public which the opposite conclusion would occasion forbid it.").

C. The Federal Circuit Disregards Core Patent Exhaustion Principles, And Its Analysis Has So Upset Settled Expectations That It Portends Unfair, Unwarranted, And Untenable Results

1. The Federal Circuit's "conditional sale" analysis is wrong

Contrary to this Court's consistent, longstanding, and principled patent exhaustion doctrine, the Federal Circuit would permit a patent holder to authorize the sale by a licensee of its patented invention and nevertheless maintain after the sale its enforceable patent rights with respect to the article sold. Pet. App. 5a-6a. The Federal Circuit's exhaustion analysis thus reveals *fundamental* misconceptions about patent law and policy, which manifest themselves in several ways.

a. As discussed above, the Federal Circuit does not appear to recognize that a sale creates a *property right* of the purchaser in the patented invention, and that under the well-established jurisprudence of this Court, such property right of the purchaser conflicts with, and outweighs, the patent holder's right to exclude. To conceptualize an authorized sale as simply a matter of "waiver" by the patent holder, *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 703 (Fed. Cir. 1992) ("[the] right to exclude may be waived in whole or in part"), mischaracterizes the transaction as one in which the legal consequences can be minimized at the option of the patent holder. The proper legal analysis teaches the opposite: no matter how ardently the patent holder may wish to retain his monopoly, and whatever conditions he

may attempt to impose upon downstream purchasers under penalty of infringement, once the patent holder or its licensee engages in an authorized sale of the patented invention, the purchaser's property interests trump and, with respect to that article, the patent holder's bundle of rights under patent law is extinguished.

b. Similarly, the Federal Circuit evaluates the enforceability of use restrictions on sales "in terms of their relation to the patentee's right to exclude," *Mallinckrodt*, 976 F.2d at 706, when, in fact, such restrictions are creatures of contract that have nothing to do with the scope of the patent monopoly. It is clear beyond cavil that "[t]he exhaustion doctrine finds its basis in the foundations of patent policy, which seeks not only to grant exclusive rights to patentees but also to limit those rights." Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation In the Software Industry*, 89 CAL. L. REV. 1, 31 (2001). "Exhaustion represents one such limit * * * : that control ceases with respect to a particular product once [the patent holder or its assignee] has sold that product." *Ibid.*

Failing to recognize that the exhaustion rule is a limitation on the patent holder's right of exclusivity after a sale, the Federal Circuit reasons that whether a patent holder's rights are deemed exhausted turns on the patent holder's own intentions in either selling the patented article outright or, alternatively, restricting the purchaser's use of it as part of the sale. But a sale subject to restrictions is nothing more than a contractual arrangement to limit the manner in which a purchaser will use the purchased article

after sale, and the restrictions derive from the contract itself, not any exclusivity right belonging to the patent holder. *Bloomer*, 55 U.S. (14 How.) at 549-550. Indeed, as petitioners point out, the Federal Circuit's "conditional sale" *non*exhaustion analysis is the same misguided notion that this Court unequivocally rejected when it overruled *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912), more than 90 years ago. *See Motion Picture Patents*, 243 U.S. at 515.

c. The Federal Circuit is also clearly mistaken to conclude that it is "reasonable" to allow a patent holder to attempt to recover, through an infringement action against downstream purchasers, "the full value of the goods" that it has sold. Pet. App. 5a. This assertion ignores the nature of the "reward" due to the patent holder (*i.e.*, a single royalty or sales price) and again, the Federal Circuit's misguided reasoning demonstrates its disregard for first principles.

A licensee owes a royalty to a patent holder when the licensee makes, uses, or sells the patented invention because it does not otherwise have any rights with respect to the invention covered by the patent. Stern, *supra*, at 465. In effect, a license buys *immunity* from the patent holder's exercise of his right to exclude—*i.e.*, a licensee purchases the right to infringe without consequences—and, of course, each individual who intends to receive such immunity must pay for it.

No royalty, other than the sales price, must be paid when there is an authorized *sale*, however, because the purchaser does not need infringement immunity. Purchasers get "complete title," *Mitchell*,

83 U.S. (16 Wall.) at 548, which "carries with it" the right to use the invention in any manner the new owner wishes, *Adams*, 84 U.S. (17 Wall.) at 455. Thus, unlike a licensee, a purchaser's use or re-sale of a product he buys *does not constitute patent infringement at all*. Put another way, the *title* is the source of the purchaser's authority to use the patented invention. Surely the purchaser need not pay for what he already owns.

2. The Federal Circuit's patent exhaustion ruling puts technological advancements in the biotechnology area at risk

Commercial arrangements related to patent "freedom to operate" require clear legal rules, so that a patent holder knows it has received full value for the sale of its invention (which exhausts its patent rights), or understands that it has protected its ongoing patent rights with a more limited license (which does not exhaust those rights). Moreover, beneficial commercial relationships are possible only when inventors who use patented inventions as building blocks know that the sale to them of a patented article, or the license to them of the right to make, use, or sell, gives them the rights they need without any threat of future infringement actions against them. Scientific progress would be hindered if a patent holder could continuously and unjustifiably assert its patent rights against those who purchase products that incorporate its patented technology, even *after* the patent holder already sold the patented technology, directly or through

authorized sale by its licensee, for use in making the products at issue.

A legal system that is clear and coherent, and that recognizes the rights and interests of all parties in commercial arrangements involving the transfer of patented articles, promotes innovation by encouraging patent holders to disclose their inventions more broadly in exchange for royalties. And it encourages others within the industry to invest in the development of life-saving innovations that use those patented building blocks, without fear that a patent holder might subsequently assert an infringement action against future downstream purchasers of products that incorporate the patented technology.

The Federal Circuit's misinterpretation of the patent exhaustion doctrine undermines this system, and thus has grave implications for the biotechnology industry. As discussed above, the biotechnology sector is second to none with respect to the amount of investment dollars that must be generated at the outset. And that is made possible only by the expectation that someday a discovery will be made, and someday a product will be developed, such that, someday, there will be a strong return on the initial investment. Many biotechnology products require the aggregation of a complex number of patented technologies or components, and the development of such biotechnology products will be significantly curtailed if the legal rules do not clearly establish a viable economic support structure. This could happen in various ways.

The seismic shift that would result from this Court's endorsement of the Federal Circuit's

restriction-based patent exhaustion theory could cause investors in patent-dependent industries to reconsider the propriety of those investments. This is particularly true in the biotechnology industry because the product development process, which can extend for decades, is already less than certain to yield a profitable outcome. Such a venture becomes even less attractive if there can be no reasonable expectation of stability in the governing legal framework.

In addition, because the development of a new biotechnology product depends upon the investors' ability to recoup and potentially profit from their initial outlay, the market price of final products has to be maintained. If biotechnology manufacturers and all downstream purchasers are subject to infringement liability despite purchasing from an authorized seller, products that incorporate patented technology will have to be sold for less than full value, jeopardizing the manufacturers' ability to get the funding necessary to generate those products in the first place. Indeed, it is untenable that a patent holder could threaten an infringement action against downstream owners and, thereby, instantly devalue the final product while it is still in production and long after investors have made the financial commitment to support it. And even the possibility of such a unilateral strike could very well cause small biotechnology manufacturers to fold up their tents and go home.

There is also little doubt that the Federal Circuit's ruling will have the practical effect of increasing the power of the patent monopoly in

business negotiations, because exhaustion will no longer serve as a limitation in *any* respect. Simply stated, if the Federal Circuit's rule were widely accepted, there likely would be no exhaustion at all in this arena because no one who has spent millions of dollars developing a compound or isolating a gene would give it away in the form of an "unconditional" sale. Pet. App. 32a. Patent holders could also extract premiums from risk-averse purchasers shopping for insurance for themselves and their customers to guard against future infringement risks. And that premium would grow, perhaps *exponentially*, based on the depth of the potential customer pool.

At the end of the day, it is hard to see how the Federal Circuit's distortion of the well-settled patent exhaustion rule could lead to any outcome other than a substantial decline in the development of marketable biotechnology products, which would hurt not only biotechnology companies but also the public at large. The consequences become even more untenable—and the Federal Circuit's rule even more absurd—when one considers that the lower court's exhaustion theory appears, on its face, to hinge solely on whether use after sale is restricted, so that a downstream purchaser might be subject to suit for patent infringement even if it *complies* with the use restrictions. For example, Gen-Probe purchases patented products that it incorporates into complex molecular diagnostic kits. It purchases some of these products subject to restrictions on their use after purchase and it complies with those restrictions when developing and producing its kits. The Federal Circuit's determination that a "conditional sale"

precludes patent exhaustion could be misinterpreted to result in Gen-Probe obtaining no freedom from the patents even though Gen-Probe purchases patented products from an authorized seller and uses them in accordance with the restriction. There is no basis in precedent or logic for permitting an infringement suit in these circumstances, but if patent exhaustion does not apply to a "conditional sale," then even a company such as Gen-Probe could be vulnerable to an infringement suit.

Whatever this Court determines regarding the merits of the instant case, it should at least decide the issue before it in a manner that prevents the Federal Circuit's unbounded patent exhaustion language from becoming this Court's rule. The Court should not allow the Federal Circuit's "conditional sale does not exhaust" holding to put at risk even careful and conscientious companies that comply with limitations on use after sale. *Amicus curiae* urges this Court to protect vital investments in life-saving technology by avoiding giving patent holders an unwarranted and unfair windfall against such purchasers. Fundamental fairness demands at least that much.

CONCLUSION

For the reasons set forth above, the Court should reverse the judgment of the court of appeals and remand the case for further proceedings.

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