No. 15-1189

IN THE

Supreme Court of the United States

IMPRESSION PRODUCTS, INC.,

Petitioner,

v.

LEXMARK INTERNATIONAL, INC.,

Respondent.

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

BRIEF FOR PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. In 2015 alone, they invested an estimated $58.8 billion to discover and develop new medicines. Pharmaceutical Research and Manufacturers of America (PhRMA), 2016 PhRMA Annual Membership Survey 5 (2016), http://goo.gl/JmXEpY. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as an *amicus curiae* in cases before this Court.

Among other issues, this case presents the question whether, in light of the Court's holding in *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351, 1363 (2013), the Federal Circuit correctly reaffirmed its precedent that the owner of a U.S. patent does not exhaust its U.S. patent rights by selling a product covered by that patent abroad. That question is critically important to the pharmaceuti-

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[1] 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 this brief. No one other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. All parties have consented to the filing of this brief.

cal industry, which relies heavily on patent protection in researching, developing, and testing medicines and in bringing new products to market, both in the United States and overseas. PhRMA submits this brief to explain the importance of the rule against automatic exhaustion of patent rights by foreign sale to the pharmaceutical industry's ability to continue to develop innovative, life-saving medicines and treatments for patients.

INTRODUCTION AND SUMMARY OF ARGUMENT

For more than a century, U.S. patent holders have operated on the understanding that their U.S. patent rights survive a first foreign sale. That rule is necessary to preserve the rights of U.S. patent holders against the uneven patchwork of patent laws around the world. The continued vitality of the rule is of particular importance to PhRMA's members, who rely heavily on strong patent protection to safeguard their investments in the development of important, life-saving medications.

Petitioner seeks to bring about a sea change in the law of patent exhaustion. Notwithstanding this Court's repeated warnings against conflating copyright and patent principles, petitioner and certain *amici* ask this Court to cast aside settled principles of patent law, and instead impose in the patent context an inapposite rule from copyright law, under which a first foreign sale automatically exhausts U.S. copyright protections. But copyright and patent laws differ in fundamental ways—both with respect to the nature, scope, and duration of the legal protections they provide, and with respect to the uniformity of those protections across international borders. Those differences belie any superficial

equivalence between these two distinct areas of intellectual property law, and preclude transposing doctrines from one context to the other.

Adopting petitioner's proposed automatic international-exhaustion rule would not only be contrary to established precedent; it would also have resounding and deleterious effects for patent-holders—including pharmaceutical manufacturers. Patent protection is critical to prevent entities from purchasing U.S.-patented pharmaceutical products abroad (often for lower prices than they are sold on the U.S. market for reasons such as foreign government price controls) and then reselling them on the grey market in the United States. The ability of pharmaceutical companies to enforce their U.S. patent rights against parallel importers protects their investment in pharmaceutical research, enabling the industry to continue to develop critical new drugs and treatments.

Petitioner's proposed international-exhaustion rule would imperil future pharmaceutical research. It would also undermine the foundational principle of innovation that has placed the United States at the forefront of the search for medical breakthroughs. This Court should decline to rewrite settled principles of patent exhaustion doctrine and should affirm the decision below.

ARGUMENT

I. The Copyright Rule of International Exhaustion Does Not Apply in the Patent Context

This Court should not transpose the international copyright-exhaustion rule that it adopted in *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2013), to the patent context. The Court has long

cautioned against relying on analogies between copyright and patent law: "There are such wide differences between the right of multiplying and vending copies of a production protected by the copyright statute and the rights secured to an inventor under the patent statutes, that the cases which relate to the one subject are not altogether controlling as to the other." *Bobbs-Merrill Co. v. Straus*, 210 U.S. 339, 346 (1908) (quotation marks and citation omitted). Patent and copyright law "are not identical twins," and this Court "exercise[s] … caution … in applying doctrine formulated in one area to the other." *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 439 n.19 (1984).

Patent and copyright law differ in critical ways. While a copyright exists upon creation of the work, 17 U.S.C. § 102(a), a patent is issued after the U.S. Patent Office examines and approves the inventor's patent application for compliance with the statutory criteria for patentability, 35 U.S.C. §§ 101 et seq. A patent provides broader protection than a copyright, as a patent holder may exclude others from "use," whereas a copyright holder may not. *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 13–14 (1913). "Unlike a patent, a copyright gives no exclusive right to the art disclosed; protection is given only to the expression of the idea—not the idea itself." *Mazer v. Stein*, 347 U.S. 201, 217 (1954). A copyright can subsist for more than a century, 17 U.S.C. § 302, whereas a patent is valid for only 20 years, 35 U.S.C. § 154, unless extended for up to 5 additional years, 35 U.S.C. § 156. And whereas international conventions have largely harmonized substantive copyright protection across the globe, *see Golan v. Holder*, 565 U.S. 302, 307–10 (2012), patent law remains a territorial regime, and the scope and enforcement of

patent rights varies widely from country to country, *see Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 454–55 (2007); *infra* pp. 7–8.

Kirtsaeng itself implicitly recognized and rejected any equivalence between copyright and patent law. The opinion contains no discussion of patent law generally or the doctrine of patent exhaustion or "first sale" specifically. Instead, *Kirtsaeng*'s holding that "[t]he 'first sale' doctrine applies to copies of a copyrighted work lawfully made abroad," 133 S. Ct. at 1352, turned on the interpretation and statutory history of § 41 of the Copyright Act, which codifies the copyright first-sale doctrine. 17 U.S.C. § 109(a). The Patent Act has never contained an analogous provision, so the Court's interpretation of the Copyright Act in *Kirtsaeng* does not and cannot control the issue here.

The Court in *Kirtsaeng* also relied on the common-law first-sale doctrine in copyright law to bolster its statutory interpretation. But that doctrine bears little more than superficial resemblance to the first-sale doctrine in patent law. Unlike the copyright first-sale doctrine, which was codified in the 1909 Copyright Act, the patent first-sale doctrine has continued to evolve over the past century and has important distinctions from its copyright counterpart. For example, whereas "the common-law [copyright first sale] doctrine makes no geographical distinctions," *Kirtsaeng*, 133 S. Ct. at 1363, the common-law patent first-sale doctrine does draw such distinctions.

Thus, in *Boesch v. Graff*, 133 U.S. 697 (1890), the Court found that importation into the United States of articles lawfully acquired in Germany without the patent owner's consent constituted patent infringe-

ment, because "[t]he sale of articles in the United States under a United States patent cannot be controlled by foreign laws." *Id.* at 703. Petitioner and its *amici* emphasize that the German seller in *Boesch* lacked authority from the U.S. patent-holder to sell the U.S.-patented product in Germany. *E.g.*, Pet. Br. 51–53; Abbott Br. 13–14. But that distinction is irrelevant here. The point—true in *Boesch* as well as in this case—is that the purchaser lacked authority to import and resell the invention in the United States simply by virtue of a foreign sale. The Federal Circuit has reaffirmed that principle on numerous occasions, including in the decision below. *Lexmark Int'l, Inc. v. Impression Prods., Inc.*, 816 F.3d 721, 774 (Fed. Cir. 2016) (en banc); *Ninestar Tech. Co. v. ITC*, 667 F.3d 1373 (Fed. Cir. 2012); *Fujifilm Corp. v. Benun*, 605 F.3d 1366 (Fed. Cir. 2010); *Fuji Photo Film Co. v. Benun*, 463 F.3d 1252, 1255–56 (Fed. Cir. 2006); *Jazz Photo Corp. v. ITC*, 264 F.3d 1094, 1105 (Fed. Cir. 2001).

In short, the mere fact that copyright and patent law both have "first sale" doctrines is no reason to apply the copyright principles formulated in *Kirtsaeng* to patent law. *See* Pet. Br. 47–48. *Kirtsaeng* concerned a specific statutory provision that has no patent-law analogue. And the basic distinctions between copyright and patent law—with respect to the nature and scope of protection, and the uniformity of that protection across international borders—preclude simply transposing *Kirtsaeng*'s copyright-specific international-exhaustion rule to the patent context.

II. The Rule Against International Patent Exhaustion Is Necessary To Protect the Rights of U.S. Patent Holders Who Sell Products Abroad

In view of the unique features of patent law—in particular the territorial nature of patent rights—the rule against exhaustion of patent rights by foreign sale is critical to protecting the intellectual property rights of U.S. patent holders who sell their products overseas.

Patent laws are not uniform across international borders. International patent law is founded on the concept of "independence of patents," under which the patent law and decisions of one country have no impact on the validity or effect of patents issued in another country. Paris Convention for the Protection of Industrial Property art. 4bis, Mar. 20, 1883 (as amended Sept. 28, 1979), 21 U.S.T. 1583, 828 U.N.T.S. 305; *see* Abbott Br. 8–9. Thus, while the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes basic substantive criteria for obtaining a patent, it leaves the actual administration of patent protection to individual countries. TRIPS, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

U.S. patent law itself does not apply extraterritorially. As this Court has explained, "[t]he presumption that United States law governs domestically but does not rule the world applies with particular force in patent law." *Microsoft*, 550 U.S. at 454–55. "Our patent system makes no claim to extraterritorial effect; 'these acts of Congress do not, and were not intended to, operate beyond the limits of the United States.'" *Deepsouth Packing Co. v.*

Laitram Corp., 406 U.S. 518, 531 (1972) (citation omitted).

Given the territorial limits of patent rights and the fact that U.S. patent protections do not apply beyond U.S. borders, it would be anomalous to extend the American patent-exhaustion doctrine to activities in other countries. Petitioner's proposed automatic exhaustion rule would give parallel importers an absolute U.S.-law shield for overseas sales, while patent owners lack any sword with which to enforce their U.S. patent rights abroad. A rule that a foreign sale automatically exhausts U.S. patent rights would severely undermine a U.S. patent holder's interests and the expected economic value of its U.S. patent—solely because the patent holder sold its products in a country that may provide dramatically different patent protection from the United States, or even no patent protection at all.

These concerns are especially pressing for the pharmaceutical industry. Pharmaceutical manufacturers strive to maximize patient access worldwide to the important medicines and treatments that they have developed. But weak foreign patent regimes, which provide companies little assurance that their intellectual property will be protected, could discourage companies from entering certain markets. *See* Iain Cockburn, Jean O. Lanjouw & Mark Schankerman, *Patents and the Global Diffusion of New Drugs*, 106 Am. Econ. Rev. 136 (2014). The existing no-international-exhaustion rule mitigates these concerns to a degree: pharmaceutical companies retain U.S. patent rights that they may assert against parties that attempt to import U.S.-patented drugs first sold abroad into the United States. Abrogating that rule would remove an important safeguard that

protects U.S. patentees against infringement of their U.S. patent rights, when those U.S. patentees take a risk and sell their products in markets where the scope and enforcement of patent rights may be weak or even nonexistent.

III. Safeguarding U.S. Patent Rights Is Critical to Innovation in the Pharmaceutical Industry

The U.S. Constitution and patent laws reflect a careful balance between fostering innovation and promoting free markets. "Pursuant to its power '[t]o promote the Progress of … useful Arts, by securing for limited Times to … Inventors the exclusive Right to their Discoveries,' U.S. Const. I, Art. I, § 8, cl. 8, Congress has passed a series of patent laws that grant certain exclusive rights over certain inventions and discoveries as a means of encouraging innovation." *Bilski v. Kappos*, 561 U.S. 593, 621 (2010). "[P]atent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and imped[ing] the flow of information that might permit, indeed spur, invention." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (citation and internal quotation marks omitted). The rule that foreign sales do not exhaust U.S. patent rights is critical to preventing foreign policies, laws, and regulations from disrupting the delicate balance that Congress has struck—a balance that is particularly important for the discovery, development, and distribution of new pharmaceutical products.

A. Pharmaceutical companies rely heavily on the period of patent exclusivity to recoup research and development costs

The period of patent exclusivity is essential to allow pharmaceutical innovators a chance to recover the massive research and development costs involved in discovering and testing new drugs, and to enjoy—for a limited period of time—the fruits of their research efforts in the way that Congress intended.

Developing and obtaining regulatory approval for new drugs is extremely time-consuming, risky, and expensive. Drug discovery and development involves significant trial and error. The vast majority of candidate drugs do not make it to market. And the costs of clinical testing and regulatory approval are extremely high. Of the many thousands of candidate drugs screened early in the research process, few ever progress to clinical studies in humans, let alone receive FDA approval. Fewer than 12% of drugs that even enter clinical testing (already a small fraction of the thousands of compounds synthesized in laboratories) ultimately receive approval. Recent estimates have placed the research and development costs behind each new approved drug at nearly $2.6 billion on average. Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 31 (2016).

In view of the high cost of discovering and developing new medicines, and in order to sustain its ongoing research efforts, the pharmaceutical industry relies heavily on the legal protections that Congress has created for inventors. Many commentators have noted the critical importance of patent protection to incentivize innovation. Without a

period of patent exclusivity, "competition would force prices down to marginal production cost, and the innovator could not recover the cost of [research and development]." Patricia M. Danzon, Pharmaceutical Price Regulation: National Policies Versus Global Interests 8 (1997). Indeed, economic returns on investments in research and development are already uncertain, and average returns have fluctuated over time, showing a decline in the most recent years studied. Ernst R. Berndt et al., *Decline in Economic Returns from New Drugs Raises Questions About Sustaining Innovations*, 34(2) Health Aff. 245, 250-51 (2015).

More than in other industries, patent protection provides a critical incentive for investment in biopharmaceutical research and development. Iain Cockburn & Genia Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, 25(7) Expert Opinion on Therapeutic Pat. 739, 741 (2015). Patents, combined with existing regulatory exclusivities, remain the core approach to encouraging research and development in the biopharmaceutical industry. Henry Grabowski, Joseph DiMasi & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34(2) Health Aff. 302, 309 (2015). Innovation would likely drop substantially without the protection that U.S. patent law currently provides. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616–17 (2003); Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 853 (2002).

B. The no-foreign-exhaustion rule protects the period of patent exclusivity from encroachment by foreign patent laws or foreign pricing controls

Permitting foreign exhaustion of U.S. patent rights would impinge on the period of patent exclusivity that U.S. law provides patent-holders as an incentive for innovation. In the pharmaceutical context, as the Federal Circuit recognized in the decision below, foreign exhaustion would create "increased arbitrage opportunities" and would "upset [the] established practices" of differential pharmaceutical pricing. *Lexmark Int'l*, 816 F.3d at 772. The resulting downward pricing pressures on pharmaceutical sales in the United States would hinder pharmaceutical companies from using the patent exclusivity period to recover their research and development costs.

While Congress has recognized that giving patentees a time-limited exclusivity period promotes innovation, foreign laws and regulations do not always reflect the same levels of protection. *See Microsoft*, 550 U.S. at 455. That is particularly true with respect to pharmaceuticals. Some countries, such as India and Canada, have imposed additional patentability criteria that allow domestic manufacturers to produce generic versions of innovator drugs protected by U.S. patents without providing the innovators with a period of exclusivity to compensate them for their investments in research and development. *See* Adrienne Blanchard, *Canada's Patent 'Utility' Regime on Trial*, Macdonald-Laurier Institute IP Newsletter (May 12, 2016), https://goo.gl/DH8nPD; Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's*

Patent System and the Rise of Indian Pharmaceutical Innovation, 68 U. Pitt. L. Rev. 491, 549-65 (2007) (explaining exclusions from patentability in Indian patent law); *id.* at 582-607 (discussing compulsory patent licenses under Indian law).

The weaker patent protections in these and other countries can contribute to lower drug prices than in the United States. But those weaker patent protections also stifle innovation. Approximately 57% of new drug inventions originate in the United States, due mainly to the exclusivity period that U.S. law grants patent-holders as an incentive for innovation and the enormous investment in research and development in the United States. *See* Ross C. DeVol, Armen Bedroussian & Benjamin Yeo, Milken Inst., *The Global Biomedical Industry: Preserving U.S. Leadership* 19, 26, 34 (2011). Allowing artificially low-priced drugs from countries with weak patent protections to be imported into and resold in the United States would reduce U.S. drug revenues, drastically eroding the value of the patentee's U.S. patent rights and diminishing the incentive to innovate.

In addition, some foreign governments often choose to keep the prices of medicines artificially low within their borders by imposing price controls on the sale of patented drugs that are sold in the United States for higher prices. *See generally* Pharmaceutical Prices in the 21st Century (Zaheer-Ud-Din Babar ed., 2015). Most European governments, for example, control the pricing of at least some medicines (typically prescription drugs) either by setting prices directly or by regulation. *See* Sabine Vogler & Jaana E. Martikainen, *Pharmaceutical Pricing in Europe*, *in* Pharmaceutical Prices in the 21st Century, *supra*,

at 343, 352. In some countries, including Cyprus, Belgium, Greece, Latvia, Lithuania, and Luxembourg, state authorities set prices for all pharmaceutical products. *Id.*

As an initial matter, the rationales for patent exhaustion do not apply when foreign prices have been set by government decree. The patent-exhaustion doctrine rests on the notion that "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 … ." *United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942). As this Court observed more than 120 years ago, a patentee "[h]aving manufactured the [patented] material and sold it for a satisfactory compensation … has enjoyed all the rights secured to him by his letters patent." *Keeler v. Standard Folding-Bed Co.*, 157 U.S. 659, 661 (1895). But where prices are set not by the patentee in light of free market forces, but rather by a foreign government, the patentee has not necessarily received "satisfactory compensation" or "enjoyed all the rights secured to him by his letters patent." *Id.*; *see* Michele L. Vockrodt, *Patent Exhaustion and Foreign First Sales: An Analysis and Application of the Jazz Photo Decision*, 33 AIPLA Q.J. 189, 200 (2005). More broadly, a rule that a foreign sale automatically exhausts U.S. patent rights would effectively usurp Congress' policy judgment about the proper balance between innovation and access to medication. It would permit foreign price controls or patent policy to encroach on the U.S. market by encouraging the grey market resale of medicines originally sold in foreign countries, at prices determined by foreign governments.

A foreign-exhaustion rule would expand the grey market in the United States and reduce revenue from drug sales. In short, it would allow other governments' policies to prevent pharmaceutical companies from capturing the very incentives for innovation that Congress promised, and reducing their ability to continue to sustainably invest in research and development. The Court should not permit that result.

C. The no-foreign-exhaustion rule is critical to discovery of and access to future medicines

1. Petitioner and its *amici* do not dispute the staggering research and development costs required to bring a single new medicine to market. Nor do they contest that permitting parallel imports into the United States would result in a decline in U.S. drug revenues. Abbott Br. at 23, 32–33. Instead, they suggest that such a decline would be beneficial to U.S. consumers and people in lower-income countries. *See* Public Knowledge Br. 28; Public Citizen Br. 3; Abbott Br. 19–20.

While PhRMA shares the goal of ensuring access to existing medicines, achieving that short-term goal need not and cannot come at the expense of long-term investment in the search for cures for diseases. *Amici*'s arguments in favor of lower drug prices worldwide overlook the magnitude of research and development costs, and the reality that the few successful new drugs are far outnumbered by the compounds that fail at various stages of the research process. Pharmaceutical companies must recover all these costs—both their successful inventions and their failures—through sales in order to sustain future research efforts. As commentators have noted, parallel imports "can be beneficial to consumers in

the short run," but they "have detrimental effects on incentives to innovate in the long run." Susan J. Méndez, *Parallel Trade of Pharmaceuticals: The Danish Market for Statins* 5 (Melb. Inst., Working Paper No. 8/16, 2016).

Indeed, some commentators have estimated that, taking into account the fact that "intermediaries would likely capture a large part of the price differences," savings to U.S. payers or consumers from parallel imports would likely range from 0.2 to 2.5 percent of current drug spending—*i.e.*, a "minimal impact on aggregate U.S. health care spending." Patricia M. Danzon et al., *Commercial Importation of Prescription Drugs in the United States: Short-Run Implications*, 36 J. Health Pol., Pol'y & L. 295, 303 n.7, 314 (2011). On the other hand, "[r]evenue losses to manufacturers will significantly exceed savings to U.S. payers/consumers," such that "in the long run, U.S. consumers may be worse off due to lower investment in R&D and distortions toward import-exempt products." *Id.* at 314-15.

Amici acknowledge the likely decline in revenue as a result of parallel trade, but they speculate that pharmaceutical companies could compensate for the drop in revenue by "reallocat[ing] budgets." Abbott Br. 24. Professor Abbott even goes so far as to speculate that lowering pharmaceutical prices would actually *increase* federal government funding for drug research. Abbott Br. at 24–25. As an initial matter, the federal government plays only a limited role in discovering and developing new medicines. Between 79 and 91% of drugs are discovered solely by private sector companies. *See* Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364:6 N. Engl. J. Med.

535, 540 (2011). But more broadly, there is no basis for Professor Abbott's conjecture that federal government savings on pharmaceutical expenditures by the Veterans' Administration would somehow be passed on for pharmaceutical research by the National Institutes of Health (NIH), a different agency in a different government department.

Private industry invests far more in biopharmaceutical R&D than the federal government. PhRMA members alone invested $58.8 billion in R&D in 2015, *see supra* p.1, while the entire enacted NIH budget for FY 2015 was $30.3 billion, *see Overview of FY 2016 President's Budget*, at 3, National Institutes of Health (NIH), NIH Office of Budget, https://goo.gl/0WWj4f. At the same time, due to the nature of the grants process in life sciences, relying on NIH to fund biopharmaceutical research and development would likely lead to significantly less efficient and more conservative discovery and development of new drugs. *See* Ranjana Chakravarthy et al., *Public and Private Sector Contributions to the Research & Development of the Most Transformational Drugs of the Last 25 Years* 14 (2015).

In any event, reallocation of resources, whether by pharmaceutical companies or by the federal government, is no panacea. A rule of automatic exhaustion by foreign sale would permit foreign regulations to undermine Congress' policy judgments to encourage innovation through patent protection. Adjusting budgets does nothing to address that broader structural concern.

2. Contrary to the suggestion of certain *amici*, *see, e.g.*, Public Citizen Br. 8–13, facilitating parallel imports by adopting an automatic foreign-exhaustion rule would impede, not promote, access to drugs.

The current rule that foreign sales do not exhaust U.S. patent rights allows pharmaceutical manufacturers to independently price and distribute medicines in a socially optimal way. Differences in pricing can provide patients in lower-income countries access to important drugs, while also providing the opportunity for pharmaceutical companies to recoup their costs and continue further research and development.

As commentators have noted, differential pricing addresses "the imperfections of the global market for innovative pharmaceuticals, and it is also consistent with standard norms of equity." Zoltán Kaló, Lieven Annemans & Louis P. Garrison, *Differential Pricing of New Pharmaceuticals in Lower Income European Countries*, 13(6) Expert Rev. Pharmacoeconomics & Outcomes Res. 735, 736 (2013). Patent exhaustion from foreign sales would destabilize this system. The inevitable rise in parallel imports would undermine a pharmaceutical company's ability to set different prices in different markets. And a move away from differential pricing would "reduce the sustainability of pharmaceutical innovation by lowering pharmaceutical prices and the profitability of manufacturers in higher income countries," and at the same time "create[] barriers to the access to medicines … in lower income countries by increasing pharmaceutical prices overall." *Id.* at 738.

Faced with the prospect of automatic foreign exhaustion—and the inability to assert its patent rights against entities importing drugs first sold in other countries for lower prices—a U.S. patent holder might decide not to sell in a foreign market at all. As one academic has noted, citing an example of a drug product in France, patentholders "may ra-

tionally choose to abandon small markets that contribute minimally to global revenues rather than accept prices that would pull down the revenues that can be achieved in other, larger markets." Danzon, Pharmaceutical Price Regulation, *supra*, at 87. A rule of automatic foreign exhaustion that would permit the importation and resale of U.S.-patented goods from overseas, free and clear of U.S. patent rights, would only compound pharmaceutical manufacturers' concerns about entering foreign markets with stringent price controls or weak patent regimes that result in lower drug revenues.

D. Statutes and regulations limiting importation are insufficient to protect pharmaceutical companies' interests

Petitioner and certain *amici* suggest that other statutes or regulations can address concerns about parallel importation of patented pharmaceuticals, and thus that pharmaceutical companies' concerns about grey markets are unfounded. That is wrong.

1. Some *amici* contend that existing statutes, in particular § 381(d) of the Federal Food, Drug, and Cosmetic Act, should dispel PhRMA's concerns about parallel importation of patented pharmaceuticals. *E.g.*, Public Citizen Br. 7. Section 381(d) prohibits any person other than the original manufacturer of a drug from importing into the United States a prescription drug that was originally manufactured in the United States and then sent abroad.

There are several flaws in that contention. First, the text of the statute makes clear that it applies only to drugs manufactured in the United States, not those produced abroad. A number of PhRMA members manufacture their products outside the United

States for sale both in the United States and abroad. Section 381(d) would not protect those manufacturers from parallel importation.

Second, § 381(d) was designed for a purpose entirely separate from protecting intellectual property rights. Congress explained in enacting § 381(d) that "[l]arge amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." Prescription Drug Marketing Act of 1987 § 2, Pub. L. No. 100-293 (Apr. 22, 1988). Section 318(d) thus forms part of the FDA's regulatory scheme and is specifically intended to protect the health and safety of the American public.

Third, § 381(d) says nothing about patent rights or remedies. Unlike a U.S. patent, § 381(d) provides no private right to sue for damages, nor enhanced damages for willful patent infringement. Section 381(d) is a poor substitute for those rights. Established principles of U.S. patent law provide that if an entity attempts to exploit price differentials (whether imposed by foreign price controls or by disparate regimes of patent law and protection) by importing U.S.-patented drugs purchased abroad into the United States for resale, the patent holder has the right to bring an action for damages and equitable relief. Abandoning the longstanding rule against foreign exhaustion would deprive U.S. patent holders of their ability to protect their intellectual property and their significant investment of resources in research and development.

Fourth, § 381(d) is subject to discretionary government enforcement; it is not a mechanism for

vindicating private rights. FDA, Regulatory Procedures Manual § 9-1-2 (2017). To PhRMA's knowledge, the federal government has never brought an action under § 381(d) against a parallel importer that legitimately purchased a drug abroad and then sought to resell it in the United States. Section 381(d) cannot substitute for patentees' ability to enforce their own patent rights against infringers.

2. Even as they point to § 381(d) as the solution to the policy implications of their proposed foreign-exhaustion rule, certain *amici* appear to acknowledge that existing regulations are in fact *in*sufficient to protect pharmaceutical companies' interests. These *amici* argue that the pharmaceutical industry should seek "legislation and policy specifically aimed at trade in medicines" to address concerns about drug pricing and arbitrage. Public Knowledge Br. 29; *see also* Public Citizen Br. 7–8; IP Professors Br. 30–31.

Amici essentially are arguing that this Court should rewrite the longstanding doctrine of patent exhaustion (which, in its current form, already serves as a defense against arbitrage and parallel imports), and that the pharmaceutical industry should then lobby Congress to change the rule back for pharmaceutical companies. That makes little sense. And in any event, *amici*'s assertion that legislation and new regulations are the appropriate solution to concerns about drug pricing and parallel trade confirms that Congress is the proper forum to consider these important and complex policy questions. If *amici* or any other parties have concerns about current drug pricing practices, their remedy lies with Congress, not this Court.

IV. The United States' Position Is the Only Potentially Reasonable Alternative to the Status Quo Rule Against International Exhaustion

In its *amicus* brief, the United States recognizes that no basis exists for petitioner's proposed rule of automatic exhaustion of patent rights upon foreign sale. U.S. Br. 26–32. The United States suggests, however, that rather than affirm the longstanding rule that foreign sales do not exhaust patent rights, this Court should adopt an intermediate position, under which a foreign sale *presumptively* exhausts U.S. patent rights, unless the patentee clearly communicates its reservation of U.S. rights. U.S. Br. 33.

The United States offers little doctrinal support for its proposed rule. But the United States' position would allow the patentee to preserve its rights by "expressly communicat[ing] an express reservation" of its U.S. rights upon the first sale. U.S. Br. 33. While PhRMA strongly believes that the current rule of no international exhaustion should prevail, the U.S. position at least has the merit of preserving a patent holder's ability to protect its rights.

* * *

Congress has long recognized—in keeping with the principle enshrined in the Constitution—that strong patent protections are an essential incentive to innovation. A new rule of automatic international exhaustion of patent rights would undermine that longstanding congressional policy. It would open the doors to parallel imports of U.S.-patented products, thereby imposing foreign pricing decisions on U.S. markets. This Court should decline petitioner's invitation to rewrite settled principles of patent law.

CONCLUSION

This Court should affirm the judgment below.

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