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 OF AMICI CURIAE BIOTECHNOLOGY INNOVATION ORGANIZATION AND CROPLIFE INTERNATIONAL IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE[1]

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry in all fifty states and abroad. BIO has more than 1,100 members, including businesses, biotechnology centers, and academic institutions. BIO members undertake research and development of biotechnological health care, agricultural, environmental, and industrial products, including life-saving drugs. BIO's members range from Fortune 500 companies to research universities and small start-up companies. The majority of BIO's corporate members are development-stage companies that have yet to bring their first commercial product to market.

CropLife International ("CropLife") is a global federation representing the plant science industry as well as a network of regional and national associations in ninety-one countries. CropLife's member companies include BASF, Bayer CropScience, Dow AgroSciences, DuPont-Pioneer, FMC, Monsanto, Sumitomo, and Syngenta. These companies are committed to sustainable agriculture through innovative research and development in the areas of crop protection, pest control, and seed and

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[1] No counsel for a party authored this brief in whole or in part, and no monetary contribution to the preparation or submission of this brief was made by anyone other than the amici curiae or their counsel. Respondent has granted a blanket consent to the filing of amicus briefs. Petitioner's consent is being lodged with the Clerk of the Court concurrently with this brief.

plant technologies. CropLife's members develop innovative products such as seeds and plants that, unlike any found in nature, have been bioengineered or bred to have one or more novel properties. These innovations increase yields and decrease the use of pesticides, herbicides, water, and nutrients, thus benefitting the environment, farmers, and the public.

BIO and CropLife members have a substantial interest in the patent exhaustion questions before the Court in this case. They invest vast resources to develop breakthrough products that will improve public health and welfare, including novel antibody therapeutics, seeds and plants with novel traits, industrial enzymes, and advances in personalized medicine for use in the United States and abroad. To ensure broad dissemination of innovative biotechnology products, these innovator companies rely on the ability to license and price their products based on the relevant market and/or intended use—along with the corresponding ability to enforce their intellectual property rights against unauthorized use.

BIO and CropLife members have relied on longstanding patent exhaustion doctrine to structure their businesses—from investment in research and development to sales of their products and ultimately to their investment in future innovation. The current territorial application of the patent exhaustion doctrine supports this innovation cycle, for the benefit of the U.S. economy and the public. It has assured U.S. patent owners that patented products will reach consumers, patients, and farmers in the foreign markets for which these goods are intended and for which they are appropriately priced. At the same

time, the patent exhaustion doctrine prevents goods intended for foreign markets from being imported into the United States and disseminated to the domestic market through unauthorized distributors in competition with the patent owner's own domestic sales. The result is broader public access to products at prices that foreign markets can afford without undermining the patent owner's ability to accurately gauge demand for, and supply of, its patented products in the domestic market and to recoup a proportional share of its investment in that market. Likewise, the conditional sale doctrine allows the value of the patented invention to be maximized for the public good, encouraging further innovation, development, and use of the product, while allowing the patent owner to obtain a commensurate return on its investment in the invention.

SUMMARY OF ARGUMENT

The Court faces two important and wholly distinct questions directed to longstanding principles of patent exhaustion. The Federal Circuit's en banc opinion below joined by ten members of that court, reaffirmed the delicate balance struck between a patent owner's ability to protect and enforce its patent rights and the public's interest in access to patented inventions, including for improvements and further innovation. *Lexmark International, Inc. v. Impression Products*, 816 F.3d 721 (Fed. Cir. 2016).

The decision below affirming the Federal Circuit's prior holding in *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), is supported by century-old Supreme

Court precedent confirming the territoriality of the U.S. patent system and furthering important public policy. Contrary to Petitioner's argument, nothing in *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2013), counsels for a change in the territorial limitation of patent exhaustion. *Kirtsaeng* concerned interpretation of the Copyright Act and has little import for the judicially-created doctrine of patent exhaustion. Key differences between copyright law and patent law diminish *Kirtsaeng*'s applicability. Among other things, copyright law is far more uniform globally than patent law, such that U.S. patent owners face considerably more uncertainty in protecting their innovations outside the United States than do copyright holders.

The territorial limitation on patent exhaustion advances public policy and economic efficiency. It permits innovators to sell patented products internationally at locally-driven market prices. The ability to deploy regional pricing internationally encourages innovators to maximize the distribution of important biotechnology products, including life-saving therapies and innovative bioagricultural products, in developing countries. In addition, regional pricing is commercially and socially efficient: market-specific prices account for factors such as the relative value of intellectual property rights in different markets, local demand, wealth distribution, price regulation, local manufacturing requirements, compulsory licensing practices, and special imposts and tariffs.

Not only is the current exhaustion regime beneficial to the public, it also helps the U.S. economy

and creates jobs for American workers. As a matter of public policy, the current regime favors domestic exporters over importers of foreign-made products. If U.S. patent owners were to lose control of their U.S. patent rights by selling abroad, the economic incentives would favor importers of foreign goods over U.S. manufacturers. Congress has had many opportunities in recent years to review and amend the patent laws, but it has chosen not to alter the territorial limitation of this enduring doctrine of patent law. Indeed, upending this tenet would harm innovative companies and the benefits of innovation enjoyed by the public, rewarding resellers and importers who seek to profit from arbitrage.

The Federal Circuit's decision below affirming its prior holding in *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992) also remains good law: conditional sales of patented products do not exhaust patent rights. In *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), this Court declined to modify the Federal Circuit's holding in *Mallinckrodt*. That is not surprising. *Mallinckrodt* rests on longstanding precedent recognizing the right of a patent owner to convey only a portion of the patent right without giving away the rest. The Court should reaffirm this precedent, on which industry members have relied for decades to structure their businesses and to establish the value of rights and products they convey through licenses and sales contracts. *See Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2409-10 (2015).

Conditional sales are important to the biotechnology industry. They are an integral part of

bioagricultural and agrichemical companies' product stewardship programs. These stewardship programs impose conditions of use on products such as seed, herbicides, and insecticides that are intended to protect the health of farmers and the environment.

Conditional sales also permit buyers and sellers of a patented product to negotiate use of a portion of the patent right at a corresponding price reflecting the buyer's intended specific use. Under current law, for example, biotechnology companies have an incentive to provide patented products, subject to research-only use restrictions, at a price lower than that of a commercial-use sale in order to further basic research and innovation. If the materials are thereafter conveyed to others who lack privity with the patent owner and who use them for commercial purposes, the patent owner can invoke patent law to enjoin or to seek fair compensation for unauthorized uses beyond the scope of the conditional sale. Without the ability to attach appropriately-priced conditions to the sale of a patented product, those products could be offered only at uniform, higher prices, effectively eliminating access for limited commercial uses (e.g., veterinary use), diagnostic uses, or purely non-commercial, research uses—including by universities and other research institutions.

Mallinckrodt has stood the test of time, and BIO and CropLife members have relied on its doctrine in structuring their businesses. Petitioner's dire public policy predictions cannot be reconciled with reality: companies have thrived under the current regime for decades while the public has enjoyed

enormous benefits from the resulting innovation. Far from Petitioner's parade of horribles, restricted domestic sales benefit the industry, the public, and the U.S. economy as a whole.

BIO and CropLife members have long relied on both doctrines to plan their research and development efforts, determine market prices of their patented products, negotiate sales of those products, and reinvest for further innovation. Given the importance of these doctrines and the public policy considerations underlying them, this Court should affirm the holding below.

ARGUMENT

I. International Sales Should Not Exhaust Patent Rights.

A. This Court should not alter over a century of precedent recognizing the territorial limits of U.S. patent law.

For over 150 years, this Court has held that our patent laws "do not, and were not intended to, operate beyond the limits of the United States." *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 195 (1857); *see also Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 441 (2007) ("It is the general rule under United States patent law that no infringement occurs when a patented product is made and sold in another country."); *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972) ("Our patent system makes no claim to extraterritorial effect."). This territoriality principle is a pillar of U.S. patent law.

The Federal Circuit's decision below rests on more than a century of Supreme Court precedent, including *Boesch v. Graff,* 133 U.S. 697, 701-3 (1890). *Lexmark*, 816 F.3d at 763-65. In *Boesch*, a third party made and sold certain patented burners in Germany, and was permitted to do so under German law because he had made preparations to manufacture the burners prior to the application for the German patent. 133 U.S. at 701. This Court held that "a dealer residing in the United States" could not purchase the patented products from the third party residing in Germany and "import them to and sell them in the United States, without the license or consent of the owners of the United States patent." *Id.* at 702. In reaching this conclusion, the Court explained that although the sale might be authorized under German law, it did not permit "defiance of the rights of patentees under a United States patent." *Id.* at 703.

Five years after deciding *Boesch*, this Court recognized and affirmed its core exhaustion holding: domestic sales of patented products "cannot be controlled by foreign laws," and there can be no exhaustion where "neither the patentee or any assignee had ever received any royalty or given any license to use the patented article in any part of the United States." *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 664-66 (1895).

In connection with their investment in research and development to bring new products to market, BIO and CropLife members, as owners of U.S. patents, have long relied on the settled

expectation that they would not lose their U.S. patent rights simply by virtue of having made a sale abroad.

B. The *Kirtsaeng* exhaustion holding is limited to copyright law.

Nothing in this Court's analysis of the Copyright Act in *Kirtsaeng* upset the judicially-created doctrine governing international patent exhaustion. *Kirtsaeng* interprets only the statutory language that appears in the Copyright Act's first-sale provision. In this provision, 17 U.S.C. § 109(a), Congress expressly permitted "the owner of a particular copy or phonorecord lawfully made under this title ... without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord." The critical question in *Kirtsaeng* was whether the scope of section 109(a) was limited geographically; in other words, whether section 109(a) conferred rights on the owner of a copy only if that copy was manufactured in the United States or regardless of where it was manufactured, so long as the copy was made with the permission of the copyright owner. 133 S. Ct. at 1355. To conclude that the Copyright Act's first-sale provision was not limited to a first domestic sale, the Court closely examined the statutory language and history of section 109(a). Given its focus on the language of the Copyright Act, the *Kirtsaeng* analysis has no application here. There simply is no counterpart to section 109(a) in the patent laws. Title 35 does not confer rights on the purchaser of a patented article; it only confers upon the patent owner the right to exclude others from making, using, selling or importing the patented invention. 35 U.S.C. § 271(a).

Moreover, this Court has long recognized that patent law and copyright law are fundamentally distinct. As explained in *Bobbs-Merrill Co. v. Straus*, 210 U.S. 339 (1908), when the Supreme Court first applied the first-sale doctrine in the copyright context, "there are differences between the patent and copyright statutes in the extent of the protection granted by them." *Id.* at 345. "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). Because patent law protects a patented invention however it is embodied, it makes sense that this Court did not make any reference to patent law in *Kirtsaeng*, nor did it even suggest that its interpretation of the Copyright Act could apply more broadly to patents. Indeed, the policy concerns analyzed by the *Kirtsaeng* Court were challenges particular to copyright law faced by museums, libraries, and book retailers. 133 S. Ct. at 1364-67.

By contrast, the courts—not Congress—created and defined the patent exhaustion doctrine. *E.g.*, *Helferich Patent Licensing, LLC v. N.Y. Times Co.*, 778 F.3d 1293, 1305 (Fed. Cir. 2015) ("Patent exhaustion is a judicially fashioned doctrine without a specific source in congressionally enacted text stating the terms of this limitation on patent rights."). Congress recently implemented far-reaching changes to the patent laws through the Leahy-Smith America Invents Act. In so doing, Congress could have altered the judicially-created patent exhaustion doctrine by codifying a patent provision parallel to section 109(a) of the Copyright Act. It did not.

Eliminating the territorial limitation on patent exhaustion would be a very significant U.S. policy change—much more so than the *Kirtsaeng* decision—because copyright law is far more uniform globally than patent law. Under the Berne Convention for the Protection of Literary and Artistic Works, international copyright protection is nearly automatic for copyrighted subject matter. Works originating in other member countries must be given the same treatment as those works by their nationals. Art. 3-4, Sept. 9, 1886, *as revised at Paris* July 24, 1971 *and as amended* Sept. 28, 1979, 102 Stat. 2853, 1161 U.N.T.S. 3. By contrast, there is considerably less global uniformity in international patent laws, and therefore much greater risk to U.S. innovators, as the Federal Circuit below recognized in *Lexmark.* 816 F.3d at 765 (stating that "foreign markets are not the predictable equivalent of the American markets in which the U.S. patentee is given a right to exclude and the rewards from that exclusivity."). Under the Paris Convention for the Protection of Industrial Property, patents granted in different territories for the same invention are independent of one another. Art. 4bis, Mar. 4, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305. Indeed, a single patent application filed under the Patent Cooperation Treaty ("PCT") can result in different, independently-granted patents in up to 151 PCT member countries—with varying scope of patent protection. In view of the lack of reciprocity among signatory countries, this Court should not unilaterally discard the long-established U.S. doctrine with respect to international patent exhaustion.

As the en banc Federal Circuit correctly recognized below, it is particularly important to recognize the territorial nature of U.S. patent laws, as compared to copyright laws, because patent laws vary significantly from country to country. *Lexmark*, 816 F.3d at 765 ("Patent law is especially territorial, and laws vary considerably from country to country."). In other words, patent protection for a given product likely varies by country in terms of scope, term, and enforceability. For this reason, Petitioner's argument that the current regime somehow enables patent owners to obtain "multiple rewards" for the same product (once for a foreign sale, and again upon importation into the United States) is wrong. Pet'r Br. at 13-15.

C. Territorial limitations on patent exhaustion facilitate regional pricing and benefit the public.

Patent owners, including BIO and CropLife members, have relied on the territorial limit on patent exhaustion when establishing their presence, cost structure, distribution network, and pricing in international markets. Territorial limits on exhaustion allow patent owners to determine efficient prices in individual countries based on the local demand, income, and need, thereby maximizing the reach of life-saving biomedical and agricultural products, especially in developing countries. Foreign markets often differ significantly from the United States with respect to the availability, scope, and enforceability of patent rights for biotechnology inventions. As a result, a patent in a foreign country based on the same underlying disclosure may be

worth much less than a U.S. patent, or a patent may not be available at all.

If the foreign sale were to trigger patent exhaustion in the United States, then the price of the patented good abroad would have to reflect the value of U.S. patent rights that would be conveyed with the foreign sale. This proposition is not only illogical, but also unfair to foreign consumers (who would object to paying for rights they do not need or want) and to patent owners (who realistically may not be able to command such a price in the foreign market). Regional pricing encourages companies to make the large and risky investments needed to develop new pharmacological, agricultural, and medical products by permitting optimal market penetration and a reasonable return on investment. The public, in turn, benefits from the development and availability of these life-changing products.

1. The current exhaustion regime permits patent owners to use regional pricing thereby benefiting the public.

The territorial limitation on patent exhaustion allows patent owners to establish regional prices based on local conditions and reach customers who could not or would not purchase the products at a higher price. *See* Jacob Arfwedson, *Re-Importation (Parallel Trade) in Pharmaceuticals*, Inst. for Policy Innovation: Policy Report 182, at 3 (July 2004). For example, in 2000, BIO member GlaxoSmithKline ("GSK") reduced the price of its AIDS drug Combivir to $3/day in developing counties, even though the

drug costs $11/day in Canada and $25/day in the United States. Scott Gottlieb, *Companies reduce prices for HIV drugs in developing countries*, 78 Bull. World Health Org. 862, 862 (2000). Three years later, GSK again reduced the price to 90 cents/day. Reed Abelson, *Glaxo Will Further Cut Prices of AIDS Drugs to Poor Nations*, N.Y. Times, Apr. 28, 2003.

Regional pricing encourages BIO and CropLife members to invest in research and development of new innovative products by permitting optimal market penetration and pricing, helping them to recoup their investment. *See* Arfwedson, *supra*, at 3. The biotechnology industry faces surging research and development costs. It takes an average of 15 years and $2.6 billion to develop and bring a new biological medicine to market. *See Drug Development Costs Rise Dramatically, Now Nearly $2.6 Billion Medicine*, Biotechnology Indus. Org. (Nov. 18, 2014), https://www.bio.org/media/press-release/drug-development-costs-rise-dramatically-now-nearly-26-billion-medicine. These costs have more than doubled in the past fifteen years. *Id.* A new plant biotechnology trait introduced between 2008 and 2012 cost approximately $136 million to develop and took 13.1 years to launch commercially. Phillips McDougall, *The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait* (Sept. 2011), https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf. In short, such innovation is an expensive, high-risk endeavor. Regional pricing gives companies greater confidence that their initial investments will be recouped when a product finally

reaches consumers. *See* Kyle Poplin, *How Price Discrimination is Good for Global Health*, NextBillion (Sept. 17, 2014), http://nextbillion.net/blogpost.aspx?blogid=4069.

Regional pricing also permits BIO and CropLife members to respond to public health needs in economically-depressed regions by providing life-saving medicine and medical technology at or close to cost, while preserving the ability to assert patent rights against third parties who attempt to resell the low-cost products in other countries. Out of 36.7 million people living with HIV worldwide, over 50% live in sub-Saharan Africa. *UNAIDS Fact Sheet*, UNAIDS (Dec. 1, 2016), http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf. The majority receive antiretroviral treatment. *Id.* The pharmaceutical industry has made lifesaving medications available at deeply discounted prices based on each country's ability to pay. *See generally* Colleen V. Chien, *HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?* 3 PLOS One 1 (2007). The resulting increase in access to antiretroviral treatment has prevented at least 7 million new HIV infections between 1995 and 2015 and averted at least 9 million AIDS deaths. *See, e.g.*, President's Emergency Plan For AIDS Relief, *Congressional Budget Justification Supplement*, PEPFAR.gov (2016), https://www.pepfar.gov/documents/organization/241600.pdf.

Many BIO and CropLife members engage in such "equitable pricing strategies." For example, Johnson & Johnson's Global Access & Partnerships Program provides many of its products to developing

countries through low, not-for-profit pricing. *See Pricing Strategies & Programs*, Johnson & Johnson, http://www.jnj.com/caring/citizenship-sustainability/strategic-framework/pricing-strategies-and-programs (last visited Feb. 7, 2017). Other members employ similar equitable not-for-profit pricing. *See 2016 Access to Medicine Overall Ranking*, Access to Medicine Index, http://accesstomedicineindex.org/overall-ranking/ (last visited Feb. 22, 2017) (listing BIO members AbbVie, Novo Nordisk, and Johnson & Johnson among top ten leading companies practicing equitable pricing).

The ability to enforce regional pricing through patent law has special significance in the biotechnology industry which, by the very nature of its products, cannot design a product operable only in a given country or region. By contrast, the high-tech industry can more easily manufacture products for specific geographic markets. For example, companies make mobile phones that operate only in Europe, deterring resale in the United States. *See* Andy Boxal, *Samsung region-locks its Galaxy smartphones*, Digital Trends (Sept. 27, 2013), http://www.digitaltrends.com/mobile/samsung-region-locked-galaxy-smartphones/. Similarly, software routinely can be designed to operate only in specific countries. *See* Ryan Vinelli, *Bringing Down the Walls: How Technology Is Being Used to Thwart Parallel Importers Amid the International Confusion Concerning Exhaustion of Rights,* 17 Cardozo J. of Int'l & Comp. Law 102, 104 (2009). Because biotechnology companies are unlikely to be able to alter therapeutic medicines or seeds with novel traits

to limit their utility to particular markets, patent law is critical to enable effective regional pricing.

2. Eliminating the territorial limits on patent exhaustion would have negative consequences especially for less affluent foreign markets.

If this Court were to upend the current exhaustion regime, it would jeopardize the benefits of regional pricing by enabling arbitrage and the diversion of patented products from less-affluent markets into the United States. Any benefits to U.S. consumers would likely accrue at the expense of poorer consumers elsewhere. "[T]he consensus among scholars of IP law and economics is that a U.S. rule of international patent exhaustion would lead to higher prices for patented products in lower-income countries…." Daniel J. Hemel & Lisa Larrimore Ouellette, *Trade and Tradeoffs: The Case of International Patent Exhaustion*, 116 Colum. Law Rev. 17, 26 (2016).[2] Indeed, the Court in *Kirtsaeng* observed that imposing international exhaustion would "make it difficult, perhaps impossible" to sell products at different prices in different countries. 133 S. Ct. at 1370.

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[2] Even Amicus Curiae Public Citizen acknowledges that international patent exhaustion would trigger the need for extensive, complicated, and nuanced remedial legislation, and the enforcement of case-by-case import and export controls to avoid detrimental effects on patients in the developing world. Br. of Amicus Curiae Public Citizen, Inc. at 12-13.

Overturning *Jazz Photo* would also make it more difficult for companies to engage in non-price-related programs in developing countries designed to increase patient access, such as non-assert agreements with generic drug makers. Through these agreements, companies agree not to enforce their patents in certain countries, giving local generic manufacturers free rein to sell inexpensive copies of a patented drug. In 2012, Johnson & Johnson agreed not to assert one of its HIV/AIDS drug patents in sub-Saharan Africa and other least-developed countries as part of its equitable pricing strategies. Ben Hirschler, *J&J Says It Won't Enforce AIDS Drug Patent in Africa,* Reuters (Nov. 29, 2012), http://www.reuters.com/article/2012/11/29/aids-jj-africa-idUSL5E8MTAP820121129. Overturning *Jazz Photo* would open the door for third parties to export and resell low-priced drugs outside of the region in need, undermining the public health benefits of these programs. GSK, for instance, lost over $18 million in sales when its AIDS drugs intended for sale in African countries were illegally resold in Europe. Gregory Crouch, *Europeans Investigate Resale of AIDS Drugs*, N.Y. Times, Oct. 29, 2002. Under the governing regime outlined in *Jazz Photo*, companies are able to enforce their U.S. patent rights by suing such resellers for patent infringement. Not so if the Court upends the current exhaustion rule.

The public harm is not mere speculation—it occurred in the copyright context after *Kirtsaeng.* Within one year after the decision, Wiley & Sons stopped selling its books in many emerging markets and increased prices in others. *First Sale Under Title 17: Hearing Before the Subcomm. on Courts,*

Intellectual Property, and the Internet of the H. Comm. on the Judiciary, 113th Cong. 6-18 (2014) (testimony of Stephen M. Smith, President and CEO, John Wiley & Sons, Inc.). The General Counsel for the Software and Information Industry Association stated, "[Publishers] have chosen to raise their prices to eliminate the profit of gray market importation…. [T]he [*Kirtsaeng*] decision has really resulted in everyone losing…. At the end of the day, that means fewer works will be created [and] the works will be updated less frequently." Anandashankar Mazumdar, Aereo, *Fallout From* Kirtsaeng, *Legislative Action Among Key Copyright Issues In 2014*, Patent, Trademark & Copyright J., Jan. 24, 2014, at 2.

The detrimental impact would be even greater in the biotechnology space, where the development costs are drastically higher and the duration of IP protection is much shorter. Copyright holders have a lifetime plus 70 years to recoup much smaller development costs, while patent owners have less than 20 years, much of which may have elapsed by the time the biotechnology product is approved for marketing. 17 U.S.C. §§ 302-5 (duration of copyrights); 35 U.S.C. § 154 (duration of patents); Hui-Hsing Wong et al., *Examination of Clinical Trial Costs and Barriers for Drug Development* 1-2 (July 25, 2014), https://aspe.hhs.gov/pdf-report/examination-clinical-trial-costs-and-barriers-drug-development. And, unlike copyright, where protection exists from the moment of creation, patent

protection can be obtained only through a long, costly application and prosecution process.[3]

3. Territorial limits on exhaustion serve additional public policy goals.

There are also important public health and safety reasons, which are not present in the copyright context, for BIO and CropLife members to monitor and control importation and resale of their products. Biopharmaceuticals and other biomedical products and services are highly regulated by each country. *See* David Vogel, *The Globalization of Pharmaceutical Regulation*, 11 Governance 1, 1-2 (1998). Each regulatory agency must review and approve almost every aspect of the product, including approved indications, dosage, shipment and storage conditions, lifespan, warnings, advertising, and packaging. *Id.* Labels may vary country by country; unauthorized importation and resale of products initially sold in a foreign country undermine the manufacturer's ability to ensure compliance, putting the safety of downstream purchasers at risk. Transgenic crops and bioagriculture products are also heavily

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[3] The USPTO reports that the average patent prosecution from filing to issuance or abandonment consumes 25.3 months. USPTO, *Performance and Accountability Report 2016* 178 https://www.uspto.gov/sites/default/files/documents/USPTOFY16PAR.pdf. Typical charges for preparing and filing an original application range from $7,622 to $11,944. Am. Intellectual Prop. Law Ass'n., *Report of the Economic Survey* I-90-91 (2015).

regulated. *See Agricultural Biotechnology*, U.S. Dep't of Agric., http://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH (last visited Feb. 7, 2017).

Because of the public and private benefits that come from a manufacturer's ability to control resale in another country through the patent system, the longstanding industry expectation is that U.S. patent rights are not conveyed as part of a foreign sale unless there is an express and affirmative grant of such rights. Adopting Petitioner's position here would force patent owners to alter their sales and licensing practices around the world, introducing needless and economically inefficient complications into each and every transaction.

Nor should this Court adopt the position of the Government, which also seeks to change the current regime in a way that provides no added benefit to anyone. U.S. Br. at 32-34. The Government contends that international sales should presumptively exhaust domestic patent rights unless the patentee makes an "express reservation" of U.S. patent rights. *Id.* This approach makes little practical sense. First, it confounds the statutory scheme, which grants to the patentee an unconditional right to exclude others from importing the patented invention. 35 U.S.C. §§ 154(a), 271(a). Second, it raises the transaction costs for U.S. patent holders by forcing them to make an "express reservation," and for foreign market participants by forcing them to ascertain the rights that were "reserved" in the licenses under which these products were first sold in the foreign market. Third, it creates uncertainty and raises the costs of the

inevitable litigation over whether the patent holder's reservation of rights was sufficiently clear or otherwise effective under foreign contract law. Finally, the Government offers no reason why, under its proposed new rule, a patent owner would not be well advised always to reserve its rights, knowing that it could not foresee every scenario in which its products may be sold downstream. The effect would be to create a trap for the unwary, and penalize small businesses who cannot afford sophisticated legal counsel to advise them of a change in longstanding doctrine.

4. Contract law does not provide an adequate substitute for regional pricing enforcement.

Contract law does not provide an adequate substitute for using the patent system to enable regional pricing. Requiring biotechnology companies to enter into elaborate contracts with every purchaser of, for example, a $100 vial of biological material, is inefficient and burdensome for both sellers and purchasers. Moreover, patent owners could enforce such contracts only against initial purchasers, not subsequent resellers, because patent owners would lack privity of contract with the latter. Such a system would invite gamesmanship by downstream resellers. In addition, the enforcement of sales contracts against initial purchasers could be subject to many different foreign laws, creating uncertainty and inefficiency. U.S. patent law, by contrast, permits the patent owner to pursue adequate remedies in federal courts or the International Trade Commission against aggregators and resellers who import the patented

products, regardless of the product's chain of custody. *See* 35 U.S.C. §§ 281, 283-84; 19 U.S.C. § 1337.

What is more, confining patent owners to actions for breach of contract would force them to bring multiple actions in multiple jurisdictions across the globe, because the initial purchasers of patented biotechnology products represent a wide and diverse group of customers, including small institutions. Not only do biotechnology companies have no desire to sue their customers, requiring them to do so would be costly and highly inefficient. It would waste judicial resources and unnecessarily target consumers and small businesses to account for the actions of subsequent resellers, who are the true cause of the harm. *See generally FACT SHEET: White House Task Force on High-Tech Patent Issues*, The White House (June 4, 2014) ("End-users should not be subject to lawsuits….").

D. Adopting an international exhaustion rule would be harmful to the domestic economy.

Petitioner's argument that the current law harms the domestic economy is mistaken. Br. at 55-58. On the contrary, protecting U.S. patent rights benefits American innovators like BIO and CropLife member companies, as well as consumers. As discussed above, the current regime is economically efficient, allowing companies to engage in regional pricing tailored to country-specific markets and needs. It does not raise prices for consumers. In fact, the perverse result of *Kirtsaeng* was to raise prices for consumers globally. *See* Mazumdar, *supra*.

The biotechnology industry represents an important, and ever-growing, part of the U.S. economy. In fact, biotech revenue growth was reported to be the equivalent of 5% of the annual U.S. gross domestic product growth for each year from 2007 to 2012. Robert Carlson, *Estimating the biotechnology sector's contribution to the US economy*, 34 Nature Biotechnology 246, 247 (2016).

The current territorial limits on patent exhaustion benefit domestic industries, including the biotechnology industry, and their workers. Most of BIO and CropLife's member companies—and in the case of bioagricultural companies, some of their customers—are exporters. For example, BIO and CropLife's bioagricultural companies sell planting seed to growers, a portion of whom sell the resulting crop for export. The United States is the world's largest producer and exporter of corn and soybeans. *Corn*, USDA Economic Research Service (Feb. 14, 2017), https://www.ers.usda.gov/topics/crops/corn/trade/; *Soybean & Oil Crops*, USDA Economic Research Service (Oct. 12, 2016), https://www.ers.usda.gov/topics/crops/soybeans-oil-crops/trade. An average of nearly 51 million metric tons of corn and corn products were exported each year between 2014 and 2016. The export numbers for soybeans and soybean products are even higher, with an average of over 63 million metric tons exported each of the calendars years 2014-2016.[4]

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[4] Data from Global Trade Atlas, a global import/export commodity trade database (https://www.gtis.com/gta/).

If the Court were to undo the current regime and adopt the international exhaustion rule, it would shift the economic incentives from American exporters to importers, including those that engage in arbitrage. This result would be harmful to domestic economic growth, including the American workers employed by these domestic manufacturers. *See* Brett Shanks, *The First Sale Doctrine and Unauthorized Imports: Feeding an Out-of-Control Gray Market*, 53 Washburn L.J. 119, 135-36 (2013).

Indeed, the brief filed by Amici Intel Corp. et al. only serves to underscore how a shift to an international exhaustion rule would provide a windfall to importers that source and manufacture their products outside the United States—to the detriment of U.S.-based manufacturers and their domestic employees who produce goods for foreign markets. Amici Intel Corp. et al. seek enhanced protection for an international supply chain of foreign manufactured components, describing how Intel's supply chain "comprises more than 16,000 suppliers in over 100 countries" and iPhones use components from over 30 countries. Intel Br. at 7. In sum, this Court should reject the arguments by Petitioner and its amici suggesting that reversal of the Federal Circuit's precedent in favor of international patent exhaustion would be good for the U.S. economy.[5]

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[5] Likewise, Petitioner and its amici incorrectly suggest that there would be a significant economic benefit arising from the purported savings in licensing and other transactional costs under an international exhaustion rule. *See, e.g.*, Intel Br. at 10-14. However, the brief filed by Intel Corp. et al. shows how

II. Restricted Domestic Sales Do Not Exhaust Patent Rights.

A. *Mallinckrodt*'s holding is consistent with longstanding Supreme Court precedent on conditional sales.

The holding of *Mallinckrodt* is built on the foundational principle of patent law, reaffirmed by over a century of Supreme Court decisions, that a patent confers upon its owner a "bundle" of distinct and separable rights, which the owner can separately transfer through restricted licenses and conditional sales. *See, e.g.*, 35 U.S.C. § 154(a)(1) (patent owner has "the right to exclude others from making, using, offering for sale, ***or*** selling the invention") (emphasis added); *Virtue v. Creamery Package Mfg. Co.*, 227 U.S. 8, 32 (1913) ("The owner of a patent has exclusive rights, rights of making, using and selling. He may keep them or transfer them to another—keep some of them and transfer others. This is elementary."); *see*

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these licensing agreements are already in place for complex, multi-component devices. *Id.* at 11. This is not surprising: large companies like Intel and Apple have the market power to negotiate worldwide licenses from their suppliers. A rule of international patent exhaustion would still require large-scale importers to do their diligence because they will still have to ascertain the scope of the initial patent grant and whether that sale was in fact authorized. Hemel & Ouellette, *supra*, at 22; *see also* Intel Br. at 17 n.5 (stating that a smartphone could practice 250,000 patents). As a result, international patent exhaustion would not eliminate transaction and associated information costs, contrary to the arguments of Petitioner and its amici.

also Adams v. Burke, 84 U.S. (17 Wall.) 453, 456 (1873) ("The right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee."); *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) (same).

Consistent with this core principle, this Court has long recognized that a patent owner may grant a license for a restricted use. In *United States v. General Electric Company*, 272 U.S. 476 (1926), this Court stated that a patent owner is entitled to grant a license "upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure." *Id.* at 489. The Court also recognized the validity of conditional sales by patent owners over a century ago in *Mitchell v. Hawley*, 83 U.S. (16 Wall.) 544 (1873), which involved an infringement suit brought by a patent owner's assignee against a subsequent purchaser. There, the Court stated that patent rights are exhausted only when the patent owner "has himself constructed a machine and sold it *without any conditions*, or authorized another to construct, sell, and deliver it ... *without any conditions*." *Id.* at 547 (emphases added); *see also Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 663 (1895) (same). *Mitchell* established that a patent owner may enforce restrictions on the post-sale use of a patented article through an infringement action.

The Court reaffirmed the principles of *Mitchell* in the context of restricted licenses in *General Talking Pictures Corp. v. Western Electric Co.*, 304 U.S. 175 (1938), *opinion on reh'g*, 305 U.S. 124 (1938). There,

the patent owners granted a license to the American Transformer Company to make and sell amplifiers for certain specified non-commercial uses. American Transformer Company sold amplifiers to General Talking Pictures, who used the amplifiers in movie theaters in violation of the restricted license. The Court held that General Talking Pictures was liable for infringement "because it ha[d] used the invention without license to do so." 305 U.S. at 127. Importantly, the patent owners had no direct relationship with General Talking Pictures, and certainly no contractual relationship. The patent owners could nonetheless seek redress from General Talking Pictures because its use of the invention exceeded the limited license the patent owners conferred on the seller.[6]

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[6] Petitioner and the Government put forward an absurd reading of *General Talking Pictures*. Pet'r Br. at 39-41; U.S. Br. at 19-22. Under their reading, a patent owner who gives a limited license to a third party to make and sell the patented product can *only* sue a purchaser for infringement if the licensee exceeds its authority and does not inform the purchaser of the license limitations. If the patentee sells the product directly to the purchaser under a restricted sale, or the purchaser buys the product from the licensee who properly informs the purchaser of the license limitations, Petitioner and the Government take the position that, if the purchaser knowingly disregards the limitations, then the patent owner has no recourse against the purchaser under patent law. Thus, the innocent purchaser that buys the product from a devious licensee can be liable for infringement, but the flagrant purchaser that knowingly violates the terms of purchase communicated either directly from the patent owner or the licensee cannot be liable for patent

The Federal Circuit's decision in *Mallinckrodt* built on fundamental principles spanning over a hundred years of Supreme Court precedent and held that unless a conditional sale "violate[d] some other law or policy ... private parties retain the freedom to contract concerning conditions of sale." 976 F.2d 700, 708 (Fed. Cir. 1992). *Mallinckrodt* involved a "single-use only" restriction on a patented medical device sold to a hospital, which in turn sold the device to the defendant for refurbishing, leading to a patent infringement action against the defendant. *Id.* at 701, 709. *Mallinckrodt* recognized this Court's clear precedent that the patent owner's right to exclude permits it to convey only part of its bundle of patent rights by restricting the sale—without giving rise to exhaustion. The Federal Circuit correctly held in *Mallinckrodt* that the appropriate inquiry is whether the patent owner's "restriction is reasonably within the patent grant, or whether the patentee has ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason." *Id.* at 708.

B. *Quanta* did not overrule *Mallinckrodt*.

Nothing in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), altered the patent owner's well-established right to impose conditions on a sale without exhausting its patent rights. When the Court decided *Quanta*, it received extensive briefing from amici, including the

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infringement. *General Talking Pictures* does not stand for such an absurd rule of law.

Government, urging it to address the first-sale doctrine in light of *Mallinckrodt*. *See, e.g.*, U.S. Amicus Br. at 18-24, *Quanta* (No. 06-937).

Instead of addressing *Mallinckrodt* and conditional sales, the Court held that because LGE's license agreement permitted Intel to make and sell microprocessors and chipsets and sell those products to Quanta without restrictions, Intel's subsequent sales to Quanta were authorized, and LGE's patent rights therefore were exhausted. *See, e.g.*, *Quanta*, 553 U.S. at 637 ("The License Agreement authorized Intel to sell products that practiced the LGE Patents. No conditions limited Intel's authority to sell products substantially embodying the patents."); *id.* at 638 ("Nothing in the License Agreement limited Intel's ability to sell its products practicing the LGE Patents."). Importantly, the Court left untouched the holding in *Mallinckrodt* that a patent owner may enforce conditions on a sale through actions for patent infringement, so long as the conditions are not anticompetitive. Those facts simply were not before the Court in *Quanta*: a licensee was selling products, not the patent owner, and there were no restrictions on the licensee's ability to sell licensed products.

This Court did not overrule *Mallinckrodt*, or the precedent supporting it, *sub silentio*, as Petitioner argues. *Mallinckrodt* is grounded in sound Supreme Court law permitting the enforcement of post-sale use restrictions. *E.g.*, *Gen. Talking Pictures*, 305 U.S. at 126-27. This Court was well aware of its precedent at the time it decided *Quanta*, and it understandably left *Mallinckrodt* intact.

C. Public policy considerations support upholding *Mallinckrodt*.

This Court should not lightly overturn decades of established law upon which domestic industries, BIO's and CropLife's members among them, have built their businesses. As this Court recently emphasized, maintaining established law is the "preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process." *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2409 (2015) (quoting *Payne v. Tennessee*, 501 U.S. 808, 827-28 (1991)). This is especially true here where the question before the Court involves the intersection of property (patents) and contracts (restricted sales and licenses). This Court has "often recognized that in just those contexts" concerns over overturning established law are "at their acme" because "parties are especially likely to rely on such precedents when ordering their affairs." *Id.* at 2410 (quoting *Payne*, 501 U.S. at 828). Companies, including those in the biotechnology industry, have long structured their licensing relationships and sales practices using conditions such as field-of-use restrictions, single-use restrictions, and the like, by negotiating royalty rates and prices to reflect the value of the rights conveyed.

This Court should not cast aside well-established law that is deeply ingrained in industry custom, permits economically efficient practices, and benefits all parties involved as well as the broader public. For instance, through field-of-use restrictions,

everyone benefits: the patent owner expands the market for its technology and maximizes its financial return, increasing the capital available to develop new technologies; the purchasers pay only for the specific patent rights they need, allowing them to obtain, at lower cost, patented articles that otherwise might be price prohibitive; and the public benefits because the patented technology can be incorporated into a broader and more diverse range of products. *See* Jay Dratler, Jr. & Stephen M. McJohn, *Licensing of Intellectual Property* § 7.04 (2015) ("[F]ield-of-use restraints serve[] to provide strong incentives for innovation and creativity …."). As the Federal Circuit recognized below, "Lexmark's Return Program provides customers an immediate up-front benefit: a choice between two options, one offering them a lower price in exchange for the single-use/no-resale limitation." 816 F.3d 721, 752 (Fed. Cir. 2016).

Likewise, within the life sciences sector, the patent owner, patient, customer, and the public all benefit from the availability of "research-only" restricted sales. Numerous BIO and CropLife members make their patented technology available at a low cost to non-profit universities and smaller companies to engage in basic research, thereby encouraging further innovation built on patented inventions. Numerous BIO member companies also sell their patented products for "diagnostic use only," at a price somewhere between a product intended for research use and a product intended for commercial use. These sales are made to entities that do not seek to commercialize a therapeutic product and typically cannot afford the cost of a full commercial sale.

There is no reason to cast aside what has long been a highly efficient system, as the biotechnology experience illustrates. An unconditional sale of a patented article to conduct early-stage testing could be cost prohibitive and unnecessary; but after initial testing to identify promising candidates for further research and development under a limited conditional sale, the parties can negotiate a more robust commercial agreement on different financial terms. As with field-of-use restrictions, patent owners benefit by seeding early research, thus maximizing access to the technology while providing a reasonable financial return; purchasers benefit by paying only for the patent rights they need; and the public benefits through expanded opportunities for basic research and experimentation as well as the subsequent development of new, potentially life-saving, products.

The ability to condition sales without exhausting patent rights also is important to BIO and CropLife members that sell self-replicating products, such as seeds and cell lines. Without the patent owner's knowledge or control, these products can be replicated, disseminated, and incorporated into other products. It is precisely for this reason that manufacturers of such products require purchasers to enter into conditions of sale. These are cases of "control by necessity." Dratler & McJohn, *supra*, § 7.05. Manufacturers of patented seed and cell lines sell their products for a low initial cost to a broad market, including farmers who could not afford higher prices, based on the assurance that their products will be used only for the limited purposes set forth in the license. The continued enforceability of their patent rights after first sale is a critical tool in

allowing these companies to police their use restrictions, particularly against unauthorized downstream users of their patented products.

As even Petitioner recognizes, the principle underlying the rule of patent exhaustion for an unconditional sale is that the patentee has bargained for, and received, an amount equal to the full value of the goods. But in the context of a conditional sale, it is more reasonable to infer that the parties negotiated a price that reflects only the value of the "use" rights conferred by the patentee. Overruling *Mallinckrodt* would eviscerate this principle, a principle upon which BIO and CropLife members and other patent owners have long relied in conducting their business practices.

Finally, BIO and CropLife members, particularly agriculture and agrichemical companies, rely on use restrictions as a means to ensure product stewardship for the good of the environment and public health. Restrictions on herbicides, for example, may require certain use patterns and application rates to minimize risks to protected plant species. Similarly, use restrictions may require that certain products will be sold only to those who are qualified to use the products in a responsible manner. *See generally Guide For Stewardship Of Biotechnology-Derived Plant Products*, Excellence Through Stewardship (2013), http://c.ymcdn.com/sites/www.excellencethroughstewardship.org/resource/resmgr/Files/Guides/Stewardship_Guide_Revision_v.pdf (describing importance of establishing licenses that include stewardship requirements).

These examples illustrate how BIO and CropLife members have a genuine and vital interest in controlling downstream use of their products to protect not only their reputation, but also downstream purchasers and the public. As the Federal Circuit correctly noted below:

> [Companies can have a] legitimate interest in not having strangers modify its products and introduce them into the market …. A medical supplier … may have similar reason to believe that reuse, when not under its own control, carries a significant risk of poor or even medically harmful performance, to the detriment of its customers and its own reputation.

816 F.3d at 752.

Contrary to Petitioner's argument, the remedies afforded by contract law do not adequately protect these interests in enforcing use restrictions. There is often no privity between the patent owner and downstream end-users or purchasers. In those circumstances, contract law provides no remedy, whereas patent law ensures that use restrictions can be enforced against a party engaging in unauthorized use. Moreover, as a practical matter, contract law varies from state to state, in contrast to the uniform U.S. patent law.

Petitioner's criticisms of the policy implications of *Mallinckrodt* are misplaced. These criticisms ignore the fact that *Mallinckrodt* has been the governing law for decades. BIO and CropLife members have long structured their businesses on

this conditional sales and licensing regime. If Petitioner's parade of horribles posed any true threat to industry and the public, everyone, including BIO and CropLife members, would have already suffered those ill effects. As the Federal Circuit stated below, there is "no basis for predicting the extreme, lop-sided impacts." 816 F.3d at 752. Rather, "*Mallinckrodt* has been the governing case law since 1992 and has been reiterated in subsequent precedent [and the court has] been given no reliable demonstration of widespread problems not being solved in the marketplace." *Id.* Petitioner's dire predictions of the death of secondary and repair markets are unsupported and cannot be squared with the ongoing existence of these markets and the ability of the market to accommodate the needs and demands of consumers. Moreover, even if Petitioner's parade of horribles were supported by evidence, claims that longstanding precedent has "'serious and harmful consequences' for innovation are … 'more appropriately addressed to Congress,'" the branch that "has the capacity to assess [the] charge" that the precedent in question "suppresses technological progress." *Kimble*, 135 S. Ct. at 2414 (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2413 (2014)).

In sum, the current legal regime has long ensured certainty and efficiency in the market. Petitioner's request to overrule *Mallinckrodt* and disrupt the way patented products have been and continue to be sold should be rejected. To do otherwise would fundamentally alter the market for many patented products: disrupting pricing strategies, restricting access to innovative products,

and creating obstacles to further innovation as well as the country's economic growth.

CONCLUSION

For the foregoing reasons, this Court should affirm the Federal Circuit's decision below.

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