Nos. 14-1617, -1619

IN THE

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

LEXMARK INTERNATIONAL, INC.,
Plaintiff-Cross-Appellant,

v.

IMPRESSION PRODUCTS, INC.
Defendant-Cross-Appellee.

(Caption continued on inside cover)

Appeal from the United States District Court for the Southern District of Ohio, Case No. 10-CV-564, Judge Michael R. Barrett

BRIEF OF *AMICI CURIAE* Biotechnology Industry Organization and CropLife International in Support of Plaintiff-Cross-Appellant

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August 19, 2015

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Defendants.

CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4 and Fed. R. App. P. 26.1, counsel for Amici Curiae Biotechnology Industry Organization and CropLife International certifies the following:

1. The full name of every party represented by me is: Biotechnology Industry Organization and CropLife International.

2. The name of the real party in interest represented by me is: N/A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties represented by me are: None.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by me and that are expected to appear in this Court are:

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STATEMENT OF INTEREST OF AMICI CURIAE[1]

The Biotechnology Industry 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. Approximately 90% of BIO's corporate members have annual revenues under $25 million.

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 plant technologies. CropLife's members develop innovative products such as seeds and plants that, unlike any found in nature, have been bioengineered

[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 other than the amicus curiae or its counsel. The filing of this brief is authorized by this Court's en banc order inviting the submission of amicus curaie briefs. Apr. 14, 2015 Order (Dkt. No. 83), at 4.

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, transgenic seeds and plants, 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. The unauthorized importation of patented products first sold in foreign markets and unauthorized domestic uses of products in violation of conditions of sale or license restrictions may be actionable under current United States patent law.

BIO and CropLife members have relied on longstanding patent exhaustion doctrine to structure their businesses — from investment in research and development through sales of their products. The territorial — but not international — application of the patent exhaustion doctrine has assured United States 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 patentee'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 return on its investment in the invention.

SUMMARY OF THE ARGUMENT

The Court faces two important and wholly distinct questions, both directed to longstanding principles of patent exhaustion. This Court's decisions in *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), and *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), are consistent with those principles. In these decisions, this Court struck a delicate balance between a patent owner's ability to protect and enforce its patent rights and the public's interest in access to the patented invention, including for further

innovation using the patented invention. These two decisions remain sound law, supported by century-old Supreme Court precedent and important public policy considerations.

Contrary to the suggestion of Impression Products, the holding of *Jazz Photo* is not called into question by *Kirtsaeng v. John Wiley & Sons, Inc*., 133 S. Ct. 1351 (2013). *Kirtsaeng* concerned the interpretation of the Copyright Act and carries little import for the judicially-created doctrine of patent exhaustion. *Jazz Photo* rests on the territoriality principles of the United States patent system, properly holding that the sale of an article outside the United States does not exhaust domestic patent rights.

This territorial limitation on the exhaustion principle has critical public policy implications. It permits innovators selling patented products internationally to set market-specific prices. The ability to deploy regional pricing internationally encourages innovators to maximize the distribution of important biotechnology products, including life-saving therapeutic products and transgenic seeds, in developing countries. In addition, such regional pricing is commercially and socially efficient; market-specific prices account for factors such as the differing value of intellectual property rights between markets, local demand, wealth distribution, price regulation, local manufacturing requirements, compulsory licenses, and special imposts and tariffs. In recent years, Congress has had the

opportunity to consider and amend the patent laws but has not altered the territorial application of this enduring common law patent doctrine.

Likewise, this Court's holding in *Mallinckrodt* remains good law: conditional sales of patented products do not exhaust patent rights. In its decision in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), the Supreme Court had the chance to modify this Court's holding in *Mallinckrodt*, but it declined to do so. This 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.

Conditional sales are important to the biotechnology industry for several reasons. For example, they are used in connection with 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 the use of a portion of the patent right and a corresponding price suited to the buyer's desired use. For example, under current law, biotechnology companies have an incentive to provide patented materials, subject to research-only use restrictions, to universities and other research institutions at a price lower than that of a full commercial sale. If the materials are thereafter conveyed to others who

use them for commercial purposes, the patent owner can invoke patent law to enjoin or to seek fair compensation for unauthorized uses that go 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 narrow commercial uses (*e.g.*, veterinary use), diagnostic uses, or purely non-commercial, research uses.

BIO and CropLife members have long relied on both doctrines to establish market prices for their patented products and to negotiate sales. There is no mandate — or even a suggestion — from the Supreme Court to revisit either exhaustion doctrine. Given the importance of these doctrines and the public policy considerations supporting them, this Court should reaffirm its prior holdings in *Jazz Photo* and *Mallinckrodt*.

ARGUMENT

I. *Jazz Photo*'s Holding That International Sales Do Not Exhaust Domestic Patent Rights Should Be Upheld.

A. *Jazz Photo* was correctly decided and remains good law.

1. *Jazz Photo* is consistent with and dictated by the territorial limits of the United States patent system.

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); *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."). In *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (2001), *cert. denied*, 536 U.S. 950 (2002), this Court recognized that territoriality principle in holding that "to invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent." *Id*. at 1105 (citing *Boesch v. Graff*, 133 U.S. 697, 701-3 (1890)).

Jazz Photo rests on a century of Supreme Court precedent, including *Boesch v. Graff*. 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. The Supreme 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 Supreme 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*, the Supreme Court in *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659 (1895), recognized the core exhaustion holding in *Boesch* and affirmed it: 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." *Id*. at 664-66. *Jazz Photo*'s holding that to exhaust patent rights, the first sale must have occurred in the United States thus rests on longstanding Supreme Court doctrine establishing that foreign laws do not alter the rights of the United States patent owner to enforce its patent rights for domestic sales.

In the fourteen years since *Jazz Photo* was decided, this Court has repeatedly relied on the extraterritorial limits of United States patent laws in reaffirming that patent exhaustion applies only when the authorized first sale occurs in the United States. *E.g*., *Fujifilm Corp. v. Benun*, 605 F.3d 1366, 1371 (Fed. Cir. 2010) (holding that "*Quanta Computer, Inc. v. LG Electronics, Inc*. did not eliminate the first sale rule's territoriality requirement"); *Fuji Photo Film Co. v. Jazz Photo Corp*., 394 F.3d 1368, 1376 (Fed. Cir. 2005) ("Fuji's foreign sales can never occur under a United States patent because the United States patent system does not provide for extraterritorial effect.... In *Jazz*, therefore, this court expressly limited first sales under the exhaustion doctrine to those occurring within the United States.").

2. The *Kirtsaeng* decision is limited to the Copyright Act and does not support overturning *Jazz Photo*.

Nothing in the Supreme Court's analysis of the Copyright Act in its *Kirtsaeng* decision had the effect of overturning the judicially-created doctrine governing international patent exhaustion. *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2013), is based entirely on statutory interpretation of the Copyright Act's first-sale provision, 17 U.S.C. § 109(a), which permits "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 that copy or phonorecord." *Id.* The critical question in *Kirtsaeng* was whether the scope of § 109(a) was limited geographically. 133 S. Ct. at 1355. To conclude that the Act's first-sale provision was not limited to domestic sales, the Supreme Court closely examined the statutory language and history of § 109(a).

Given its focus on the language of the Copyright Act, the *Kirtsaeng* analysis has no application here. Although there are similarities between patent and copyright law, the Supreme 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).[2] Because patent law protects a patented invention however it is embodied, it is not surprising that the Supreme Court made no reference to patent law anywhere in *Kirtsaeng*, or otherwise suggested that its interpretation of the Copyright Act could apply more broadly to patents.

By contrast, the patent exhaustion doctrine was defined by the courts, not by statute. As this Court recently explained, "Patent exhaustion is a judicially fashioned doctrine without a specific source in congressionally enacted text stating the terms of this limitation on patent rights." *Helferich Patent Licensing, LLC v. N.Y. Times Co*., 778 F.3d 1293, 1305 (Fed. Cir. 2015). Congress recently implemented substantial changes to the patent laws through the America Invents Act. In so doing, Congress could have codified the patent exhaustion doctrine so that it paralleled the provisions of the Copyright Act. But Congress did not alter the judicially-created patent exhaustion doctrine.

Another critical difference between copyright and patent law is that copyright law is far more uniform globally than patent law. Under the Berne Convention for the Protection of Literary and Artistic Works Paris Text 1971,

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[2] *LifeScan Scot., Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361 (Fed. Cir. 2013) is not to the contrary. Although the case cited *Kirtsaeng*, it recognized that it was "not 'controlling' regarding issues of patent law." *Id*. at 1375-76.

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. Articles 3 & 4. By contrast, there is far less global uniformity in the patent laws, and therefore much greater international risk to the protection of United States innovators. Under the Paris Convention for the Protection of Industrial Property, patents granted in different territories for the same invention are independent of one another. *See* Article 4bis. Indeed, a single patent application filed under the Patent Cooperation Treaty ("PCT") can result in different, independently-granted patents in up to 148 PCT member countries. Given the general lack of reciprocity among signatory countries, the United States should not unilaterally discard our current patent exhaustion doctrine.

B. The *Jazz Photo* decision rests on sound public policy.

Jazz Photo not only rests on a solid legal foundation, it is supported by sound public policy. 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. *Jazz Photo* allows patent owners to determine 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.

Moreover, foreign markets often differ significantly from the United States with respect to the availability, scope, and enforceability of patent rights for biotechnology inventions. A patent in a foreign country may be worth much less than a United States patent, or such 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 product would have to reflect the value of the domestic patent rights conveyed in such a 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 may not realistically be able to command such a price in the foreign market). Moreover, 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 products.

1. *Jazz Photo* allows patent owners to employ regional pricing.

As explained above, the territorial limitation on patent exhaustion allows patent owners to establish regional prices based on local conditions. For instance, many pharmaceutical companies sell drugs for treating AIDS at a dramatically lower price in African countries than in developed countries. *See* Scott Gotlieb, *Companies reduce prices for HIV drugs in developing countries*, Bulletin of the

World Health Org., 2000, at 862. 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. *Id.* Three years later, GSK reduced the price again 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 allows patent owners to 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).

Patent owners rely on the territorial application of patent exhaustion to enforce regional pricing. Third parties can otherwise undermine regional pricing by purchasing products in a lower-priced country and re-selling them in a higher-priced country. *Id.* at 3-4. GSK, for instance, lost over $18 million in sales when its AIDS drugs meant for African countries were illegally resold in Europe. Gregory Crouch, *Europeans Investigate Resale of AIDS Drugs*, N.Y. Times, Oct. 29, 2002. Under *Jazz Photo*, companies are able to enforce their United States patent rights by suing such resellers for patent infringement. If this Court overrules *Jazz Photo*, patent owners will lose an important tool to prevent resellers from undermining regional pricing. Indeed, the Supreme Court in *Kirtsaeng* observed that permitting international exhaustion would "make it difficult, perhaps

impossible" to sell products at different prices in different countries. 133 S. Ct. at 1370.

The ability to enforce regional pricing through patent law is particularly significant in the biotechnology industry. The high-tech industry is more easily able to manufacture products for particular geographic markets. For example, one can manufacture a phone that is technologically able to operate only in Europe, and therefore would be unlikely to be resold in the United States. By contrast, the biotechnology industry is unlikely to be able to alter specific transgenic seeds or medicines so that they are useful only in certain markets. These limitations on the industry's ability to develop products operable in a specific markets makes patent law a particularly important way to protect the industry's ability to employ regional pricing.

Contract law does not provide an adequate substitute for the use of the patent system to enforce 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 not have privity of contract with the latter. In addition, the enforcement of any such contracts against initial purchasers could be subject to a plethora of foreign laws, creating

uncertainty and inefficiency. United States patent law, by contrast, permits the patent owner to seek an adequate remedy in federal courts or the International Trade Commission against anyone who infringes the patent domestically, regardless of the chain of custody of the product. *See* 35 U.S.C. §§ 281, 283-284; 19 U.S.C. § 1337.

Moreover, 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 individual consumers and small institutions. Not only do biotechnology companies have no desire to sue their customers, requiring them to do so would be highly inefficient. It would waste judicial resources and unnecessarily target consumers and small businesses 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….").

2. Regional pricing benefits the public.

Regional pricing encourages BIO and CropLife members to invest in research and development of new innovative products by permitting optimal market penetration and pricing. *See* Arfwedson, *supra*, at 3. The public benefits from the development and widespread availability of these products.

Investment incentives are particularly important for the biotechnology industry, which faces substantial research and development costs. The cost of developing a new plant biotechnology trait introduced between 2008 and 2012 was approximately $136 million. 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. It takes, on average, 13.1 years from discovery to commercial launch of a new crop. *Id*. It takes about 15 years to develop and bring a new medicine to market, and it costs about $2.6 billion to develop, making it almost two-and-a-half times more costly than in 2003. *See Drug Development Costs Rise Dramatically, Now Nearly $2.6 Billion per Medicine*, Biotechnology Indus. Org. (Nov. 18, 2014), https://www.bio.org/media/press-release/drug-development-costs-rise-dramatically-now-nearly-26-billion-medicine; Peter Gwynne & Gary Heebner, *Drug Discovery and Biotechnology Trends: Recent Developments in Drug Discovery: Improvements in Efficiency*, Science, Feb. 7, 2003.

These figures illustrate a familiar problem for member companies: developing new biotechnology is an "extremely expensive, complex, and risky endeavor, and grows more so each year." Biotechnology Indus. Org., *supra*. While the industry has achieved astounding medical breakthroughs, they "are a

result of the hard work and financial risks taken every day by biopharmaceutical companies." *Id.* Moreover, extensive lab development, clinical testing, and regulatory approval are required before many new biopharma products can come to market, a process that takes approximately 15 years.[3] Consequently, if a company does see a return on its investment, that return will only come many years later. *See* Arfwedson, *supra*, at 3. 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 crises in economically-depressed regions by providing life-saving medicine and medical technology at or close to cost. *Jazz Photo* assures patent owners that they can provide these products to patients who cannot afford the full price while preserving their ability to assert patent rights against any third parties attempting to resell the low-cost products in other countries.

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[3] *See* Hui-Hsing Wong et al., *Examination of Clinical Trial Costs and Barriers for Drug Development* 1-2 (July 25, 2014), http://aspe.hhs.gov/sites/default/files/pdf/EXAMINATION%20OF%20CLINICAL%20TRIAL%20COSTS%20AND.pdf.

Many BIO and CropLife members engage in these so-called "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 Aug. 18, 2015). Other members employ similar equitable not-for-profit pricing. *See Pricing, Manufacturing & Distribution*, Access to Medicine Index 2014, http://www.accesstomedicineindex.org/pricing-manufacturing-distribution-0 (listing BIO members AbbVie, Novo Nordisk, Bayer, and Johnson & Johnson among top five leading companies practicing equitable pricing).

Overturning *Jazz Photo* would also make it more difficult for companies to engage in non-price-related programs in developing countries designed to increase 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.[4] Overturning *Jazz Photo* would open the door for generic manufacturers and other third parties to export and to resell low-priced drugs outside of the region in need, undermining these public interest programs.

The public harm that would result from overturning *Jazz Photo* is not mere speculation — it occurred in the copyright context after *Kirtsaeng*. Within one year after the decision, the publisher Wiley & Sons stopped selling its books in many emerging markets and increased prices in others.[5] 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*, 87 Patent, Trademark & Copyright J. 591 (2014).

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[4] 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.

[5] Sofia Catillo, *First Sale: Congressional hearing on Kornrumpf decision*, Copyright Alliance (June 3, 2014), http://copyrightalliance.org/2014/06/first_sale_congressional_hearing_and_kornrumpf_decision#.VX_LZvlVikq.

The detrimental impact would be even greater in the biotechnology space, where the development costs and risks of failure 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 has often elapsed before a biotechnology product is even approved for marketing. 17 U.S.C. §§ 302-305 (duration of copyrights); 35 U.S.C. § 154 (duration of patents). 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. [6]

In addition to member companies' desire to provide broad access to their products in order to address public health crises worldwide, foreign patents may not even exist covering the product in every jurisdiction in which the product is sold. In those instances, the patent owner cannot be said to have received any reward for his invention because the product is not patented where the sale occurred — and if *Jazz Photo* were overruled, patent owners selling abroad would be unable to seek compensation for infringement of their United States patent.

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[6] *See* David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 Tex. L. Rev. 1677, 1709 (2007) ("[In] 2004 the median prosecution time for a biotechnology patent was 3.2 years ….").

Companies would see the need to recoup their investment in research and development by charging a uniformly higher price upfront. *See* Mazumdar, *supra*. This would likely limit the distribution of the product, because some consumers and markets simply could not bear the resulting price increase.

There are also important public health and safety reasons — not found 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, lifespan, warnings, advertising, and packaging. *Id.* Labels may vary 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 regulated. *Agricultural Biotechnology*, U.S. Dep't of Agric., http://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH (last visited Aug. 18, 2015).

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 practice and expectation is that United States patent rights are not conveyed as part of a foreign sale unless there is an express and affirmative grant of such rights. Adopting the Government's position would force patent owners to alter their sales and licensing practices around the world, introduce needless complication into each and every transaction, and ultimately restrict access to patented biological products, to the detriment of both patent owners and the public. Notably, the Government, after having long advocated for domestic-only exhaustion, has not offered any explanation of how its shift in patent exhaustion policy would benefit trade policy or innovation in the United States.

II. Restricted Domestic Sales Do Not Exhaust Patent Rights.

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

Mallinckrodt's holding that restricted sales do not exhaust patent rights is rooted in fundamental principles of patent law giving the patent owner the right to exclude. 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"). Patent rights may be conferred as an entire bundle of rights, or granted separately through conditional sales. *See, e.g.*, *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.").

This Court recognized in *Mallinckrodt* that "[t]he practice of granting licenses for restricted use is an old one." 976 F.2d 700, 705 (Fed. Cir. 1992). In *United States v. General Electric Co*., 272 U.S. 476 (1926), the Supreme Court reaffirmed 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 Supreme Court 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).[7] *Mitchell* established that a patent owner may enforce restrictions on the post-sale use of a patented article through an infringement action.

[7] *Mitchell* remains good law: not only was it the foundation of *General Talking Pictures Corp. v. Western Electric Co*., 304 U.S. 175 (1938), which approved the legality of field-of-use restrictions, but it was also cited recently in *Bowman v. Monsanto Co*., 133 S. Ct. 1761, 1766 (2013).

In *Mallinckrodt*, this Court built on these fundamental principles spanning over a hundred years of Supreme Court precedent concerning patent rights, founded in both patent law and contract law, holding that unless a conditional sale "violated some other law or policy ... private parties retain the freedom to contract concerning conditions of sale." 976 F.2d 700, 708 (Fed. Cir. 1992). The case involved a "single-use only" restriction on the use of 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 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. It held 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.

This Court has since confirmed the patent owner's ability to enter into conditional sales without exhausting its patent rights. In *B. Braun Medical, Inc. v. Abbott Laboratories*, 124 F.3d 1419 (Fed. Cir. 1997), the Court explained that the principle underlying the rule of patent exhaustion for an unconditional sale is that "in such a transaction, the patentee has bargained for, and received, an amount equal to the full value of the goods." *Id.* at 1426. By contrast, 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." *Id*. 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.

B. The Supreme Court's *Quanta* decision 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 Supreme Court decided *Quanta*, it received extensive briefing from amici, including the Government, urging it to address the first-sale doctrine in light of *Mallinckrodt*. The Court held that, because the license agreement permitted Intel to make and sell microprocessors and chipsets while imposing no restriction on its ability to sell to Quanta, Intel's subsequent sales to Quanta were authorized, and LGE's patent rights therefore were exhausted. *Id*. at 637. Importantly, the Supreme 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.

The Supreme Court did not overrule *Mallinckrodt* or the precedent supporting it sub silentio. *Mallinckrodt* is grounded in black-letter Supreme Court

law permitting the enforcement of post-sale use restrictions. *E.g.*, *Gen. Talking Pictures*, 305 U.S. at 126-27 (holding field-of-use restrictions enforceable through licenses divided between those who could sell for commercial purposes and those who could sell for home purposes). The Supreme Court was well aware of this precedent at the time it decided *Quanta*, and it left *Mallinckrodt* intact.

The Government's brief argues for a distinct treatment of conditional sales vis-à-vis restricted licenses, arguing the patent exhaustion doctrine should apply to conditional sales. Br. for the U.S. of Am. as Amicus Curiae at 5-8. But there should be no difference in the treatment of a conditional sale. Indeed, in BIO and CropLife members' experience, the two are often conjoined. For example, the online purchase of a patented product often requires the purchaser to execute a license, whereby purchasers simply click their assent to its terms as part of the sales transaction. Similarly, grower agreement licenses are signed in connection with the sale of bags of transgenic seed. Indeed, in *Mallinckrodt* itself, Mallinckrodt argued that notice of the "single use only" restriction made it a "label license." 976 F.2d at 701.

The distinction advocated by the Government between conditional sales and field-of-use or other restricted licenses makes little sense in the real world. So long as the licensee/purchaser has notice of the restriction, there is no reason to engage in semantic debates or costly, inefficient litigation to maintain a distinction

between a conditional sale and a restricted license. The need for certainty and efficiency in business transactions dictates rejection of the Government's formalistic approach.

C. Public policy considerations support upholding *Mallinckrodt.*

Sales conditions benefit not only patent owners, but also the public at large. For this reason, BIO and CropLife members support conditional sales and rely on their continued enforceability through patent law. 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 and the broader public.

Through field-of-use restrictions, everyone benefits: the patent owner expands the market for its technology and maximizes its financial return, increasing its incentive and capital available to develop new technologies; the purchasers pay only for the specific patent rights they need, allowing them to obtain patented articles that otherwise might be price prohibitive; and the public benefits because the technology can be incorporated into a 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 ….").

Likewise, within the life sciences area, the patent owner, 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.[8] Likewise, numerous BIO member companies sell their patent 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 the product or its use and typically cannot afford the cost of a full commercial sale. These sales also allow research institutions and other biotechnology companies to have access to otherwise unavailable technology when conducting early-stage, exploratory research for a range of potential medicinal products or when using the product for diagnostic purposes.

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[8] *See, e.g.*, *Academic Research Agreements*, Monsanto (Sept. 17, 2009), http://www.monsanto.com/newsviews/pages/public-research-agreements.aspx; *Extramural Research Alliances*, Amgen, http://www.amgen.com/partners/research.html (last visited Aug. 19, 2015); *Testing Methods Using OncoMouse® Transgenic Models of Cancer*, DuPont http://dupont.t2h.yet2.com/t2h/page/techpak?id=26128 (last visited Aug. 19, 2015) ("Free academic non-commercial research licenses [to DuPont's OncoMouse transgenic animals] have been executed with nearly 350 nonprofit universities and research institutions worldwide.").

The Government acknowledges, as it must, that patent owners can validly impose restrictions on a license and that exceeding the scope of a limited license can constitute not only a breach of contract but also patent infringement. Nonetheless the Government draws an ill-defined distinction between a limited license and a conditional sale, applying patent exhaustion to the latter but not the former. Yet, for a consumer or retailer there is no practical difference between purchasing a product from the patentee directly in a "conditional sale" and purchasing the same product from an authorized licensee (who, due to its limited license, can confer no better title than it has). *See Mitchell*, 83 U.S. (16 Wall.) at 548; *Gen. Talking Pictures*, 304 U.S. at 181 (holding that the licensee "could not convey to petitioner what both knew it was not authorized to sell"). Treating otherwise indistinguishable purchases differently for purposes of patent exhaustion will cause uncertainty in the marketplace. In turn, this uncertainty could stifle transactions and lead to costly disputes over whether the transaction was a license or a conditional sale — a distinction without substance.

There is no reason to cast such clouds of confusion over what has long been an extremely efficient system, as the biotechnology experience illustrates. An unconditional sale of a patented article could be cost prohibitive and unnecessary in order to conduct early-stage testing; 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.

As another example, the ability to condition sales without thereby exhausting patent rights 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 self-replicating 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 small 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.

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. Use 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://excellencethroughstewardship.org/wp-content/uploads/ETS-Stewardship-Guide-Final-Revised-12-13.pdf (describing importance of establishing licenses that include stewardship requirements).

Contrary to the Government'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 users or purchasers. In those circumstances, contract law provides ***no*** remedy, whereas patent law does ensure 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 unified United States patent law.

In sum, the current legal regime has long ensured certainty and efficiency in the market. Impression Products' 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 inventions: disrupting pricing strategies, restricting access to innovative products, and creating obstacles to further innovation.

CONCLUSION

For the foregoing reasons, this Court should uphold its prior decisions in *Jazz Photo* and *Mallinckrodt*.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,943 words, excluding parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in proportionally spaced typeface using Microsoft Word in 14 point Times New Roman.

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I hereby certify that on August 19, 2015, I electronically filed the foregoing document with the United States Court of Appeals for the Federal Circuit using the CM/ECF system. I certify that all of the parties of record or their counsel are registered as ECF Filers and that they will be served by the CM/ECF system.

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