Nos. 2014-1617, 2014-1619

United States Court of Appeals for the Federal Circuit

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

v.

IMPRESSION PRODUCTS, INC.,
Defendant and Appellant,

QUALITY CARTRIDGES, INC., JOHN DOES, 1-20, BLUE TRADING LLC, EXPRINT INTERNATIONAL, INC., LD PRODUCTS, INC., PRINTRONIC CORPORATION, TESEN DEVELOPMENT (HONG KONG) CO. LTD., and BENIGNO ADEVA AND HIS COMPANIES,
Defendants.

Appeal from the United States District Court for the Southern District of Ohio in Case No. 1:10-CV-00564-MRB, Judge Michael R. Barrett

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PLAINTIFF AND CROSS-APPELLANT LEXMARK INTERNATIONAL, INC.

John E. Nilsson
Kristan L. Lansbery
Samuel Drezdzon
ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004
(202) 942-5000

Willow White Noonan
ARNOLD & PORTER LLP
Three Embarcadero Center
San Francisco, CA 94111
(415) 471-3100

Counsel for amicus curiae *PhRMA*

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

1. The full name of every party or amicus represented by me is:

Pharmaceutical Research and Manufacturers of America.

2. The name of the real party in interest (if the party named in the caption is not 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 party represented by me are:

None.

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

John E. Nilsson
Kristan L. Lansbery
Samuel Drezdzon
ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004

Willow White Noonan
ARNOLD & PORTER LLP
Three Embarcadero Center
San Francisco, CA 94111

/s/ *John E. Nilsson*
John E. Nilsson

TABLE OF CONTENTS

Page

CERTIFICATE OF INTEREST i

STATEMENT OF *AMICUS CURIAE* 1

INTRODUCTION 3

ARGUMENT 5

I. The Supreme Court In *Kirtsaeng* Did Not Overrule *Jazz Photo* 5

A. The Court's Analysis Centered On Statutory Language Specific To Copyright 5

1. The Text and History Of The Statutory Provisions At Issue In *Kirtsaeng* Have No Analogy In Patent Law 6

2. *Kirtsaeng*'s Analysis Focused On Where Copies Were Made And Not Where They Were Sold 7

B. *Kirtsaeng*'s Discussion Of Common Law Does Not Apply Here 8

II. The Differences Between Patent Law and Copyright Law Warrant a Different Outcome with Respect to International Exhaustion 11

A. Copyright Protection Is Much More Globally Uniform Than Patent Protection 12

B. Patent Law Does Not "Apply Internationally" In The Way The Supreme Court Described Copyright Law In *Kirtsaeng* 14

III. Policy Considerations Favor Adhering To *Jazz Photo* 16

IV. Overruling *Jazz Photo* Could Disincentivize U.S. Pharmaceutical Companies From Selling Life-Saving Drugs Abroad 18

A. International Exhaustion Would Change The Balance Congress Has Set Between Promoting Innovation And Free Markets 21

B. The Reliance Of *Amici* On 21 U.S.C. § 381(d) To Address These Concerns Is Unavailing 27

CONCLUSION 28

TABLE OF AUTHORITIES

Page(s)

Cases

Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,
133 S. Ct. 2107 (2013).....22

Bilski v. Kappos,
561 U.S. 593 (2010).....22

Biotechnology Indus. Org. v. Dist. of Columbia.,
496 F.3d 1362 (Fed. Cir. 2007).....24

Bobbs-Merrill Co. v. Straus,
210 U.S. 339 (1908).....9, 11, 12

Boesch v. Graff,
133 U.S. 697 (1890).....10, 16

Daimler Mfg. Co. v. Conklin,
170 F. 70 (2d Cir. 1909).....10

Deepsouth Packing Co. v. Laitram Corp.,
406 U.S. 518 (1972), *superseded by statute*.....15, 16

Diamond v. Chakrabarty,
447 U.S. 303 (1980).....22

Dickerson v. Matheson,
57 F. 524 (2d Cir. 1893).....10

Dickerson v. Tinling,
84 F. 192 (8th Cir. 1897).....10

Fuji Photo Film Co. v. Benun,
463 F.3d 1252 (Fed. Cir. 2006).....10

Fujifilm Corp. v. Benun,
605 F.3d 1366 (Fed. Cir. 2010).....11

Golan v. Holder,
132 S. Ct. 873 (2012).....12, 13

Griffin v. Keystone Mushroom Farm, Inc.,
453 F. Supp. 1283 (E.D. Pa. 1978).....10, 18

Jazz Photo Corp. v. ITC,
264 F.3d 1094 (Fed. Cir. 2001) .....*passim*

Keeler v. Standard Folding Bed Co.,
157 U.S. 659 (1895).....25

Kirtsaeng v. John Wiley & Sons, Inc.,
133 S. Ct. 1351 (2012).....*passim*

LifeScan Scotland, Ltd. v. Shasta Techs., LLC,
734 F.3d 1361 (Fed. Cir. 2013) 26

Microsoft Corp. v. AT&T Corp.,
550 U.S. 437 (2007).....15

Morrison v. Nat'l Australia Bank Ltd.,
561 U.S. 247 (2010).....16

Ninestar Tech. Co. v. ITC,
667 F.3d 1373 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 1656
(2013).....11

Pharm. Research & Mfrs. of Am. v. D.C.,
406 F. Supp. 2d 56 (D.D.C. 2005).....24

Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.,
711 F.3d 1348 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 900 (2014) 15

Quality King Distribs., Inc. v. L'anza Research Int'l, Inc.,
523 U.S. 135 (1998).....24, 25

Quanta Computer, Inc. v. LG Elecs., Inc.,
553 U.S. 617 (2008).....8, 11

Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA,
944 F.2d 870 (Fed. Cir. 1991) 8

Statutes

17 U.S.C. § 109(a) (2008).....5, 7

21 U.S.C. § 381(d) 28, 29

Copyright Act.....*passim*

Copyright Act of 1909, § 41, 35 Stat. 1084 6

Copyright Act of 1947, § 27, 61 Stat. 660 7

Fed. R.App. P. 29 1

Fed.R.App. P. 32(a)(7)(B)(iii) 1

Fed. R.App. P. 29(d) 1

Patent Law Amendments Acts of 1984, Pub. L. No. 98-622, 98 Stat. 3383 (codified at 35 U.S.C. § 271(f)) 15

Prescription Drug Marketing Act, Pub. L. No. 100-293 (Apr. 22, 1988) (codified at 21 U.S. C. § 381(d)(1)) 28

U.S. Const. Art. I, § 8, cl. 8.....22

Other Authorities

Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575 (2003) 20

David A. Malueg and Marius Schwartz, *Parallel Imports, Demand Dispersion, and International Price Discrimination* 37 J. Int'l Econ. 167 (1994).....27

Ernst R. Berndt et al., *Decline in Economic Returns from New Drugs Raises Questions About Sustaining Innovations*, 34 Health Affs. 245 (Feb. 2015).....21

Global Health Progress Initiative, http://www.globalhealthprogress.org 26

Henry Grabowski, et al., *The Roles of Patents And Research And Development Incentives In Biopharmaceutical Innovation* 20

Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*
5 J. Int'l Econ. L. 849 (2002) 21

John A. Vernon et al., *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 Am. J.L. & Med. 175 (2006) 23

Mainak Mazumdar *et al*., *On Price Discrimination, Parallel Trade and the Availability of Patented Drugs in Developing Countries*, 32 Int'l Rev. L. & Econ. 188 (2012) 27

Michele L. Vockrodt, *Patent Exhaustion and Foreign First Sales: An Analysis and Application of the Jazz Photo Decision*, 33 AIPLA Q.J. 189 (2005) 25, 26

Patricia M. Danzon, *Pharmaceutical Price Regulation: National Policies Versus Global Interests*, 8 (American Enterprise Institute for Public Policy Research ed., 1997) 20

PhRMA & Battelle, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, 21 (2014) 21

PhRMA.org, 2015 Profile, Biopharmaceutical Research Industry, 36 fig. 13 (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf 1

PhRMA's Global Efforts, http://www.phrma.org/access/international 26

Tufts Center for the Study of Drug Development & Tufts School of Medicine, Briefing: Cost of Developing a New Drug 5, 18 (Nov. 18, 2014), *available at* http://bit.ly/1NijBFO 19

STATEMENT OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines. PhRMA members have invested approximately $500 billion in discovering and developing new medicines since 2005.[1] PhRMA closely monitors pertinent legal issues and has frequently participated in cases before this Court. The question presented in this case—whether, in light of *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2012), this Court should overrule *Jazz Photo Corp. v. ITC*, 264 F.3d 1094 (Fed. Cir. 2001), to the extent it ruled that a sale of a patented item outside the United States never gives rise to United States patent exhaustion—is of critical importance to the pharmaceutical industry. PhRMA submits this brief in response to the Court's invitation to *amici curiae* to submit their views and pursuant to Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29. No party's counsel authored any part of this brief.[2] No party or

[1] *See* PhRMA.org, 2015 Profile, Biopharmaceutical Research Industry, 36 fig. 13 (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf (last visited Aug. 18, 2015).

[2] A list of PhRMA's member companies resides at: http://www.phrma.org/about/member-companies (last visited Aug. 7, 2015).

other person besides PhRMA contributed money to fund preparation or submission of this brief.

INTRODUCTION

Leaning on flawed analogies to the Copyright Act and a strained reading of *Kirtsaeng v. John Wiley & Sons, Inc*., 133 S. Ct. 1351 (2012), Appellant Impression Products, Inc. ("Impression") and its *amici* urge this Court to overrule *Jazz Photo Corp. v. ITC*, 264 F.3d 1094 (Fed. Cir. 2001). It should not do so. Nothing in the Supreme Court's analysis of the Copyright Act, in its analysis of common-law copyright decisions, or in the policy concerns that underwrote its decision suggests—let alone requires—that this Court turn away from *Jazz Photo* or its other established precedent dictating that the overseas sale of an article protected by a U.S. Patent does not exhaust the patentee's right to enforce the patent to the extent that the item is resold in the United States. To the contrary, the Court's analysis in *Kirtsaeng* was steered by: (1) specific language in the Copyright Act without analogue in the patent statutes; (2) common-law copyright decisions that depart from their patent law counterparts; and (3) policy considerations that simply do not apply in the patent context.

Beyond this Court's interest in following its own precedent and not overruling it lightly, there are compelling practical reasons not to transplant *Kirtsaeng*'s copyright rule into the patent law. Whereas copyright law imposes a monopoly on selling a work that may endure for well over a hundred years, patent law allows for a much briefer period of control, as this Court is well aware. In

order to recoup and continue the extraordinary investment necessary to research and develop patented technology, inventors must be allowed to preclude others from competing against them in selling the claimed invention. Copyrights are more uniformly protected across the world than patents. Inventions protected by U.S. patents are not necessarily similarly protected outside the United States. Therefore, when selling products abroad, U.S. patentees cannot necessarily rely on exclusivity in pricing their products. The mischief threatened by Impression's position is that it would require U.S. innovators either to raise those prices or to abandon those markets altogether.

This mischief is all the more pernicious in the field of life-saving and life-enhancing drugs and treatments. Such products are often the most complex, time-intensive, and expensive to develop and to bring to market. They are also often the most critically important to doctors and consumers in other parts of the world, as well as doctors and consumers in the United States. U.S. patents allow innovators in this space to provide their products to doctors and their patients abroad at a lower price, or indeed for free, without forfeiting their right to enforce their patents against those who would attempt to exploit arbitrage to resell the products in a U.S. "grey market." *Jazz Photo* and its progeny protect these rights. They should not be overruled.

ARGUMENT

I. The Supreme Court In *Kirtsaeng* Did Not Overrule *Jazz Photo*

A. The Court's Analysis Centered On Statutory Language Specific To Copyright

Appellant and many *amici* insist that *Kirtsaeng* imposes a sweeping policy of international exhaustion that applies not only to copyrights, but also to patents. That is not so. *Kirtsaeng* was strictly a copyright case, and the Court's decision was based on the statutory interpretation of a very specific provision in the Copyright Act—one which has no analogue in the patent statutes. Specifically, the Supreme Court was interpreting the Copyright Act's statutory first-sale doctrine, which is codified at 17 U.S.C. § 109(a). That provision, in relevant part, provides as follows:

> Notwithstanding the provisions of section 106 (3), the owner of a particular copy or phonorecord *lawfully made under this title* . . . is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord.

17 U.S.C. § 109(a) (2008) (emphasis added). The defendant, Mr. Supap Kirtsaeng, had imported into and sold within the United States copies of the plaintiff Wiley's text book that Kirtsaeng had purchased abroad. The question before the Court was whether these copies of Wiley's textbooks manufactured and sold abroad were "lawfully made under this title," which would have exhausted the U.S. copyright. If they were not, Wiley could invoke U.S. copyright law to prevent importation into and sale within the United States of these foreign editions.

The *Kirtsaeng* Court ultimately decided that the phrase "lawfully made under this title" contains no geographic limitation of the statutory first-sale provision to products made in the United States. The Court's decision was a specific and nuanced interpretation of the language of the Copyright Act's explicit first-sale provision. In particular, the Court's analysis focused on (1) the evolution of the statutory language in question; and (2) *where* the copies were made (as opposed to where they were sold). Neither of these central considerations from *Kirtsaeng* applies to the common-law doctrine of patent exhaustion.

1. The Text and History Of The Statutory Provisions At Issue In *Kirtsaeng* Have No Analogy In Patent Law

The Court in *Kirtsaeng* analyzed how the statutory language of the copyright first-sale provision had changed over time. Specifically, the Court endeavored to determine whether the addition of the statutory language "*lawfully made under this title*" had introduced a geographical limitation. Because patent law has no analogous statute codifying the first-sale doctrine, *Kirtsaeng*'s analysis of changes to the statutory language of the Copyright Act does not apply to patent law.

Copyright law's first-sale doctrine was first codified in 1909. At that time the statute provided, "nothing in this Act shall be deemed to forbid, prevent, or restrict the transfer of any copy of a copyrighted work *the possession of which has been lawfully obtained*." Copyright Act of 1909, § 41, 35 Stat. 1084 (emphasis added); *see also* Copyright Act of 1947, § 27, 61 Stat. 660. In 1976, Congress

changed the language of the first-sale provision to refer to "*the owner* of a particular copy . . . *lawfully made under this title.*" Looking at this change, the *Kirtsaeng* Court asked "whether Congress, in changing its language implicitly *introduced* a geographical limitation that previously was lacking." 133 S. Ct. at 1360 (emphasis in original). The Court concluded that it did not.

Importantly, the *Kirtsaeng* Court was looking not only at that specific statutory language in the Copyright Act, but also at the language of a prior statute to determine the nature of the statutory change. Patent law has neither an analogous first-sale statute, nor an analogous *predecessor* first-sale statute. The first-sale doctrine in patent law is, and always has been, a matter of common law. The Court's interpretation of the Copyright Act's first-sale provision—and its analysis of changes to the statutory language of the Copyright Act—is thus entirely inapposite.

2. *Kirtsaeng*'s Analysis Focused On Where Copies Were Made And Not Where They Were Sold

The particular question of statutory interpretation in *Kirtsaeng* was whether a foreign-manufactured copy could be "lawfully *made* under this title" as required by the statutory first-sale provision. 17 U.S.C. § 109(a) (emphasis added). Tracking the statutory language, the Court focused on the location of *manufacture*, rather than the location of an authorized *sale*. In contrast, the conduct at issue for purposes of the judicially created doctrine of patent exhaustion is not *making* but

rather *selling*. *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 636 (2008) ("Exhaustion is triggered only by a sale authorized by the patent holder."). Within the "bundle of rights" granted by a patent, the right to sell is distinct from the right to manufacture. *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 875 (Fed. Cir. 1991). The question under the specific common-law doctrine of patent exhaustion is whether a certain item has been *sold*—not manufactured—in a place and manner such that the sale has extinguished the U.S. patent holder's exclusive right to sell the patented product in the United States. Thus, the focus of the Court's inquiry in *Kirtsaeng* is inapplicable to the common-law patent first-sale doctrine.

B. *Kirtsaeng*'s Discussion Of Common Law Does Not Apply Here

Just as *Kirtsaeng*'s analysis of the statutory first-sale provision in the Copyright Act is inapposite in the context of common-law patent exhaustion, so too is *Kirtsaeng*'s review of the common-law first-sale doctrine in the copyright context. ***First***, the Supreme Court omitted from its opinion in *Kirtsaeng* any discussion of patents, patent law, or cases involving the first-sale doctrine in the patent context. Such cases were available, but the Court chose not to rely on them. Instead, the Court focused its discussion only on the common law of copyright exhaustion.

Second, the discussion of the common law in *Kirtsaeng* was limited to a review of the copyright common law leading up to 1909, when Congress first enacted the copyright first-sale statute. The Supreme Court recognized that the common law prior to 1909—in particular, the Court's decision in *Bobbs-Merrill Co. v. Straus*, 210 U.S. 339 (1908)—was relevant to interpreting the meaning of the 1909 first-sale statute. But the Court stopped there, assuming that the 1909 statute was meant to codify the common law as it existed at that point and looked only to statutory changes to the copyright first-sale provision after that point. In contrast, the first-sale doctrine in patent law was never codified, and it has continued to evolve for over one hundred years since the copyright first-sale statute was first enacted in 1909. Thus, the *Kirtsaeng* Court's discussion of the common-law copyright first-sale doctrine prior to 1909 has little, if any, relevance to the common-law evolution of the first-sale doctrine in the patent context.

***Third*,** the common-law cases cited by the Supreme Court in *Kirtsaeng* do not address the issue of international exhaustion, even in the copyright context. For instance, the Court relied heavily on *Bobbs-Merrill*, a case that involved only domestic conduct. The *Kirtsaeng* Court did not claim that *Bobbs-Merrill* addressed international conduct; rather, the Court merely made the observation that "the common-law [copyright first-sale] doctrine makes no geographical distinctions." *Kirtsaeng*, 133 S. Ct. at 1363.

In contrast, both the Supreme Court and this Court have made such geographical distinctions in applying the common-law patent first-sale doctrine. *See Boesch v. Graff*, 133 U.S. 697, 703 (1890); *Jazz Photo*, 264 F.3d at 1105. In *Boesch*, the only Supreme Court case to address exhaustion of U.S. patent rights based on a first sale abroad, the Court held that the lawful foreign first sale did not exhaust the patentee's U.S. patent rights. *Boesch*, 133 U.S.at 703 (finding infringement by articles lawfully acquired in Germany and imported into the United States without the patentee's consent based on the principle that "[t]he sale of articles in the United States under a United States patent cannot be controlled by foreign laws").[3]

It was against this backdrop that this Court decided *Jazz Photo*, which reaffirmed the common-law principle that "United States patent rights are not exhausted by products of foreign provenance…. Imported [products] of solely foreign provenance are not immunized from infringement of United States patents by the nature of their refurbishment." *Jazz Photo*, 264 F.3d at 1105. Three times in the following dozen years this Court reaffirmed that holding. *See Fuji Photo Film Co. v. Benun*, 463 F.3d 1252, 1255–56 (Fed. Cir. 2006) (declining to find

[3] Courts after *Boesch* reaffirmed the general rule against exhaustion of U.S. patent rights based on a first sale abroad. *See, e.g., Daimler Mfg. Co. v. Conklin*, 170 F. 70 (2d Cir. 1909); *Dickerson v. Tinling*, 84 F. 192 (8th Cir. 1897); *Dickerson v. Matheson*, 57 F. 524 (2d Cir. 1893); *Griffin v. Keystone Mushroom Farm, Inc*., 453 F. Supp. 1283 (E.D. Pa. 1978).

Fujifilm's patent rights exhausted by an international sale of its disposable camera product); *Fujifilm Corp. v. Benun*, 605 F.3d 1366 (Fed. Cir. 2010) (rejecting defendants' argument that *Quanta* eliminated the territoriality requirement for patent exhaustion announced in *Jazz Photo* (2001)); *Ninestar Tech. Co. v. ITC*, 667 F.3d 1373 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 1656 (2013) (declining to find international exhaustion notwithstanding *Quanta*). Nothing in the Supreme Court's *Kirtsaeng* decision undermines these cases, let alone overrules them. The limited discussion of pre-1909 common-law *copyright* exhaustion in *Kirtsaeng* is not informative about the common-law doctrine of *patent* exhaustion, which has evolved considerably since copyright exhaustion was codified in 1909. The common-law doctrine of patent exhaustion, in contrast to the Copyright Act's first-sale provision, does not support a regime of international exhaustion of U.S. patent rights.

II. The Differences Between Patent Law and Copyright Law Warrant a Different Outcome with Respect to International Exhaustion

Copyrights and patents are imperfect legal analogies. In fact, the common-law case on which the Supreme Court relied in *Kirtsaeng* contains significant warnings about equating copyright and patent laws. That case, *Bobbs-Merrill*, addressed the exhaustion issue in the copyright context, and the Court there explicitly declined to import into copyright law principles from patent law:

> If we were to follow the course taken in the argument, and discuss the rights of a patentee, under letters patent, and then, by analogy, apply the conclusions to copyrights, we might greatly embarrass the consideration of a case under letters patent, when one of that character shall be presented to this court.

210 U.S. at 345–46. The *Bobbs-Merrill* Court thus specifically acknowledged the often significant differences between the laws of patents and copyrights, and in particular, the varying scopes of protection they provide:

> We may say in passing, disclaiming any intention to indicate our views as to what would be the rights of parties in circumstances similar to the present case under the patent laws, that there are differences between the patent and copyright statutes in the extent of the protection granted by them. This was recognized by Judge Lurton, who wrote a leading case on the subject in the Federal courts (Button Fastener Case, supra), for he said in the subsequent case of [*John D. Park & Sons Co. v. Hartman*]: "There are such wide differences between the right of multiplying and vending copies of a production protected by the copyright statute and the rights secured to an inventor under the patent statutes, that the cases which relate to the one subject are not altogether controlling as to the other."

Bobbs-Merrill, 210 U.S. at 345–46. The significant differences between the laws of patents and copyrights, and the rights provided thereunder, are particularly evident when international activity is considered.

A. Copyright Protection Is Much More Globally Uniform Than Patent Protection

As Appellee and Cross-Appellant Lexmark International, Inc. ("Lexmark") notes in its brief, copyright protection, on an international level, is much more uniform and universal in its operation than patent protection. The Berne

Convention minimized the formalities of securing copyright protection for a creative work. *Golan v. Holder*, 132 S. Ct. 873, 878 (2012) ("Nationals of a member country, as well as any author who publishes in one of Berne's 164 member states, thus enjoy copyright protection in nations across the globe."). Pursuant to the Berne Convention, copyright protection for traditional subject matter—such as textual works, music, and video—is virtually automatic regardless of where an author creates a copyrightable work.

On the other hand, while the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes substantive criteria for securing a patent, there can be country-specific implementation. Patents must be secured in each country where patent protection is desired, and even when an invention is patented in multiple countries, the scope of the claimed invention, the protections afforded by the patent, and the legal mechanisms for determining infringement may vary. Because patent protection and enforcement may vary across borders, it is all the more difficult—indeed, it is virtually impossible—to determine whether a sale abroad fairly may be said to have provided the benefit of, and thus exhausted, an inventor's rights to an invention claimed in a U.S. patent.

B. Patent Law Does Not "Apply Internationally" In The Way The Supreme Court Described Copyright Law In *Kirtsaeng*

In *Kirtsaeng*, the Supreme Court also based its holding on the extraterritorial application of the Copyright Act, noting "that the American Copyright Act is applicable to all pirated copies, including those printed overseas. Indeed, the Act itself makes clear that (in the Solicitor General's language) foreign-printed pirated copies are 'subject to' the Act." *Kirtsaeng*, 133 S. Ct. at 1359. Similarly, the Court explained that the Act would apply extraterritorially to protect a work created abroad "without regard to the nationality or domicile of the author" because "ordinary English permits us to say that the Act 'applies' to an Irish manuscript lying in its author's Dublin desk drawer as well as to an original recording of a ballet performance first made in Japan and now on display in a Kyoto art gallery." *Id*.

Patent law has no such international application. An inventor must apply for a patent in each country desired and meet the requirements of each country's patent laws, although treaties streamline the procedural process. And because patent rights are national, the patent law's presumption against extraterritorial application is particularly strong. *Microsoft Corp. v. AT&T Corp*., 550 U.S. 437, 454–55 (2007) ("The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law."); *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972) ("Our patent system makes no

claim to extraterritorial effect; 'these acts of Congress do not, and were not intended to, operate beyond the limits of the United States' . . . ." (quoting *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 195 (1856))), *superseded by statute*, Patent Law Amendments Acts of 1984, Pub. L. No. 98-622, 98 Stat. 3383 (codified at 35 U.S.C. § 271(f)); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1371 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 900 (2014) ("It is axiomatic that U.S. patent law does not operate extraterritorially to prohibit infringement abroad.").

Although Impression and its *amici* argue that application of the first-sale doctrine abroad is not equivalent to extraterritorial application because the effect is felt in the United States, the Supreme Court has cautioned against sidestepping the presumption against extraterritoriality simply because some domestic activity is involved. *Morrison v. Nat'l Australia Bank Ltd.*, 561 U.S. 247, 266 (2010) ("But the presumption against extraterritorial application would be a craven watchdog indeed if it retreated to its kennel whenever some domestic activity is involved in the case."). In discussing the presumption against extraterritorial application of patent law in *Deepsouth*, the Supreme Court cited its prior decision in *Boesch*, which declined to apply the first-sale doctrine to a patented product that had been lawfully manufactured and purchased abroad:

> Our patent system makes no claim to extraterritorial effect; "these acts of Congress do not, and were not intended to, operate beyond the

> limits of the United States," *Brown v. Duchesne*, 19 How., at 195 (1856), and we correspondingly reject the claims of others to such control over our markets. *Cf. Boesch v. Graff*[.]

Deepsouth, 406 U.S. at 531. Thus, the Supreme Court has explicitly endorsed the presumption against extraterritorial application in the context of the first-sale doctrine in patent law.

III. Policy Considerations Favor Adhering To *Jazz Photo*

In *Kirtsaeng*, the Court noted the possibility of "perpetual" downstream control of copyrighted works not manufactured in the United States. The *Kirtsaeng* Court was particularly concerned that, because the copyright first-sale provision applies only to copies made "under this title," a copyright holder might be able to control indefinitely the distribution and sale of copies manufactured abroad, even after a first sale in the United States. *See Kirtsaeng*, 133 S. Ct. at 1366, 1371. That concern is not applicable to patent law. There is no dispute that the common-law doctrine of patent exhaustion would apply upon the first authorized sale in the United States, even to patented goods manufactured abroad.

In contrast, strong policy considerations militate in favor of adhering to *Jazz Photo's* holding that sale of a patented article abroad does not exhaust the U.S. patentee's rights. In those instances in which a U.S. patentee is not able to obtain equivalent patent protection abroad, prices will likely be significantly lower in those foreign markets. *Jazz Photo* ensures that the products may not be imported

back into the U.S. and sold in competition against the patentee's own products. If it were to be overruled, the U.S. patentee could confront three options: (1) not compete in the foreign market at all; (2) attempt to compete against market forces in that country by selling at a higher price; or (3) sell the patented product in the United States at the same, lower price as sold abroad—thus depriving the patentee of the temporary premium vouchsafed under U.S. patent law. Thus, if a patentee were forced to compete in the United States against its own products sold abroad without protection of its U.S. patent, the economic benefits of that patent would be abrogated.

Even if the U.S. patentee were able to secure a foreign patent in addition to the U.S. patent, there may be differences between the scopes of protections and mechanisms of enforcement under the U.S. and foreign patents. For this reason, sales in a foreign country under a foreign patent may not provide the full benefit to which the patentee is entitled under the U.S. patent. *See Griffin*, 453 F. Supp. at 1287. And as the *Griffin* court observed, an inquiry to determine if there are differing protections or benefits between the U.S. and foreign patents would be both inappropriate and burdensome:

> For us to hold that the United States patent monopoly was destroyed because Carminati took free of the Italian patent monopoly, we believe we would have to determine under defendant's theory that those monopolies were virtually identical or, at least, very similar. Even if we were to accept conceptually that unjust enrichment

> defense, accordingly, we would have to make some inquiry into exactly what the plaintiff had under the Italian patent.

453 F. Supp. at 1286. Any differences in scope or enforcement could lead to the lowest common denominator problem. The patented goods will command the lowest price where foreign patent protection is the weakest, and those lower-cost (but nevertheless authorized) goods can be imported back into the Unites States, undermining the patentee's rights under the United States patent.

IV. Overruling *Jazz Photo* Could Disincentivize U.S. Pharmaceutical Companies From Selling Life-Saving Drugs Abroad

Perhaps nowhere are these policy considerations more evident than with respect to the life-saving and life-enhancing medicines and treatments that PhRMA's members discover, develop, and bring to market. Developing and testing new drugs is incredibly time consuming and expensive. This is because (1) drug discovery involves much trial and error and most candidate drugs do not make it to market, and (2) costs associated with clinical testing and regulatory approval are extremely high. Of the thousands of candidate drugs screened, on average only nine will ever progress to clinical studies in humans and only one will ultimately receive FDA approval. Tufts Center for the Study of Drug Development & Tufts School of Medicine, Briefing: Cost of Developing a New Drug 5, 18 (Nov. 18, 2014), *available at* http://bit.ly/1NijBFO (last visited Aug. 18, 2015). It takes, on average, at least 10 years from the initial discovery of a new

drug to take it through the FDA approval process and make it available to consumers. *Id*. Recent estimates have put the cost of developing and testing a new drug at about $2.6 billion dollars. *See id.*

In view of the high cost of discovering and developing new medicines, the pharmaceutical industry relies heavily on patent protection and the period of exclusivity for its hard earned discoveries. As commenters have pointed out, "[i]f imitators could immediately copy a new invention, competition would force prices down to marginal production cost, and the innovator would not recover the cost of R&D." Patricia M. Danzon, *Pharmaceutical Price Regulation: National Policies Versus Global Interests* 8 (American Enterprise Institute for Public Policy Research ed., 1997). As a result, patent protection is especially critical in the pharmaceutical industry. *See, e.g.*, Henry Grabowski et al., *The Roles of Patents And Research And Development Incentives In Biopharmaceutical Innovation*, 34 Health Affs. 302 (2015) ("Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is long, costly, and risky, and the costs of imitation are low."), *available at* http://bit.ly/1MxiMqW (last visited Aug. 18, 2015); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616–17 (2003) ("The ratio of inventor cost to imitator cost, therefore, is quite large in the

absence of effective patent protection. As a result, it is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."); Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 851 (2002) ("Absent patent protection . . . imitators could free ride on the innovator's FDA approval and duplicate the compound for a small fraction of the originator's costs."); Grabowski, at 853 ("Without a well-structured system of patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, as the rate of new product introductions and patent expirations would decline significantly."); PhRMA & Battelle, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It* 21 (2014) ("[T]he importance of IP protection cannot be overemphasized because it is directly linked to their ability to potentially recoup the significant investments needed for biopharmaceutical R&D and to provide the revenues needed to make up for the many R&D failures and continued investments in the future."), *available at* http://onphr.ma/1fXUbfj (last visited Aug. 11, 2015).[4]

[4] Notably, the pharmaceutical industry already faces decreasing returns from research. *See* Ernst R. Berndt et al., *Decline in Economic Returns from New Drugs Raises Questions About Sustaining Innovations*, 34 Health Affs. 245, 248, 251–52 (Feb. 2015) (noting that "returns on drug development peaked in the late 1990s and early 2000s" and are presently at "their lowest levels in two decades"), *available at*

Footnote continued on next page

A. International Exhaustion Would Change The Balance Congress Has Set Between Promoting Innovation And Free Markets

The United States has made the policy decision, embedded in our Constitution, that innovators should be allowed a limited period of exclusivity via the patent system. *See* U.S. Const. Art. I, § 8, cl. 8; *Bilski v. Kappos*, 561 U.S. 593, 621 (2010) ("Pursuant to its power '[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries,' U.S. Const., Art. I, § 8, cl. 8, Congress has passed a series of patent laws that grant certain exclusive rights over certain inventions and discoveries as a means of encouraging innovation." (alterations in original)). This period of exclusivity is critically important to PhRMA's member companies, who rely on increased revenues during this time in order to recoup the incredible cost of research and development and to incentivize further innovation. Congress has enacted various statutes, including the patent laws, which establish this deliberate balance of national interests. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) ("The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts."). Both this Court and the Supreme Court have long recognized that encouraging

---

Footnote continued from previous page
http://bit.ly/1Em1czQ (last visited Aug. 11, 2015). Such low levels of return may "not be sufficient to sustain medical innovation over the long term." *Id.* at 252.

innovation entails a careful balancing act. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) ("[P]atent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention.") (internal quotation marks and alterations omitted)). Many have argued that this focus on innovation has propelled the U.S. to a world leader in the search for cures to debilitating diseases.

Whereas Congress has attempted through U.S. patent law to encourage invention through economic incentives, many foreign governments make policy decisions to keep the prices of medicines artificially low within their borders, imposing—for instance—price controls on the sale of patented drugs that are sold in the U.S. for higher prices. In so doing, commentators have noted, such governments are arguably taking a "free-ride" on the innovation of other countries, forcing foreign innovators to provide medicines to their citizens at below-market costs. John A. Vernon et al., *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 Am. J.L. & Med. 175, 176 (2006). Overturning *Jazz Photo* would compound the effect of such controls, threatening to impose the artificially lowered prices of foreign markets on the U.S. by, for instance, encouraging the grey market resale of medicines from those markets here. This, in turn, would usurp the policy judgment of the United States to allow

pharmaceutical companies to price in a way that reflects the incentives for innovation provided by the patent system. It would also make it harder (or impossible) for PhRMA's members to recoup the cost of research and development, and to fund future efforts, which they would otherwise attempt to do through increased revenues permitted by patent protection.

This Court has previously recognized the economic and Constitutional dangers of imposing foreign pricing regulations on the domestic economic balance established by Congress. In *Biotechnology Indus. Org. v. Dist. of Columbia.*, 496 F.3d 1362 (Fed. Cir. 2007), this Court found that a District of Columbia statute which forced drug manufacturers to sell their patented drugs at 30% or less of foreign prices was preempted by the federal patent laws. *Biotechnology Indus. Org.*, 496 F.3d at 1374. "The underlying determination about the proper balance between innovators' profit and consumer access to medication," this Court said, "is exclusively one for Congress to make." *Id.* In holding the D.C. statute preempted, this Court agreed with the district court's conclusion that "by allowing foreign drug prices to serve as the benchmark by which excessiveness may be determined in this country, the [District's] City Council is effectively substituting Congress' regulatory scheme for this industry with the regulatory system that has been formulated by these enumerated foreign countries." *Pharm. Research & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56, 67 (D.D.C. 2005).

Such foreign price controls also undermine certain justifications—cited in the context of copyright's first-sale doctrine—for the principle that a sale of a work abroad should exhaust the owner's rights. In *Quality King*, for example, the Supreme Court took a skeptical view of whether the law should protect the copyright holder's "decision to limit its promotional efforts to the domestic market and to sell its products abroad at discounted prices that are so low that its foreign distributors can compete in the domestic market." *Quality King Distribs., Inc. v. L'anza Research Int'l, Inc.*, 523 U.S. 135, 153 (1998). In contrast, a pharmaceutical company subject to foreign price controls is not necessarily making a voluntary decision to lower its prices abroad.

Similarly, justifications for finding exhaustion in the patent context do not apply where foreign prices have been set by government decree. For example, the Supreme Court has that said that a patentee, "[h]aving manufactured the [patented] material and sold it for a satisfactory compensation, . . . has enjoyed all the rights secured to him by his letters patent." *Keeler v. Standard Folding Bed Co*., 157 U.S. 659, 661 (1895) (quoting *Goodyear v. Rubber Co*., 1 Cliff. 348, Fed. Cas. No. 5,557). But where prices are set not by the patentee but by a foreign government, the patentee has not necessarily received "satisfactory compensation" or "enjoyed all the rights secured to him by his letters patent." *Id.*; *see also* Michele L. Vockrodt, *Patent Exhaustion and Foreign First Sales: An Analysis and Application*

of the Jazz Photo Decision, 33 AIPLA Q.J. 189, 200 (2005) ("For example, a first sale that occurred in a foreign market where prices are artificially low due to price controls, or in a developing country where lower economic standards keep prices down, would not be sufficient to justify forcing the patent-holder to give up the more valuable rights under the U.S. patent.").

In addition, PhRMA's member companies have a long history of providing medicines to the developing world at low or no cost. *See* Grabowski, at 857 ("[M]any drug manufacturers have agreed to provide their medicines at cost, and some now provide their products without charge as charitable donations to these countries.").[5] In the case of AIDS drugs, for instance, "even the marginal costs of most AIDS drugs, whether supplied by large pharmaceutical firms or generic entities, far exceed the total per capita health expenditures of these countries . . . [S]ome pharmaceutical firms have an impressive history of in-kind donations to developing countries and this is something that should be encouraged as part of the overall solution to the crisis." *Id.*

Thus, one notably perverse effect of overruling *Jazz Photo* would be to punish drug companies for these socially responsible activities by precluding them from enforcing their patent rights at home against "gray market" importers and

[5] *See also* PhRMA's Global Efforts, http://www.phrma.org/access/international; Global Health Progress Initiative, http://www.globalhealthprogress.org.

resellers. This Court recently held that exhaustion applies to both sales and charitable gifts. *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1375–77 (Fed. Cir. 2013). Without the ability to provide their products at lower prices (or free of charge) in certain countries abroad, "[c]ompanies may rationally choose to abandon small markets that contribute minimally to global revenues rather than accept prices that would pull down the revenues that can be achieved in other, larger markets." Danzon, at 87; *see also* Mainak Mazumdar *et al*., *On Price Discrimination, Parallel Trade and the Availability of Patented Drugs in Developing Countries*, 32 Int'l Rev. L. & Econ. 188, 189 (2012) ("Our findings suggest that price discrimination alleviates the problem of non-availability of a patented drug compared to the uniform pricing strategy."); David A. Malueg and Marius Schwartz, *Parallel Imports, Demand Dispersion, and International Price Discrimination*, 37 J. Int'l Econ. 167 (1994) (finding that without price discrimination "too many markets go unserved").

Alternatively, to eliminate the incentive for the gray market importer or reseller, manufacturers could be encouraged to raise prices in foreign markets to match U.S. prices. And "[i]f governments in these countries are unwilling to pay the higher price, the launch of new products is likely to be delayed or even totally abandoned in these countries, leading to loss of access for consumers to the innovative drugs, although they may be willing to pay a price that covers their

marginal cost." *Id*. These concerns are not merely theoretical, as history has shown. *Id.* (discussing a specific example where a drug manufacturer's "refusal to accept a relatively low price for its new [drug] . . . delayed launch for several years despite marketing approval").

B. The Reliance Of *Amici* On 21 U.S.C. § 381(d) To Address These Concerns Is Unavailing

Certain *amici* argue that pharmaceutical companies have no real concern if *Jazz Photo* is overruled because 21 U.S.C. § 381(d) independently prevents importation of patented pharmaceuticals. *See, e.g.,* LGE Br. 8. In 1988, Congress enacted this special restriction on importation of pharmaceutical products as "American goods returned." *See* Prescription Drug Marketing Act (PDMA), Pub. L. No. 100-293 (Apr. 22, 1988) (codified at 21 U.S. C. § 381(d)(1)). That restriction prohibits any person other than the original manufacturer to import into the U.S. a prescription drug that was originally manufactured in the U.S. and sent abroad. It is part of the Federal Food, Drug, and Cosmetic Act's comprehensive and closed regulatory scheme and was enacted to protect the health and safety of the American public. *See* PDMA § 2 (finding by Congress that "[l]arge amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.").

Section 381(d), however, does not supplant or alter patent rights. As Lexmark points out, § 381(d) is subject to discretionary government enforcement. FDA, Regulatory Procedures Manual § 9-1, -2 (2008). And the government has never brought an action under section 381(d) against a parallel importer that legitimately purchased a drug abroad but then sought to resell it in the United States. As noted above, section 381(d) is addressed to safety rather than patent concerns. Section 381(d) does not abrogate such crucial patent rights as the patentee's private right to sue for damages, including enhanced damages for willful infringement, and to protect its own invention during the term of its patent. If an entity attempts to exploit price differentials (whether imposed by foreign price controls or by disparate regimes of patent law and protection) by attempting to bring drugs purchased abroad into the United States and reselling them here, U.S. companies have the right under patent law to bring an action for damages and for equitable relief. Section 381(d) does not take away these rights and there is no basis for the assertion of certain *amici* that patentees should be forced to rely on the FDA to protect their private rights.

CONCLUSION

For the foregoing reasons, PhRMA as *amicus curiae* respectfully submits that this Court should confirm the holding of *Jazz Photo Corp. v. ITC*, 264 F.3d

1094 (Fed. Cir. 2001) that a foreign sale of an item protected by a United States patent does not exhaust the patentee's rights under the U.S. patent.

Dated: August 19, 2015

Respectfully submitted,

/s/ *John E. Nilsson*

John E. Nilsson
Kristan L. Lansbery
Samuel Drezdzon
ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004
Telephone: (202) 942-5000
Fax: (202) 942-5999

Willow White Noonan
ARNOLD & PORTER LLP
Three Embarcadero Center
San Francisco, CA 94111
Telephone: (415) 471-3100
Fax: (415) 471-3400

Counsel for amicus curiae
Pharmaceutical Research and Manufacturers of America

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of August, 2015, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served on all counsel of record via electronic delivery through the Court's CM/ECF system.

/s/ *John E. Nilsson*
John E. Nilsson

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(d). The brief contains **6,525** words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

/s/ *John E. Nilsson*
John E. Nilsson