In the

## Supreme Court of the United States

IMPRESSION PRODUCTS, INC.,

Petitioner,

v

LEXMARK INTERNATIONAL, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

### AMICUS CURIAE BRIEF OF THE ASSOCIATION OF MEDICAL DEVICE REPROCESSORS IN SUPPORT OF IMPRESSION PRODUCTS, INC.

ROBERT A. SURRETTE

Counsel of Record
CHRISTOPHER M. SCHARFF
McAndrews, Held, and Malloy, Ltd.
500 West Madison Street, Suite 3400
Chicago, Illinois 60661
(312) 775-8000
bsurrette@mcandrews-ip.com

Counsel for Amicus Curiae Association of Medical Device Reprocessors

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### INTEREST OF THE AMICUS CURIAE<sup>1</sup>

The Association of Medical Device Reprocessors ("AMDR") is a trade organization consisting of member companies that reprocess medical devices. Member companies collect, clean, repair, and re-sterilize (among other steps) discarded medical devices that can safely be reused pursuant to Food and Drug Administration (FDA) regulations. The devices that AMDR member companies reprocess include used cardiovascular, patient monitoring and compression therapy, general surgery, and orthopedic devices, as well as opened but unused devices. AMDR member companies provide hospitals with safe and effective reprocessed devices, which lower healthcare costs and reduce the impact of medical waste on the environment.

The FDA regulates companies that market medical devices in the United States, including medical device reprocessors.aBefore a reprocessed medical device can be marketed or sold, a third-party reprocessor must demonstrate—and the FDA must agree—that the reprocessed device is substantially equivalent in

<sup>1.</sup> No party or its counsel authored this brief in whole or in part, or contributed money to fund preparing or submitting this brief. No person or their counsel, other than the *amicus* party or its members (Stryker Sustainability Solutions, Inc., a whollyowned subsidiary of Stryker Corporation, Medline ReNewal, Innovative Health, Vanguard AG, and Hygia Health Services), contributed money intended to fund preparing or submitting the brief. Respondent Lexmark International, Inc. filed a letter of blanket consent to *amici*. Petitioner Impression Products, Inc. granted consent to *amicus curiae* AMDR on January 5, 2017 via electronic mail, a copy of which is being submitted herewith.

terms of safety and efficacy to the predicate originally-manufactured device. A third-party reprocessor must comply with the same requirements that apply to original equipment manufacturers, including:

- Registering all reprocessed products;
- Obtaining premarket clearance or approval;
- Verifying compliance with FDA's quality system regulation;
- Submitting adverse event reports;
- Tracking devices whose failure could have serious outcomes;
- Correcting or removing from the market unsafe devices;
- Meeting manufacturing and labeling requirements; and
- Submitting the reprocessing facilities to regular inspection.

The savings realized through the use of reprocessed single-use devices allows hospitals and healthcare providers to cut costs significantly and redirect those funds toward hiring more medical professionals or improving patient care. Many of the hospitals with whom AMDR members work are able to save more than \$1 million annually by purchasing AMDR members' reprocessed single-use devices. Smaller community hospitals report saving more than \$250,000 annually.

The reprocessing services offered by AMDR members also have a drastic positive effect on the environment. AMDR members help hospitals divert millions of pounds from local landfills per year. On average, medical device reprocessing can divert over 50,000 pounds of medical waste from a single hospital each year—the equivalent weight of more than five elephants. Regulated medical waste, also known as "red bag" waste, costs up to 5-10 times more to dispose of than regular solid waste.

The Federal Circuit's decision, however, would significantly erode or erase medical device reprocessing. If an original manufacturer can avoid the patent exhaustion/first sale doctrine simply by including a "single-use" restriction with the sale of a patented product, then reprocessors of such devices would risk liability for patent infringement. A manufacturer could force consumers, including the hospitals served by AMDR members, to purchase a new replacement device from the manufacturer and to dispose of devices that have only been used once or opened but unused.

Similarly, if foreign sales do not trigger U.S. patent exhaustion, manufacturers would be able to exact multiple payments for a single sale of a product (e.g., when it is originally sold abroad and again when imported or sold into the U.S.) or engage in more aggressive discriminatory pricing. If the Court does not reverse the decision of the Federal Circuit, healthcare costs will multiply, medical waste will pile up, and competition in the medical device market will be reduced.

AMDR, therefore, seeks to provide this Court with the perspective of an industry impacted by the decision in this case. Specifically, AMDR submits this *amicus curiae* brief in support of Petitioner Impression Products, Inc. to address both Questions Presented.

#### SUMMARY OF ARGUMENT

For over 150 years, the law has encouraged the right of consumers to reprocess, repair, recycle, or resell their property as they see fit—free from any restrictions on downstream use that might otherwise be attached to those products. This principle, also referred to as a prohibition against "restraints on alienation" or restraints that "run with chattels," is deeply rooted in our common law.

This principle manifests itself in patent law as the patent exhaustion doctrine—a defining boundary of the limited monopoly afforded by a patent. Under this doctrine, the first authorized sale of a patented product exhausts the patentee's rights. Put another way, after title of a patented product passes to a purchaser through a sale authorized by the patentee, the patentee cannot thereafter use patent law to control how that product is subsequently used, recycled, resold, or repaired. As this Court has recognized, "the purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward . . . by the sale of the article"; once that "purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold." United States v. Univis Lens Co., 316 U.S. 241, 249-50 (1942).

The patent exhaustion doctrine makes secondary markets for reprocessed or refurbished patented goods possible—secondary markets that are good for commerce, competition, and the public. In particular, the medical device reprocessing industry provides affordable alternatives to new patentee-controlled medical devices. It also provides beneficial competition resulting in lower prices for new devices. Reprocessed medical devices save hospitals hundreds of millions of dollars per year along with eliminating millions of pounds of medical waste per year. Meanwhile, reprocessed devices are just as tightly regulated by the FDA as new devices and just as safe.

Until the Federal Circuit's en banc decision in this case, it was widely understood that the patent exhaustion doctrine protected medical device reprocessing. In particular, an original equipment manufacturer ("OEM") could not use the threat of patent infringement to prohibit a third-party reprocessing company from reselling a product after the patentee willingly parted with it via an authorized first sale. A 1992 Federal Circuit panel decision to the contrary (Mallinckrodt, Inc. v. Medipart, Inc., 976) F.2d 700 (Fed. Cir. 1992)) did not change this view—that decision was understood to be decided incorrectly and not good law. Subsequently, this Court reinforced the view that any authorized sale triggers patent exhaustion (Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008)). Most commentators and several district courts believed definitively that Quanta overruled Mallinckrodt.

The Federal Circuit's *en banc* decision in this case, however, up-ends the over 150 years of law protecting secondary markets. It effectively eliminates the patent exhaustion doctrine through two exceptions that swallow the rule.

First, the Federal Circuit incorrectly held that a patentee can include post-sale restrictions in a sales contract to opt out of patent exhaustion for U.S. sales (what it termed a "conditional sale"), reaffirming its decision in *Mallinckrodt*. Whereas the Supreme Court had articulated patent exhaustion as a bright-line limit on a patentee's ability to control post-sale use of a patented product, the Federal Circuit's decision makes patent exhaustion an optional result for sales in the United States. The Federal Circuit's holding, however, directly contradicts this Court's repeated articulation of the patent exhaustion doctrine. As recently as Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008), this Court recognized that any sale authorized by the patent holder triggers patent exhaustion. See, e.g., id. at 638. The Federal Circuit bases its contrary holding on misinterpretations of Supreme Court precedent, misapplications of Title 35 of the U.S Code ("the Patent Statute"), and/or misperceived non-existent policy or practical concerns.

Second, the Federal Circuit carved out another exception to patent exhaustion in connection with foreign sales, reaffirming its decision in Jazz Photo Corp. v. International Trade Commission, 264 F.3d 1094 (Fed. Cir. 2001). The Federal Circuit held that no sales made outside of the U.S., even if authorized by the patentee, trigger patent exhaustion. Under this standard, a patentee is free to dictate how a product that it first willingly sold abroad can be subsequently used, reused, or resold domestically. This result, however, similarly misapprehends Supreme Court precedent. In particular, this Court reached the opposite holding in Kirstaeng v. John Wiley & Sons, Inc., 133 S. Ct. 1351 (2013), in the copyright exhaustion context. The Federal Circuit ignored

that the general common law rule against restraints on alienation makes "no geographical distinctions" (133 S. Ct. at 1363), and the Federal Circuit illogically and incorrectly distinguished the holding of *Kirstaeng*.

In short, the Federal Circuit's decision creates just the sort of "end-run" around patent exhaustion that this Court has expressly prohibited. *See Quanta*, 553 U.S. 617 at 630 ("This case illustrates the danger of allowing such an end-run around exhaustion.") (emphasis added). If allowed to stand, the Federal Circuit's decision will allow patent holders to do the very thing that patent exhaustion prohibits—control downstream use and resale or else enrich themselves by demanding second, third, or fourth license fees in excess of the patent reward.

Further, the Federal Circuit overlooked many practical problems with its ruling. New information costs alone (e.g., the cost of investigating whether a product is covered by patents, whether any conditions or restrictions on resale, reuse, etc. were included in the original sales contract, and where the product was first sold (U.S. or abroad)) may drive many secondary market companies out of business and eliminate the benefits of competition to consumers. A reprocessing company would no longer be able to rely just on proof of an authorized first sale to end all patent concerns. The reprocessing company would have to undertake that investigation for each individual item—because it would be possible for the OEM to change its sales contracts at any time.

Even if a reprocessing company is able to bear such costs, any such investigations would be rife with uncertainties. Among other things, consumers and reprocessing companies targeted by these post-sale restrictions may have no way of knowing whether postsale restrictions exist (such as in this case, where only Lexmark's packaging—and not its product—was labeled with a single-use-only designation). Even if a product itself contains an embossed single-use-only indication, a third party reprocessor may have no way of knowing whether it reflects just a mere warning (that does not trigger exhaustion) or whether it reflects a condition in the actual original sale contract. Moreover, if the reprocessing company is unable to ascertain definitively that a product does not have a post-sale "restriction" attached to it, it may be unwilling to take the risk of investing in a reprocessing effort just to have an OEM later send a cease-and-desist letter with "notice" of a restriction to bar future sales.

Reaffirming a bright-line scope of patent exhaustion avoids all of the problems with the Federal Circuit's test. It recognizes the importance of the common law rule against restraints on alienation. It is consistent with Supreme Court precedent. And it is best for commerce, consumers, the environment, and the public.

### **ARGUMENT**

# I. A BROAD PATENT EXHAUSTION DOCTRINE IS GOOD FOR COMMERCE

### A. Reprocessed Medical Devices Promote Competition, Reduce Waste, and Lower Medical Costs

1. The secondary market for goods, and reprocessed medical devices in particular, is a significant industry. Most of the nation's 5,500 or so acute care hospitals have implemented reprocessing programs, and this number has grown every year. AMDR's members reprocess medical devices for all of the 20 hospitals recognized on the *US News & World Report* "Honor Roll," including Mayo Clinic, Cleveland Clinic, Johns Hopkins, Massachusetts General, Stanford Healthcare and many others. Analysts, such as Transparency Market Research, estimate that the total savings to all hospitals from reprocessing is upwards of \$500 million per year.

In 2012, the Commonwealth Fund, with support from Health Care Without Harm and the Robert Wood Johnson Foundation, extrapolated existing data regarding reprocessed medical device usage to estimate that, if adopted nationwide, single-use device (SUD) reprocessing cost savings would amount to \$540 million annually or \$2.7 billion over five years.

The Healthier Hospitals Initiative, an alliance of hospitals and health systems that seeks to boost sustainability in healthcare, released a report in April 2013 finding that its 185 hospitals saved \$32 million

in 2012 by reprocessing single-use medical devices. And Tenet Healthcare Corp. reported saving \$9.4 million and diverting more than 1.5 million pounds of medical waste from landfills in 2012. For that reason, customers of AMDR's members have described medical device reprocessing as "the right thing to do, both environmentally and economically." See http://www.beckershospitalreview.com/supply-chain/the-ins-and-outs-of-third-party-reprocessing.html (last visited January 5, 2017). The American Nurses Association, Association of Peri-Operative Nurses, Healthcare Without Harm, and Practice Greenhealth have also all written in support of the environmental benefits of single-use device reprocessing. See http://www.amdr.org/environmental/ (last visited January 5, 2017).

2. Even the FDA has recognized the significant benefits of reprocessed medical devices. The FDA has cleared approximately 252 single-use medical devices for reprocessing. The FDA appreciates that "[r]eprocessing and reusing single-use devices (SUDs) can save costs and reduce medical waste." FDA Device Advice: Comprehensive Regulatory Assistance, Reprocessing of Single-Use Devices, http://www.fda. gov/MedicalDevices/DeviceRegulationandGuidance/ Reprocessing of Single-Use Devices (last visited January 9, 2017). Agency testimony to Congress on the issue also indicated that hospitals "responded overwhelmingly that they view the use of reprocessed SUDs as providing a significant cost savings to their facilities and as being an environmentally sound practice." See, Testimony of Dr. Daniel Schultz, http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121067.htm (last visited January 5, 2017).

### B. Patent Exclusion Power is Not Needed as a Policy Matter to Ensure that Reprocessed Medical Devices are Safe

The Federal Circuit based its ruling, in part, on a misguided policy finding regarding the safety of reprocessed medical devices. Without citing to any evidence, the Federal Circuit majority concluded that enforcing post-sale restrictions through patent law allegedly makes sense because, for example, a medical device supplier may have "reason to believe that reuse, when not under its own control, carries a significant risk of poor or even medically harmful performance, to the detriment of its customers and its own reputation." See Pet. App. at 60a-61a. According to the Federal Circuit's unsupported speculation, "[s]uch interests are hardly unrelated to the interests protected by the patent law the interests both of those who benefit from inventions and of those who make risky investments to arrive at and commercialize inventions." Id. at 61a. The Federal Circuit's finding in this regard, however, has no factual basis.

1. The Federal Circuit failed to recognize that the FDA itself ensures that reprocessed devices comply with the "same regulatory framework as original equipment manufacturers (OEM)s." See Testimony of Dr. Daniel Schultz, http://www.fda.gov/MedicalDevices/Device RegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121067.htm (last visited January 5, 2017). The FDA's former Director of the Center for Devices and Radiological Health has therefore recognized that the "FDA believes that reprocessed SUDs [single-use devices] that meet FDA's regulatory requirements are as safe and effective as a new device." Id. (emphasis added).

In fact, the "pre-market submission of data to the Agency [for clearance of a reprocessed device] ... exceed[s] the requirements for OEMs." *Id.* (emphasis added). That is because in 2002, Congress enacted the Medical Device User Fee and Modernization Act ("MDUFMA"), which provides in § 302 additional specific regulatory requirements for reprocessed single-use devices, including that a reprocessor must:

- "prominently and conspicuously" label the device as reprocessed;
- allow the FDA to review devices previously exempted from FDA 510(k) clearance; and
- submit a new, additional category of premarket submission—the premarket report—for any reprocessed Class II device.
- 2. There is nothing inherently unsafe in reprocessing a device that an original manufacturer chose to designate as single use only. The decision to put a "single use" label on a device's packaging is made by the original manufacturer—not the FDA. A manufacturer typically makes that label designation to avoid having to submit evidence supporting re-use to the FDA. See U.S. Government Accountability Office, GAO-08-147, Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate that Use Presents an Elevated Health Risk (Jan. 2008), available at http://www.gao.gov/products/GAO-08-147 (last visited January 5, 2017).

3. In any event, this Court long ago resolved the proper policy balance between a patentee's interest in using patent law to control the use of an invention versus the public's interest in using their purchased property as they see fit. That is the very origin of the patent exhaustion doctrine. See, e.g., Bloomer v. McQuewan, 55 U.S. 539, 14 How. 539, 549, 14 L. Ed. 532 (1853) ("[W]hen the machine passes to the hands of the purchaser, it is no longer within the limits of the monopoly."); *Motion* Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 518 (1917) (observing that "the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is 'to promote the progress of science and useful arts"). Regardless of the patentee's purported motivation for wanting to control downstream use (whether for safety or otherwise), and regardless of whether the patented product is a reprocessed medical device, refurbished smartphone, or replacement part for an automobile, the same policy stands.

### C. Reprocessing Companies Have Long Operated Under the Understanding That Post-Sale Restrictions Cannot Avoid Patent Exhaustion

1. Secondary market companies (and reprocessing companies in particular) have long operated with the understanding that their industry is protected by the law—that the doctrine of patent exhaustion encourages repair, reprocessing, recycling, and reuse of patented products. See, e.g., Amber Hatfield Rovner, Practical Guide to Application of (or Defense Against) Product-Based Infringement Immunities Under the Doctrines of Patent Exhaustion and Implied License, 12 Tex. Intell. Prop. L.J. 227, 269-270 (2004) ("The prevailing view is

that the distinction between permitted and prohibited activities, with respect to patented items after they have been placed in commerce by an authorized source, has been distilled into the terms 'repair' and 'reconstruction.' The law recognizes the right of the purchaser to 'repair' a lawfully acquired product . . . .").

2. These companies did not believe that *Mallinckrodt* changed the law when it was decided in 1992. Rather, it was believed that *Mallinckrodt* was wrongly decided, as it contradicted earlier precedent of this Court. *See*, e.g., Richard H. Stern, *The Unobserved Demise of the Exhaustion Doctrine in US Patent Law*, 15 Eur. Intel. Prop. Rev. 460-65 (1993) ("The flaws in *Mallinckrodt's* legal analysis appear overwhelming. . . . Because *Mallinckrodt's* precedential support is negligible, its viability as a precedent may be limited. Subsequent panel decisions may distinguish it or limit it to its facts to the point of irrelevance.") (emphasis added).

One article soon after *Mallinckrodt* described the following from discussions with corporate patent counsel:

Their fear was that *Mallinckrodt* might not endure as a new rule of law because its support as precedent seems fragile or shaky. Courts may distinguish it and confine it narrowly to its facts. The Federal Circuit may ignore its ruling in subsequent cases. Hence, counsel who recommended aggressive business strategies based on *Mallinckrodt* might later be embarrassed by a judicial retreat from it and a return to the exhaustion doctrine.

Richard H. Stern, Post-Sale Patent Restrictions After Mallinckrodt—An Idea In Search of Definition, 5 Alb. L. J. Sci. & Tech. 1, 9 (1994).

3. Most observers, moreover, agreed that Quanta definitively overruled Mallinckrodt in 2008. See Alfred C. Server and William J. Casey, Contract-Based Post-Sale Restrictions on Patented Products Following Quanta, 64 Hastings L.J. 561, 596 (Apr. 2013) (stating that "a majority of commentators" have adopted the view that Quanta overturned the conditional sales doctrine); Herbert Hovenkamp, Innovation and the Domain of Competition Policy, 60 Ala. L. Rev. 103, 111 & n.35 (2008) (believing Quanta overruled Mallinckrodt); Thomas G. Hungar, Observations Regarding the Supreme Court's Decision in Quanta Computer, Inc. v. LG Electronics, Inc., IDEA—The Intellectual Property Law Review, Vol. 49, No. 4 (June 7, 2009) at 529-30 (same).

Likewise, numerous lower court judges determined that Quanta overruled Mallinckodt. See, e.g., Ergowerx Int'l, LLC v. Maxell Corp. of Am., 18 F. Supp. 3d 430, 449 (S.D.N.Y. 2014); Lexmark Int'l, Inc. v. Ink Techs. Printer Supplies, LLC, 2014 WL 1276133, \*\*6-7 (S.D. Ohio Mar. 27, 2014); JVC Kenwood Corp. v. Arcsoft, Inc., 966 F. Supp. 2d 1003, 1010 n.1 (C.D. Cal. 2013); Intergraph Hardware Techs. Co. v. Dell, Inc., 2009 U.S. WL 166559, \*3 (E.D. Tex. Jan. 16, 2009).

Accordingly, the status quo has not, as the Federal Circuit majority and Lexmark incorrectly assert, been one where companies have operated under *Mallinckrodt's* "conditional sale" exception to patent exhaustion. Should this Court decline to reverse the Federal Circuit's

sweeping *en banc* decision, however, post-sale restrictions will undoubtedly become far more common. Secondary markets for medical devices, cell phones, home electronics, automotive parts, and other goods may very well largely disappear. *See infra* at § II.A.

# II. THE FEDERAL CIRCUIT'S NARROWED PATENT EXHAUSTION DOCTRINE WOULD HARM COMMERCE

If this Court finds that the *en banc* Federal Circuit ruled correctly, then both the patent exhaustion doctrine and the common law against restraints on alienation would be eviscerated.

1. Under the Federal Circuit's "conditional sale" exception to patent exhaustion, a patentee is able to dictate the terms of any sales and uses of a patented product, including all downstream instances. All a patentee has to do to dictate such terms and uses is include a post-sale restriction in the purchase agreement. Many direct purchasers will likely agree to (or not notice or dispute) such post-sale restrictions in the sales contract as they may not be affected directly by them or may receive some consideration in return. The secondary market—the reprocessing, repair, recycling, and resale companies that did not agree to the restrictions and received no consideration for them—would be the real entities impacted by such post-sale restrictions.

Indeed, if the Federal Circuit's "conditional sale" test is taken to its logical conclusion, a patentee could avoid patent exhaustion on its own accord by placing a "clearly communicated" provision in every sales contract stating that "THIS SALE DOES NOT TRIGGER PATENT EXHAUSTION." A patentee would then be able to use the threat of patent infringement liability to either prohibit reuse/resale entirely or to extract second, third, or fourth license fees. The patentee could raise that threat against not only reprocessing or resale companies, but even ordinary consumers. The Federal Circuit's rule could lead to a slippery slope where a consumer could be liable for patent infringement by, for example, selling a used car or even having a garage sale.

2. The Federal Circuit's second ruling—that authorized foreign sales do not result in patent exhaustion—would also significantly disrupt secondary markets and harm consumers if it is allowed to stand. At the same time, it would only enrich patent holders by allowing them to demand multiple payments on a single tangible good after it is sold, or to enforce country-by-country price discrimination.

For example, a medical device reprocessor could face allegations of patent infringement if it were to bring foreign-sold medical devices into the U.S. to reprocess those devices in a U.S. reprocessing facility. Even if the U.S. reprocessor intends to simply take devices from the original authorized foreign purchaser, send them to the U.S. to reprocess them as a service for the owner, and send them back to the original purchaser, that act of importation could expose the reprocessor or original purchaser to infringement liability. See 35 U.S.C. § 271 (importing a patented good can be an act of infringement). Therefore, such a U.S.-based reprocessor—who otherwise performs mere reprocessing-for-hire services, would now have to trace the patent rights of every individual

product and every separately-sourced component of those products. Or, the U.S.-based reprocessor would have to set up duplicative and wasteful reprocessing facilities around the globe.

The Federal Circuit's decision would also result in higher costs for medical devices in the United States. A U.S.-based reprocessor who engages in the business of buying lower-cost medical devices overseas for resale in the U.S. would be exposed to increased risk of patent infringement allegations. Meanwhile, the patentee could potentially charge a lower price outside of the U.S. for a device, but a much higher price for sales in the United States. A U.S. hospital or other consumer would be unable to buy the products at a lower price outside of the U.S. and import them for use.

3. Both parts of the Federal Circuit's ruling would also harm commerce by driving up information costs for remaining permissible secondary markets, namely the costs associated with investigating potential liability risk. See, e.g., Molly Shaffer Van Houweling, The New Servitudes, 96 Geo. L.J. 885, 915 (2008) ("Refusal to enforce chattel servitudes avoids adding an extra level of informational complexity to what might otherwise be relatively simple and fluid commerce"); Samuel F. Ernst, Patent Exhaustion for the Exhausted Defendant: Should Parties Be Able to Contract Around Exhaustion in Settling Patent Litigation?, 2014 U. Ill, J.L. Tech. & Pol'y 445, 472 (describing information costs that would be involved without patent exhaustion).

Before the Federal Circuit's ruling, a repair/ refurbishment company did not need to investigate whether a product it was reselling was covered by any patents owned by or licensed to the product's OEM. The issue was moot—even if the product was covered by such a patent, any patent rights were exhausted by the first authorized sale. A repair/refurbishment company also did not have to investigate the terms of the original sales contract—because it was not a party to that contract, any "conditions" in the contract were inapplicable to it. Further, the repair/refurbishment company did not have to determine if the product's first sale occurred in the U.S. or abroad—it did not matter for exhaustion. If postsale restrictions in a sales contract can be enforced on third party repair/refurbishment companies, however, then those companies would have to undertake such investigations in every instance or else risk potential patent infringement. For many secondary market companies, these information costs could be unbearable, driving them out of business.

4. The Federal Circuit's "conditional sale" exception would also likely be unworkable as a practical matter. In many instances, a downstream purchaser will have no way of knowing the terms of the original sale contract, or be able to distinguish between a "condition" that runs with the patented good versus a mere instruction or label warning.

The Federal Circuit's *en banc* decision partly recognized this concern and tacked onto its "conditional sale" exception a requirement of "notice" to all purchasers, including "downstream buyers." *See* Pet. App. at 62a-63a. The Federal Circuit, however, provided no guidance as to what would constitute "notice" of a "clearly communicated" restriction to downstream purchasers—it expressly declined to do so. *See* Pet. App. at 14a.

The Federal Circuit's own precedent, meanwhile, reveals several problems with its "notice" requirement. For example, the Federal Circuit had previously held in *Jazz Photo* that only post-sale restrictions in a sales contract can constitute "conditions" that would avoid patent exhaustion. Merely putting "instructions and warnings" on packaging stating that a product is "for single use only" is insufficient, because mere labeling cannot constitute a contract and thus a condition on the sale. *See Jazz Photo Corp. v. ITC*, 264 F.3d 1094, 1108 (Fed. Cir. 2001) ("We do not discern an enforceable restriction on the reuse of these cameras based on the package statements [stating that the cameras were for single use]. These statements are instructions and warnings of risk, not mutual promises or a condition placed upon the sale.")

Yet the *Jazz Photo* holding contradicts the very facts of *Mallinckrodt*. In that case, the only "notice" that a downstream purchaser (Medipart) had of the "single use only" restriction was a label on the product—not notice of the actual sales agreement with the original customer/hospital. *See Mallinckrodt*, 976 F.2d at 702.

This begs the question, then—how can a third party ever know whether a "notice" on a product or its labeling was (a) an actual contractual limitation that precludes patent exhaustion, or (b) a mere "instruction" or "warning" that does not? And if a product includes only a mere label warning, how is a third party purchaser to know what terms might be in the original sales contract?

This uncertainty may in many instances effectively put an impossible burden on third party reprocessing companies. If a reprocessing company is unable to definitively ascertain that there is *not* a post-sale restriction in the original sale contract, can the company take that risk? It may be unwilling to invest in reprocessing and reselling a product line, just to later receive "notice" from the OEM of a previously-unknowable condition in the original sales contract (to which it was not a party). While the past sales without "notice" may be protected, it is unclear under the Federal Circuit's decision whether an OEM can use such a cease-and-desist letter to preclude future sales.

5. The Federal Circuit's ruling that patent exhaustion does not apply to goods that a U.S. patentee sells abroad raises even more practical problems. Even if it is located in the U.S., a downstream purchaser may often have no way of knowing whether the first authorized sale of a product occurred in the U.S. or not. Under the Federal Circuit's decision, however, the downstream purchaser's knowledge of whether a first sale was made in the U.S. or abroad is irrelevant. The fact that a product was first sold abroad does not even need to be "clearly communicated" to a downstream purchaser in order to avoid patent exhaustion. See Pet. App. at 63a-103a.

The bright-line patent exhaustion doctrine of *Quanta* and the bright-line rule of *Kirstaeng* against geographical distinctions on restraints against alienation remove all of this uncertainty. They strike the proper balance between patentee and purchaser rights and relegate contract disputes to their proper place.

### III. THE FEDERAL CIRCUIT'S HOLDING THAT PATENTEES CAN OPT OUT OF DOMESTIC PATENT EXHAUSTION IS ERRONEOUS

### A. The Supreme Court Has Repeatedly Held that Any Authorized Sale, Regardless of Post-Sale Restrictions, Triggers Patent Exhaustion

The Federal Circuit's "conditional sale" exception to patent exhaustion contradicts 150 years of Supreme Court precedent. While the Federal Circuit described its "conditional sale" exception as fitting within the seams of this Court's prior cases, it would in fact upend those cases and create an end-run around patent exhaustion that could swallow it entirely.

1. Since 1853, this Court has recognized a fundamental limit on the scope of patent rights. Once a patentee authorizes a sale of a patented product, that article "passes outside" the patent's coverage "and is no longer under the protection of the act of Congress." *Bloomer v. McQuewan*, 55 U.S. 539, 549-550 (1853) (emphasis added). Ever since then, the Court has repeatedly reaffirmed this doctrine of patent exhaustion from a first authorized sale.

In *Hobbie v. Jennison*, the Court explained that patent exhaustion is premised on the concept that the "reward" to which a patentee is entitled is the compensation for which he (or one acting with his authority) first parts with title. 149 U.S. 355, 361-363 (1893). A few years later, the Court reiterated that after a first authorized sale, a patentee cannot enforce downstream restrictions on the use of a patented article "under the inherent meaning and effect of the patent laws." *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666 (1895).

In Motion Picture Patents Co. v. Universal Film Manufacturing Co., the Court reiterated that "the right to vend is exhausted by a single, unconditional sale, the article sold being thereby carried outside the monopoly of the patent law and rendered free of every restriction which the vendor may attempt to put upon it." 243 U.S. 502, 516 (1917). In that case, a patentee attempted to impose a post-sale restriction on patented film machines, dictating that the machine could only be used with certain motion picture film reels. See id. at 516. The patentee sued Universal Film (who was not a party to any contract with the patentee) for alleged patent infringement based on its sales of unauthorized film reels to users of the patented machines. The Court held that the post-sale restriction was void—the initial authorized sale by the licensee exhausted the patents. See id. at 516.

Later, in *United States v. Univis Lens Co.*, 316 U.S. 241 (1942), the Court again relied on patent exhaustion in concluding that post-sale restrictions could not be enforced via patent law. There, the patentee had attempted to control retail prices of its patented lenses. The Court found that patent exhaustion precluded the post-sale restriction; that "the purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward for the use of his invention by the sale of the article . . . once that purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold." *Id.* at 251.

2. The Supreme Court's patent exhaustion case law culminated in the recent *Quanta* decision. *See* 553 U.S. 617, 638. In *Quanta*, the Court reaffirmed a patent exhaustion standard that is both broad and simple: "[T]he

authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and <u>prevents the patent holder from invoking patent law to control postsale use of the article." *Id.* at 638 (emphasis added).</u>

3. The Supreme Court's patent exhaustion cases have addressed the very issue raised by the Federal Circuit's *en banc* decision in this case—whether a "conditional sale" avoids patent exhaustion.

Namely, for a short time in the early 1900's, post-sale restrictions such as the one at issue in this case were found to avoid patent exhaustion. See Henry v. A.B. Dick Co., 224 U.S. 1, 24-25 (1912) ("[I]f the right of use be confined by specific restriction, the use not permitted is necessarily reserved to the patentee. If that reserved control of use of the machine be violated, the patent is thereby invaded."). Although A.B. Dick used the term "specific restriction" rather than the Federal Circuit's term "conditional sale," the concept was the same—a patent holder could, notwithstanding patent exhaustion, put conditions on post-sale use that, if violated, would result in patent infringement. See id. at 24-25.

The Supreme Court, however, soon overruled *A.B. Dick*. Just a few years later in *Motion Picture Patents*, the Court held that post-sale restrictions *cannot* be used to prevent patent exhaustion. 243 U.S. 502, 518 (1917). The Court expressly held that *A.B. Dick* "must be regarded as overruled." *Id.* at 518. In particular, the Court explained that the "defect in [*A.B. Dick*'s] thinking" was its "failure to distinguish between the rights which are given to the inventor by the patent law . . . and rights which he may create for himself by private contract." *Id.* at 514.

As one commentator pointed out, "the Federal Circuit's subsuming of patent exhaustion in antitrust [in *Mallinckrodt*] is identical to *A.B. Dick*'s discredited ruling." Douglas Fretty, *Both a License and a Sale: How to Reconcile Self-Replicating Technology With Patent Exhaustion*, 5 J. Bus. Entrepreneurship & L. 1 (2011).

### B. The Federal Circuit's and Lexmark's Rationales for a "Conditional Sale" Exception to Patent Exhaustion Are Erroneous

Notwithstanding the broad holdings of *Motion Picture Patents*, *Univis* and *Quanta*, the Federal Circuit rationalized an exception to the patent exhaustion doctrine—that a "conditional" sale subject to otherwise lawful post-sale restrictions would not trigger exhaustion. *See* Pet. App. at 20a-63a. But the Federal Circuit's reasoning is flawed. The Federal Circuit's exception would in fact eliminate the very purpose of patent exhaustion and cannot be reconciled with Supreme Court precedent.

1. A key error in the Federal Circuit majority's decision was its incorrect reading of the Patent Statute. The Federal Circuit read the Patent Statute to suggest that the *very doctrine of patent exhaustion itself should not exist. See* Pet. App. at 20a-25a. Namely, 35 U.S.C. §§ 271(a) and 154(a)(1) empower a patent holder to exclude use of a patented invention that is "without authority." *See id.* The Federal Circuit read this language to mean that even after a product is sold, a patentee should be able to control any subsequent or downstream use that is made "without authority" of the patentee. *See id.* 

As the Federal Circuit dissent explained, however, "[t]hat reliance is misplaced." Pet. App. 119a-120a. The entire thrust of the patent exhaustion doctrine is that it "limits a patentee's right to control what others can do with an article embodying or containing an invention." Bowman v. Monsanto Co., 133 S. Ct. 1761, 1766 (U.S. 2013) (emphasis added). The Supreme Court has explicitly recognized that § 271(a) only allows a patentee to control use of a patented invention until exhaustion takes title of the product outside of the patent's control. See id. at 1766 n2. That is the very point of *Motion Picture Patents* and Quanta. In those cases, the patentee had not given "authority" for the post-sale use of the patents—that was the reason for the dispute in the first place. See Motion Pictures Patents, 243 U.S. at 514-15, Quanta, 553 U.S. at 638. Nevertheless, an "authorized" first sale triggered patent exhaustion. See id.

The Federal Circuit's explanation for how patent exhaustion could have any viability under its reading of the Patent Statute is likewise flawed. The Federal Circuit asserted that patent exhaustion would still survive, but instead of being a limit on a patentee's control, it would just be a "default rule for determining whether authority has been conferred . . . where an express conferral is missing." Pet. App. at 40a (emphasis added). That position, however, makes no sense—if, as the Federal Circuit majority reasoned, any use "without authority" from the patentee constitutes infringement, then how can the "default" be that authority for all post-sale uses was conferred if the patentee was silent?

2. The Federal Circuit also erred in distinguishing the Supreme Court's prior statements on patent exhaustion.

Again, this Court has repeatedly stated a simple test for patent exhaustion—that it is triggered by any "authorized sale." See supra at § III.A. The Federal Circuit, however, characterized the Supreme Court's statements in this regard as mere dicta. The Federal Circuit reasoned that, despite articulating a seemingly broad test, the Supreme Court's prior decisions really only found exhaustion if there was either no post-sale restriction imposed or the restriction would otherwise have violated the antitrust laws. See Pet. App. at 54a-55a. That theory, however, has no basis.

The Supreme Court in *Quanta*, for example, did not state that its broad rule for determining patent exhaustion was dependent on the relationship of the parties, the terms of the purchase contract, or whether there were any tangential covenants, warranties, or ongoing duties in the contract. Rather, the Court in *Quanta* unequivocally held as a general matter that "the authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights . . . ." *Id.* at 638

Nor do *Quanta's* facts suggest that its holding is narrow or limited. In *Quanta*, a patentee (LGE) had licensed a manufacturer (Intel) to make and sell products practicing LGE's patents. *Id.* at 636. What LGE argued were "conditions" on Intel's license to sell the products were found by the Court to be merely collateral agreements between LGE and Intel (i.e., Intel was required to notify any purchasers not to combine the patented products with non-Intel components). *Id.* The Court found that regardless of whether or not a third party purchaser (Quanta) later complied, post-sale, with that notification from Intel, the initial sale from Intel to Quanta was "authorized" by LGE

at the time it was made, which exhausted LGE's patent right. *Id.* at 638. In other words, *Quanta* broadly found that the existence of collateral post-sale restrictions in the original sales contract was irrelevant—all that mattered was that LGE had authorized Intel to sell its products and Intel's initial sale was within that authority. Anything that Intel's customer (Quanta) did after that sale fell outside of LGE's control.

The Federal Circuit similarly misinterpreted *Motion Picture Patents*. The Federal Circuit found that it only established that *unlawful* post-sale restrictions (e.g., price fixing) did not circumvent patent exhaustion. *See* Pet. App. at 53a-54a. The Court in *Motion Picture Patents*, however, put no such limitation on its holding. In fact, the decision does not even mention price fixing or antitrust. The Court simply held that "the right to vend is exhausted by a single, unconditional sale, the article sold being thereby carried outside the monopoly of the patent law and rendered free of every restriction which the vendor may attempt to put upon it." *Motion Picture Patents*, 243 U.S. at 516, 518.

Univis likewise did not turn on whether a post-sale restriction is legal under antitrust law. In *Univis*, the Court broadly found that where a patent holder has sold a patented product he has "thus parted with his right to assert the patent monopoly with respect to it and is no longer free to control the price at which it may be sold ...." 316 U.S. at 251. In arriving at that conclusion, *Univis* started its analysis with patent law, stating that "before considering whether the defendants' conduct violated antitrust law, the Court first asked whether that conduct was excluded by the patent monopoly from the operation of the Sherman Act." *Univis*, 316 U.S. at 244 (emphasis

added). To answer that question, the Court turned to patent exhaustion. *Id.* In other words, *Univis* found that the post-sale restrictions at issue were <u>also</u> illegal under antitrust law only <u>after</u> concluding that patent exhaustion first voided them. That is why *Quanta*—which did not turn on or discuss any antitrust issues—recognized that "*Univis* governs." *Quanta*, 553 U.S. at 617.

In any event, the Federal Circuit's theory for distinguishing these Supreme Court cases overlooks a simple fact—if all those cases stood for is the proposition that post-sale arrangements that violate antitrust law are unenforceable (but others are enforceable), then why would those cases mention patent exhaustion at all? They could simply have been resolved through antitrust law. Instead, they were resolved based on a broad patent exhaustion standard.

3. The Federal Circuit also incorrectly premised its decision on a misinterpretation of a term used in some older Supreme Court decisions. The Federal Circuit found that its "conditional sale" exception to patent exhaustion was supported by the Supreme Court's own past use of the term "unconditional sale" to describe a sale that triggers patent exhaustion. See Motion Picture Patents, 243 U.S. at 516. Similarly, Lexmark points to the Court's decision in *Mitchell v. Hawley*, 83 U.S. 544, 547 (1873), which states that patent rights are exhausted when the patentee "has himself constructed a machine and sold it without any conditions, or authorized another to construct, sell, and deliver it . . . without any conditions." See Opp. to Cert. Br. at 8-9. But the Federal Circuit and Lexmark misapprehended the way that the Supreme Court in those decisions used the terms "unconditional sale" or a sale "without any conditions."

Traditionally, a "conditional sale" of property was one in which title did not pass *until a condition-precedent* had passed. See Pet. App. at 115a, citing Harkness v. Russell, 118 U.S. 663, 665 (1886) and Motion Picture Patents, 243 U.S. at 520-21 (Holmes, J. dissenting ("[A] conditional sale retaining the title until a future event after delivery has been decided to be lawful again and again by this court."). In the post-sale restrictions at issue here, however, there is no "condition" that must occur before title to the patented product passes to the purchaser. The post-sale restrictions here are more properly characterized as collateral or tangential contract provisions.

4. The Federal Circuit majority further incorrectly reasoned that without a "conditional sale" exception to patent exhaustion, there would be two different patent exhaustion tests for (a) "a practicing-entity patentee that makes and sells its own product" versus (b) a "non-practicing-entity that licenses others to make and sell the product." Pet. App. at 26a. The Federal Circuit, however, misunderstood the actual distinction in the law.

The distinction that exists under the Supreme Court's broad exhaustion test is not between licensee sales and patentee sales—it is between authorized and unauthorized sales. The *Quanta* test itself reflects this distinction. *Quanta* requires a sale "authorized" by the patentee in order to exhaust the patent, regardless of who actually makes the sale. *Quanta*, 553 U.S. at 638. This gives rise to four possible scenarios:

(a) Any sales directly made by the patentee are of course logically "authorized" by the patentee and trigger exhaustion.

- (b) Any sales by an infringing, unrelated third party are logically "unauthorized" by the patentee and do not trigger exhaustion.
- (c) A patentee can grant a license to another company to make and sell the patented product. If it wishes, the patentee can give that manufacturer-licensee permission to sell the product only within a certain geographic area or field of use. If the manufacturer-licensee makes an <u>authorized</u> sale to a customer (e.g., the manufacturer licensee sells within the scope of its authorization in the license), patent exhaustion is then triggered. That was the exact scenario in *Quanta*. See Quanta, 553 U.S. at 625.
- (d) A manufacturer-licensee, however, might also make a sale in violation of its license (e.g., sales outside of a permitted area or field of use). In that scenario, the sale by the manufacturer-licensee in violation of the agreement is <u>unauthorized</u> because the patentee never gave the manufacturer-licensee permission to make the sale. And because the patentee never sold the product to the manufacturer-licensee (it only licensed the manufacturerlicensee to make the product) there was no "authorized sale" between them to trigger patent exhaustion either. With no authorized first sale, patent exhaustion is not triggered, and subsequent use is infringing. That was the exact scenario in Mitchell v. Hawley, 83 U.S. 544, 550 (1872) (unauthorized sale by licensee did not trigger patent exhaustion) and General Talking Pictures Corp. v. Western Elec. Co., 305 U.S. 124, 127 (1938) (same).

In other words, a broad patent exhaustion doctrine does not treat sales by a licensee/manufacturer differently from those by a patentee—it treats authorized and unauthorized sales differently, regardless of who made them. Nor does a broad patent exhaustion rule mean that "non-practicing entities" have "greater power to maintain their patent rights than practicing entities," as the Federal Circuit incorrectly found. See Pet. App. at 45a. A practicing patentee can decide for itself when to make an authorized sale, while a non-practicing patentee can decide under what conditions a licensee's sale is authorized. The end result is the same—the patentee decides which sales are authorized, and all authorized sales trigger patent exhaustion.

For the same reasons, the Federal Circuit's concern that a broad patent exhaustion doctrine would "introduce practical problems," such as determining where "the line [would] be drawn along the spectrum from original patentees to assignees (e.g., regional assignees) to exclusive licensees . . . to nonexclusive licenses," is nonexistent. For each of these entities, the line is the same—if the patentee authorized the first sale, then exhaustion is triggered, regardless of any post-sale restrictions.

# IV. THE FEDERAL CIRCUIT'S HOLDING THAT FOREIGN SALES DO NOT TRIGGER PATENT EXHAUSTION IS ERRONEOUS

### A. The Federal Circuit's Complete Rejection of Patent Exhaustion for Foreign Sales is Contrary to This Court's Precedent

The Federal Circuit also incorrectly decided whether non-U.S. sales of a patented product exhaust U.S. patent rights. Namely, the Federal Circuit *en banc* upheld an earlier panel decision in *Jazz Photo*, 264 F.3d at 1102-07

that such sales do not trigger patent exhaustion. This decision contradicts *Kirstaeng*, 133 S. Ct. at 1363-64 and the common law articulated therein.

1. In *Kirstaeng*, the Court concluded that an authorized sale of a copyrighted book outside the U.S. *did* give rise to copyright exhaustion. *See id.* at 1363-64. Although the Court there addressed copyright exhaustion, rather than patent exhaustion, it found that the deeply-seated common law prohibiting restraints on property *generally* mandated this result. *See Kirstaeng*, 133 S. Ct. at 1363.

The Court found that the first sale doctrine is a "common-law doctrine with an impeccable historical pedigree" rather than something unique to the copyright statute. Id. The Court broadly recognized that "[a] law that permits a copyright holder to control the resale or other disposition of a chattel once sold" is "against Trade and Traffic, and bargaining and contracting." Id. The Court also recognized (a) "the importance of leaving buyers of goods free to compete with each other when reselling or otherwise disposing of those goods" and (b) that a broad first sale doctrine frees courts from "the administrative burden of trying to enforce restrictions upon difficult-totrace, readily movable goods." Id. at 1363-64. The Court then concluded that "[t]he common-law doctrine makes no geographical distinctions" and that a "straightforward application" of the rule "would not preclude the 'first sale' defense from applying to authorized copies made overseas." Id. at 1363-64.

Each of these rationales applies equally to patent exhaustion. International patent exhaustion—just like the international copyright first sale doctrine—will promote the same consumer interests and avoid the same administrative burdens. The Court has previously noted parallelisms between the property interests in a copyright versus a patent. *See, e.g., Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 439 (1984) (recognizing a "historic kinship between patent law and copyright law").

It was only <u>after</u> the Court in *Kirstaeng* recognized the general common law principles of patent exhaustion that it analyzed whether the copyright statute (§109(a)) nevertheless <u>limited</u> the common law rule. *See Kirstaeng*, 133 S. Ct. at 1364. It found that although the copyright statute did address first sale, it did not mandate against exhaustion based on international sales. *See id.* Because the patent statute has no applicable statutory provision that even needs analysis, it also cannot limit the broad common law rule disfavoring restraints on alienation.

2. The Federal Circuit and Lexmark base their contrary conclusion—that foreign patent exhaustion should be treated differently than foreign copyright exhaustion—on a misinterpretation of *Boesch v. Graff. See* 133 U.S. 697, 701-02 (U.S. 1890). *Boesch*—decided over 100 years ago—does not stand for the proposition claimed by the Federal Circuit and Lexmark.

Boesch did not hold that authorized foreign sales cannot exhaust a U.S. patent. See id. at 701-02. Rather, in Boesch, there was no foreign sale that was authorized by the U.S. patentee (e.g., a sale from the U.S. patentee or from an entity licensed by the U.S. patentee)—the sale in Boesch was made in Germany by an unrelated third party, who was only able to sell there due to a provision of German law. Id. at 701-02. Boesch recognized that the

party attempting to subsequently import the patented product into the U.S. was doing so "without the license or consent of the owners of the United States patent." *Id.* at 702. In other words, *Boesch's* ruling is completely consistent with applying *Quanta's* test to foreign authorized sales.

# B. The Court Should Not Adopt the Government's "Express Reservation" Standard

Rather than argue in favor of either Impression's straight-forward position (consistent with *Kirstaeng*) that patent exhaustion is triggered by a first authorized sale regardless of geography, or the Federal Circuit's complete rejection of patent exhaustion for foreign sales, the United States as *amicus curiae* has proposed a third alternative. The government contends that U.S. patent rights should be exhausted by a foreign sale unless they are "expressly reserved." *See* U.S. Br. at 15. The government cited a number of various lower-court decisions to that effect. *See id.* at 18. The government's position, however, is unsupported for two reasons.

1. Each of the lower court decisions cited by the government predates *Kirstaeng*, which settled any ambiguities regarding exhaustion of U.S. property rights through international sales. *See id.* Prior to *Kirstaeng*, numerous lower courts had also believed (similar to the government's position for patents) that foreign sales of a copyrighted material authorized only for sale abroad did not trigger domestic exhaustion. *See*, *e.g.*, *Adobe Sys.*, *Inc. v. Christenson*, 891 F. Supp. 2d 1194, 1203-1204 (D. Nev. 2012) (gathering cases). *Kirstaeng*, however, overturned those cases based on the general common law against restraints on alienation of goods. *See supra* at § IV.A.

2. The same reasoning articulated in Quanta, Univis, and Motion Picture Patents compels that a foreign postsale "reservation of rights" can no more circumvent patent exhaustion than can a domestic "conditional sale." See supra at § III.A. As this Court has recognized, "[t]he common-law doctrine [against restraints on alienation of goods] makes no geographical distinctions." Kirstaeng, 133 S. Ct. at 1363 (emphasis added). See also id., citing 1 E. Coke, Institutes of the Laws of England § 360, at 223 (1628) (recognizing in the context of foreign sales of U.S.-protected goods "the importance of leaving buyers of goods free to compete with each other when reselling or otherwise disposing of those goods"). Moreover, the same policy reasons and practical concerns that make the Federal Circuit's "conditional sale" exception to exhaustion unworkable for domestic sales (e.g., how to determine whether downstream purchasers had sufficient notice) make the government's foreign "reservation of rights" exception untenable. See supra at § II.C.

### **CONCLUSION**

For the reasons discussed,  $amicus\ curiae\ AMDR$  requests that the  $en\ banc$  decision of the Federal Circuit below be reversed.

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ROBERT A. SURRETTE

Counsel of Record

CHRISTOPHER M. SCHARFF

McAndrews, Held, and Malloy, Ltd.
500 West Madison Street, Suite 3400

Chicago, Illinois 60661

(312) 775-8000

bsurrette@mcandrews-ip.com

Counsel for Amicus Curiae Association of Medical Device Reprocessors