Nos. 2014-1617, -1619

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

LEXMARK INTERNATIONAL, INC.,

Plaintiff-Cross-Appellant,

v.

IMPRESSION PRODUCTS, INC.,

Defendant-Appellant,

(Caption Continued on Inside Cover)

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO IN NO. 1:10-cv-00564-MRB, JUDGE MICHAEL R. BARRETT

BRIEF OF *AMICUS CURIAE* MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF LEXMARK INTERNATIONAL, INC.

JOSEPH S. CIANFRANI
Counsel of Record
KENT N. SHUM
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404

Attorneys for Amicus Curiae
Medical Device Manufacturers Association

August 19, 2015

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.

CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4 and Fed. R. App. P. 26.1, counsel for *Amicus Curiae* Medical Device Manufacturers Association certifies the following:

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

Medical Device Manufacturers Association.

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: **N/A.**

3. All parent corporations and any publicly held companies that own more than 10 percent or more of the stock of the party represented by me:

None.

4. The name of all law firms and the partners or associates that appeared for the party now represented by me who appeared in the trial court or are expected to appear in this Court: Joseph S. Cianfrani and Kent N. Shum of KNOBBE, MARTENS, OLSON & BEAR, LLP.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Date: August 19, 2015

By: */s/ Joseph S. Cianfrani*
Joseph S. Cianfrani

Attorney for Amicus Curiae
Medical Device Manufacturers Association

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Medical Device Manufacturers Association ("MDMA") is a national trade association based in Washington, D.C., providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies.[1] Since 1992, MDMA has been the voice for smaller companies, playing a proactive role in helping to shape policies that impact the medical device innovator. MDMA's mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology.

SUMMARY OF THE ARGUMENT

Amicus MDMA submits this brief in support of plaintiff-cross-appellant Lexmark International, Inc. to address three issues relating to the Court's second *en banc* question that may not be apparent from the briefs of the Parties and other *amici*.

[1] This brief is filed in response to the Court's invitation for *amicus* briefs as stated in the April 14, 2015 *en banc* Order. In accordance with Federal Rule of Appellate Procedure 29(c)(5), MDMA states that no party's counsel in this matter authored this brief in whole or in part; no party or party's counsel contributed money intended to fund preparing or submitting this brief; and no person, other than the *amicus curiae* or its counsel, contributed money that was intended to fund preparing or submitting this brief.

First, this Court's decision regarding whether *Mallinckrodt* remains good law following the Supreme Court's *Quanta* decision affects technologies well beyond the printer cartridges involved in this case. Many medical devices are designed, labelled, and expressly sold as "single-use only" for reasons of efficacy and patient safety. For decades, medical device manufacturers have relied on *Mallinckrodt* and the conditional-sale doctrine to aid them in ensuring compliance with safety-related restrictions on the use of their devices.

Amicus MDMA writes to respond to the criticisms of Defendant Impression Products and other *amici* suggesting that post-sale restrictions are merely intended to enhance the profitability of a patented product to the detriment of downstream purchasers. While patentees are entitled, even encouraged, to maximize the pecuniary benefits that a patent affords during the limited exclusivity period, single-use restrictions in the medical device field are often intended to maximize patient safety. Single-use restrictions frequently reflect the judgment of the manufacturer, often based on engineering analysis and testing, that the device cannot be safely reused. By restricting the patent license to a single use as permitted under this Court's *Mallinckrodt* line of cases, medical device manufacturers have an important tool to protect public safety and health, and also enforce their patent rights against third-party reprocessors with whom they have no contractual relationships.

Second, *amicus* MDMA writes to show that the Supreme Court's *Quanta* decision, as well as the decisions that preceded it, are fully consistent with this Court's reasoning in *Mallinckrodt* and its progeny. The exhaustion doctrine is a default legal rule that parties are free to contract around within the limits of antitrust and misuse law. Both the Supreme Court and this Court have consistently recognized that patentees are free to grant as many or as few of their patent rights as they desire, so long as the patentee does not attempt to enlarge their market power beyond the proper scope of their patent rights. Despite calls from numerous *amici* in *Quanta*, including the United States, to expressly overrule *Mallinckrodt*, the Supreme Court declined. That choice can be read as either implicitly agreeing with *Mallinckrodt's* reasoning, or a recognition that the viability of post-sale restrictions were not implicated by the Court's decision. In either case, there is no basis to interpret *Quanta* as having implicitly overruled all of this Court's decisions in the *Mallinckrodt* line.

Finally, *amicus* MDMA responds to several of the arguments from *amici* supporting the Defendant and their view that this Court should abandon the reasoning in the *Mallinckrodt* line in order to preserve the economic interests of businesses that reprocess and refurbish goods of all types. Arguments predicting the doom of repair and reconditioning businesses ignore that the conditional sale doctrine applies only to patented goods that contain an express limitation of the

implied license attending the sale of the product. Given the enormous financial success boasted by the reprocessing industry, the number of products implicated by the conditional sale doctrine appears to be relatively small, particularly since *Mallinckrodt* has been the prevailing law for more than 20 years.

Amicus MDMA respectfully submits that the Supreme Court's *Quanta* decision did not overrule the fundamental concept that patent owners are free to restrict the patent rights conveyed with a sale of a patented device. Accordingly, this Court should reverse the district court's dismissal of Lexmark's patent-infringement claims based on the doctrine of patent exhaustion.

ARGUMENT

I. Single-Use Restrictions On Medical Devices Protect Patient Safety

Medical device manufacturers provide patients and clinicians with timely access to life-saving medical technologies. Their research and development efforts create new and innovative technologies and improve existing medical technologies to achieve better patient care. One such important technological improvement is the single-use device, which arose in response to patient safety concerns. A single-use device is a medical device that is designed or designated by the manufacturer for use in a single medical procedure on a single patient and

is intended to be discarded after the procedure.[2] Prior to the 1980s, medical devices were typically reusable.[3] Their reuse was facilitated by their shape, design, size, and the fact that they were made of materials that could be prepared for reuse through relatively simple sterilization processes.[4]

Single-use devices arose in response to a heightened awareness of risk from infectious disease transmissions, such as hepatitis and HIV, from reusing contaminated syringes and other medical devices that contact a patient's skin or bodily fluids.[5] Technological manufacturing improvements enabled the development of more sophisticated and complex medical devices. For example, new devices developed for mini-invasive procedures had smaller lumens and more intricate, delicate working mechanisms that were difficult to clean or

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[2] Arjan W. van Drongelen, Adrie C.P. de Bruijn, *Reprocessing of Medical Devices: Possibilities and Limiting Factors*, National Institute for Public Health and the Environment (RIVM) at 7 (2008), online at http://nl.sitestat.com/rivm/rivm-nl/s?link.en.documents_and_publications.scientific.reports.2010.januari.reprocessing_of_medical_devices_possibilities_and_limiting_factors.download_pdf&ns_type=pdf&ns_url=http%3A%2F%2Fwww.rivm.nl%2Fdsresource%3Fobjectid=rivmp:13793&type=org&disposition=inline&ns_nc=1.

[3] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *The Safety of Reprocessed Medical Devices Marketed for Single-Use*, at 8 (European Commission 2010), online at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf.

[4] *Id.*

[5] *Id.*

sterilize properly.[6] Some new devices were made with novel lightweight plastics that could not withstand high-temperature sterilization processes.[7] Because, in the judgment of the manufacturers, some devices could not be safely reconditioned for reuse, the devices were intended and labelled for "single-use only."[8]

Reusable medical devices that are designed to be reprocessed are generally manufactured so that the device can be completely disassembled and properly cleaned.[9] Manufacturers of reusable devices provide information on proper cleaning agents and procedures, instructions for assembly and disassembly, and appropriate water treatment exposure to ensure proper reprocessing.[10, 11]

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[6] *Id.*

[7] *Id.*

[8] *Id.*; *cf. Amicus Curiae* Br. of the Ass'n of Med. Device Reprocessors in Support of Impression Prods., Inc. [Dkt. 187] at 28 (suggesting that a reason some manufacturers designate medical devices as "single use" is because of financial incentives).

[9] Michelle R. Tinkham, *Reprocessing of Single-Use Devices: Do the Benefits Outweigh the Potential Dangers*?, 5 Perioperative Nursing Clinics 377, 379 (2010).

[10] *Id.*; Francesco Tessarolo et al., *Critical Issues in Reprocessing Single-Use Medical Devices for Interventional Cardiology*, Biomedical Engineering, Trends, Research and Technologies 619, 626 (Malgorzata Komorowska & Sylwia Olsztynska-Janus eds., 2011).

[11] Although some medical device manufacturers reprocess their own reusable devices, most do not reprocess single-use devices. But when original

In contrast, third-party reprocessing presents potential safety concerns because the reprocessor may not have complete information or specifications for the single-use devices they reprocess, due to the fact that original manufacturers are not required to provide reprocessing procedures for single-use devices.[12] General industry-wide procedures for reprocessing and determining the integrity and functionality of single-use devices sometimes are not well-documented because each device is unique and presents different safety challenges.[13] For example, proper cleaning and disinfection of catheters, as well as determining a catheter's structural integrity and functionality, depend on the particular design and the materials used.[14]

Some reprocessed single-use devices may show contamination and reduced quality because the devices were never designed or intended to be

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manufacturers do reprocess their own single-use devices, they have the technical specifications and institutional know-how to do so safely and effectively. *See e.g.*, Smith & Nephew, Inc., *JET-X External Fixator Recertification Program*, at 4 (2011) online at http://www.smith-nephew.com/global/assets/pdf/products/surgical/jet-x_recertification.pdf ("As the original manufacturer of these products, the exact specifications are known and met. Products reprocessed by other companies cannot be inspected to the original manufacturer's guidelines established for patient safety, potentially putting the patient and hospital at risk.").

[12] Tessarolo, at 626–27.

[13] *See* Tessarolo, at 622; Peter J. Goss, *Beyond the "Yuck Factor": Product Liability Implications of Medical Device Reprocessing* 7–8 (Washington Legal Foundation Working Paper Series No. 141, Sept. 2006).

[14] Tessarolo, at 622.

reconditioned or reused.[15] Many single-use devices are made of plastic, which have many good properties including flexibility and ease of manufacturing of complex designs.[16] The durability and performance of a new plastic single-use device is perfectly acceptable—but if the device is reprocessed and reused without adequate quality control, the performance or structural integrity of the device may be compromised.[17] Single-use devices may not withstand cleaning and sterilization processes without damage.[18] Also, testing reprocessed devices may not expose devices in which the reprocessing resulted in decreased performance.[19] For example, catheters have complex designs that make it difficult to predict their performance or failure.[20]

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[15] Peter Heeg et al., *Decontaminated Single-Use Devices: An Oxymoron that May Be Placing Patients at Risk for Cross-Contamination*, 22 Infection Control & Hosp. Epidemiology 542, 542 (2001); *see also* Monica Valero da Silva et al., *Safety Evaluation of Single-Use Medical Devices after Submission to Simulated Reutilization Cycles*, 88 J. AOAC Int'l 823, 828 (2005) ("The imperfections on [single-use device] surfaces observed through SEM [scanning electron microscopy], as well as the presence of *Bacillus subtilis* spore agglomerates and with the microbiological tests results puts into serious questioning the safety of reprocessed medical devices fabricated for "single use only.").

[16] Van Drongelen, at 11.

[17] *Id.*

[18] *Id.*

[19] *See* Eucomed, Eucomed White Paper on the Reuse of Single Use Devices, at 13, 37 (2009), online at http://www.eucomed.org/uploads/Modules/Publications/Eucomed%20White%20Paperon%20the%20Reuse%20of%20Single%20Use%20Devices.pdf (finding no statistically significant differences in mechanical testing between new and reprocessed harmonic scalpels, but finding

Contrary to the suggestion of various *amici*, this Court's decision regarding whether to overrule its *Mallinckrodt* line of cases will not merely affect the profitability of printer cartridges. It will also affect the ability of medical device manufacturers to ensure compliance with safety-based "single-use" restrictions. The original device manufacturers are in the best position to know whether a device can be safely reprocessed, and allowing them to enforce their judgment as they have done since the *Mallinckrodt* decision is an important tool in protecting public health.

II. Patent Infringement Claims Are An Essential Tool For Ensuring Compliance With Post-Sale Restrictions On Medical Devices

Various *amici* argue that contract law, not patent law, is the appropriate vehicle for enforcing post-sale restrictions.[21] To be clear, post-sale restrictions are not directly enforceable under the patent laws. Rather, a valid contractual post-sale restriction limits the scope of the patent license conveyed with the sale of a patented product. If the product is then used outside of the limited license

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that *in vivo* mechanical testing demonstrated significantly decreased performance for reprocessed harmonic scalpels compared with new harmonic scalpels in terms of hemostasis).

[20] *Id.* at 37 ("Another challenge when reusing catheters is that it is difficult to predict when a catheter will degrade to a degree that it will break. When and if depends on the type of polymer used and how it is manufactured. While some plastics degrade over time and show signs of wear others seem to fail spontaneously.").

[21] Br. of the Ass'n of Med. Device Reprocessors at 11–12.

granted, the patentee may seek patent infringement remedies against the user. Accordingly, while patent law does not directly "enforce" a post-sale restriction, the violation of the restriction subjects subsequent purchasers and users to a patent infringement claim because their use is unlicensed.

Nevertheless, although contract remedies may be available against the original purchasers of the product that agreed to the contractual restriction (and paid a price that reflected the effect of the use limitation), contract law can be ineffective for this purpose because the subsequent users often were not parties to the original contract containing the restriction.[22] Because medical device manufacturers typically sell their products directly to hospitals, clinics, and other healthcare facilities, contractual remedies are often unavailable against third-party reprocessors who violate the use restrictions, such as reprocessing single-use devices, because they were not parties to the original sales contract. Although some reprocessors are related to hospitals and health care facilities, many are independent companies which merely obtain the devices from hospitals. Accordingly, there is often no contractual privity between the patent

[22] *Restatement (Second) of Contracts* § 302 (1981) (explaining that third parties to the contract have a basis for recovery only where they were an intended beneficiary); 1 Donald S. Chisum, *Chisum on Patents* § 16.01 (2015).

owner and the reprocessor, and no available remedy to enforce the single-use restriction under contract law.

Various *amici* also argue that this Court should overrule *Mallinckrodt* because it would be unfair to enforce post-sale restrictions against third-party reprocessors who are not privy to the original sales contract.[23] The *amici* contend that, without privity, they "would be left guessing as to their rights" if post-sale restrictions remain enforceable through patent law.[24] However, the issue before this Court is not whether hypothetical single-use restrictions on medical devices operate as a valid restriction on the patent rights that accompany the sale of a patented article. Rather, the issue for this Court is whether the district court incorrectly decided that *Quanta* overruled *Mallinckrodt*, thereby foreclosing the possibility of *any* valid post-sale restrictions, regardless of assent by the purchasing party or notice to subsequent purchasers.[25]

Even so, reprocessors would not be left guessing as to whether multiple uses are licensed by the patent owner. The vast majority of single-use devices state directly on the product, its packaging, and/or its instructions, that the

[23] *See* Br. of the Ass'n of Med. Device Reprocessors at 29.
[24] *Id.*
[25] A14–15.

device is for "single-use only."[26] Even if a used single-use device has no markings when it is received by a reprocessor, a basic investigation will ascertain whether the device is restricted to "single-use only." Reprocessors must conduct at least this level of investigation because they need to obtain any available information about the device prior to investing resources to recondition the device. Thus, even if the reprocessors are not a party to the original contract, they are frequently on notice of the single-use restriction to which the original purchaser agreed. Moreover, medical device manufacturers could also affirmatively put reprocessors on notice that certain devices are for single-use only by sending notifications directly to reprocessors identifying which products lack a license for multiple uses.

The FDA has also encouraged medical device manufacturers to provide information about reprocessing their medical devices. However, if this Court determines that *Quanta* overruled *Mallinckrodt*, not only will medical device manufacturers be unable to bring patent infringement claims against third parties who operate beyond the license granted, medical device manufacturers will also

[26] *See Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 702 (Fed. Cir. 1992) ("The device is marked with the appropriate patent numbers . . . and the inscription 'Single Use Only'. The package insert provided with each unit states 'For Single Patient Use Only' and instructs that the entire contaminated apparatus be disposed of in accordance with procedures for the disposal of biohazardous waste.").

be unable to enforce ***any*** restrictions or guidelines for reprocessing their devices, particularly safety restrictions and guidelines.[27] The FDA has stated that "[r]educing the risk of exposure to improperly reprocessed medical devices is a shared responsibility among various stakeholders . . . [including] manufacturers, responsible for providing adequate reprocessing instructions that are user-friendly and proven to work."[28] But if all post-sale restrictions are *per se* ineffective, medical device manufacturers will also have no ability to ensure compliance with the guidelines for safely reprocessing reusable devices.

III. *Mallinckrodt* Is Consistent With Supreme Court Precedent

By holding that valid agreed-upon restrictions can alter the application of patent exhaustion, this Court's *Mallinckrodt* decision has assisted medical device manufacturers in effectively ensuring compliance with post-sale use restrictions on patented devices through infringement actions. Nothing in the Supreme Court's *Quanta* decision contradicts the basic premise that, within the limits of antitrust and misuse, patentees are free to grant any license scope they choose when selling a patented product. In *Quanta*, the Supreme Court

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[27] U.S. Food and Drug Administration, *Working Together to Improve Reusable Medical Device Reprocessing*, at 1 (2015), online at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252901.htm.

[28] *Id.*

analyzed the specific agreements between LGE and Intel and held that they did not create any post-sale conditions on Intel's sales to third parties. Because there were no post-sale restrictions on Intel's sales, *Quanta* did not implicate this Court's *Mallinckrodt* line of cases. Further, this Court's *Mallinckrodt* decision is consistent with prior Supreme Court precedent that patentees are free to separately transfer or license their patent rights such as the right to sell, use, and manufacture.

A. *Quanta* Did Not Implicitly Overrule *Mallinckrodt*

Although Defendant Impression Products contends that *Quanta* overruled *Mallinckrodt*, *Quanta* did not address *Mallinckrodt* despite invitations to do so from *amici*.[29] Rather, in *Quanta*, the Supreme Court held that LGE's patent rights were exhausted due to an unconditional sale.[30] Specifically, the Supreme

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[29] *See e.g.*, Br. for the United States as *Amicus Curiae* Supporting Petitioners at 18–24, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008); *see also* Amelia Smith Rinehart, *Contracting Patents: A Modern Patent Exhaustion Doctrine*, 23 Harvard J. L. & Tech. 483, 503 (2010) ("*Quanta* does not address the viability of *Mallinckrodt* or whether exhaustion doctrine should be considered immutable rather than the default rule."); *see also* Shubha Ghosh, *Carte Blanche, Quanta, and Competition Policy*, 34 Iowa J. Corp. L. 1209, 1226 (2009) ("The explanation for the absence is straightforward. The Court [in *Quanta*] is not overruling *Mallinckrodt*.").

[30] *Quanta*, 553 U.S. at 636–37; *see also* William LaFuze, Justin Chen & Lavonne Burke, *The Conditional Sale Doctrine in a Post-Quanta World and its Implications on Modern Licensing Agreements*, 11 J. Marshall Rev. Intell. Prop. L. 295, 309–10 (2011) ("However, since the Court [in *Quanta*] based its ruling

Court held that LGE's patent rights were exhausted because there were no conditions in the agreement restricting the customers to whom Intel could sell. The Supreme Court held that exhaustion applied because "[n]o conditions limited Intel's authority to sell products substantially embodying the patents," and therefore "Intel was authorized to sell its products to Quanta."[31] Not only did the license agreement lack any conditions on Intel's sales, the license agreement "broadly permit[ted] Intel to 'make, use, [or] sell' products free of LGE's patent claims."[32] Thus, the license and unconditional subsequent sales by Intel exhausted LGE's patent rights because they were authorized, unrestricted sales.

Moreover, *Quanta* suggested that valid post-sale conditions could avoid patent exhaustion. The Supreme Court stated: "Nothing in the License Agreement restricts Intel's right to sell its microprocessors and chipsets to purchasers who intend to combine them with non-Intel parts."[33] That language

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on the conclusion that the license agreement between LGE and Intel was unconditioned with regard to sales of Intel products, there was no need for the Court to address the conditional sale doctrine.").

[31] *Quanta*, 533 U.S. at 637.

[32] *Id.* at 636; *but see id.* at 636–37 (a related agreement included a condition requiring Intel to notify its customers that LGE had not licensed those customers to practice the patents, but the Court concluded that the notice requirement was not a condition on Intel's right to sell its microprocessors).

[33] *Id.* at 636.

suggests that, if there were a restriction in the license to Intel, the outcome may have been different.

It is also telling that the Supreme Court did not overrule *General Talking Pictures*.[34] Instead, the Court stated that, unlike the license in *General Talking Pictures* that restricted the customers to whom the licensee could sell products, LGE's license did not place any conditions on Intel's sales.[35] Thus, the Supreme Court's focus on the lack of conditions in the agreements between LGE and Intel suggests that, if valid restrictions had been present, LGE could have enforced its patent rights against Quanta. If the Supreme Court had intended to overrule *Mallinckrodt* and hold that all post-sale restrictions are ineffective to alter the default exhaustion rule, there would have been no need for the Court to conduct a lengthy analysis of the specific contracts between LGE and Intel. The Court's analysis would not have needed to analyze whether conditions were created by the parties' contracts because they could have no effect on the result. The Court also would have had to overrule *General Talking Pictures*, which it did not do.

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[34] *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 181 (1938) ("*Gen. Talking Pictures I*"); *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124 (1938) ("*Gen. Talking Pictures II*").

[35] *Quanta*, 533 U.S. at 636. ("[E]xhaustion did not apply because the manufacturer had no authority to sell the amplifiers for commercial use.") (citing *Gen. Talking Pictures I*, 304 U.S. at 181).

In addition, the Supreme Court's framing of the question presented in *Quanta* also suggests that the Court did not believe the conditional sale doctrine needed to be addressed, much less overruled. Specifically, the Court stated: "In this case, we decide whether patent exhaustion applies to the sale of components of a patented system that must be combined with additional components in order to practice the patented methods."[36] That issue has no relation to *Mallinckrodt*.[37]

Defendant and various *amici* argue that *Quanta* overruled *Mallinckrodt* based on the statement that patent rights were exhausted by "the authorized sale of an article that substantially embodies a patent" and because the Court did not state that patent rights are exhausted by an "authorized *and* unconditional sale."[38] However, an "authorized sale" necessarily implies that the sale was either unconditional, or that the condition was met. If the sale was conditional and that condition was violated, the sales would not be "authorized." In fact, the *amici* concede that if the license from LGE to Intel had been conditional, the sale may have been unauthorized.[39] Moreover, the Supreme Court based its decision on its conclusion that "No conditions limited Intel's authority to sell

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[36] *Id.* at 621.
[37] *Mallinckrodt*, 976 F.2d at 709.
[38] Br. of the Ass'n of Med. Device Reprocessors at 7–8 (emphasis added).
[39] *Id.* at 8–9 ("What the patentee argued were 'conditions' on the manufacturer's license to sell the products . . . were found by the Court to be merely collateral agreements that did not render the sales by Intel 'unauthorized.'").

products substantially embodying the Patents."[40] Because there were no conditions restricting Intel's sales, the Supreme Court concluded that the sales were "authorized." Accordingly, the *Quanta* opinion suggests that "authorized sales" refer to either unconditional sales or sales in compliance with any conditions.

Amici also argue that "the focus of the patent exhaustion doctrine is not 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."[41] That argument is contrary to the Court's analysis in *Quanta*. As discussed above, the Court spent significant time analyzing the relationship and contracts between LGE and Intel. Had the Supreme Court intended to overrule *Mallinckrodt* and more than 20 years of settled law, it would have done so expressly.

B. *Mallinckrodt* Is Consistent With Prior Supreme Court Precedent

Mallinckrodt holds that a patent owner may restrict the license granted with a sale of a patented device so long as the restrictions are within the scope of

[40] *Quanta*, 553 U.S. at 637.
[41] Br. of the Ass'n of Med. Device Reprocessors at 8.

the patent grant and do not violate another body of law.[42] This Court's conclusion in *Mallinckrodt* that post-sale restrictions are not *per se* impermissible is consistent with the Supreme Court's case law prior to *Quanta*.

While the Supreme Court has held that an "authorized" sale exhausts a patent owner's rights, the Supreme Court has never held that ***all*** post-sale restrictions are ineffective. The only such restrictions the Supreme Court has held ineffective involved illegal tying or price fixing. The Supreme Court has long recognized a patent owner's freedom to separately confer its rights to manufacture, sell, and use.[43] The Supreme Court has also held that a patentee's restrictions upon the right to sell are valid "provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly."[44] The Supreme Court has also permitted patent owners to enter into

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[42] *Mallinckrodt*, 976 F.2d at 708.

[43] *Adams v. Burke*, 84 U.S. 453, 456 (1873) (stating that the "right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee."); *United States v. Gen. Elec. Co.*, 272 U.S. 476, 490 (1926) ("The patentee may make and grant a license to another to make and use the patented articles, but withhold his right to sell them.").

[44] *Gen. Elec.*, 272 U.S. at 490.

restricted, conditional licenses that grant only limited authority to the licensee without exhausting all rights in the licensed patents.[45]

Contrary to arguments from various *amici*, the Supreme Court's decision in *Motion Picture Patents* did not hold that all post-sale restrictions are ineffective to prevent patent exhaustion.[46] In *Motion Pictures Patents*, a license notice was attached to the patented movie projectors stating that the purchaser had the right to use the machine only with motion picture films that were leased from the patentee.[47] The defendant used the patented machine with films leased from other sources.[48] The Supreme Court held that the patentee's tie-in restriction was invalid because it extended the scope of its patent monopoly to unpatented products.[49] That holding did not extend beyond illegal tying.

Various *amici* also argue that the Supreme Court confirmed in *Quanta* that post-sale restrictions are unenforceable because the Court relied on its prior *Univis* decision. However, in *Univis*, the Supreme Court merely found that

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[45] *Gen. Talking Pictures II*, 305 U.S. at 126–27 (upholding enforcement of field-of-use restrictions through licenses divided between those who could sell for commercial purposes and those who could sell for home purposes); *Mitchell v. Hawley*, 83 U.S. 544, 549–50 (1873) (recognizing that a patent owner might grant a manufacturer a license to make a patented invention limited to the original patent term and expressly excluding any extension of the term).
[46] *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917).
[47] *Motion Picture Patents Co.*, 243 U.S. at 506–07.
[48] *Id.* at 507.
[49] *Id.* at 518.

restrictions relating to price-fixing, extending the scope of a patent owner's monopoly, were invalid.[50] The *Quanta* Court only cited to *Univis* to show that patent exhaustion applies when an item sufficiently embodies the patent.[51] The Court did not, and could not, rely on *Univis* for the proposition that all post-sale restrictions are trumped by patent exhaustion. *Univis* simply did not extend that far. Accordingly, *Mallinckrodt* and its progeny are fully consistent with prior Supreme Court case law, which has found illegal tying and price-fixing restrictions invalid. But the Supreme Court has never suggested that exhaustion trumps ***all*** post-sale restrictions.

IV. Post-Sale Restrictions Permit Patent Owners To Efficiently Allocate Their Patent Rights

Patent rights have the same characteristics as personal property.[52] The property rights conferred by a patent have been analogized to a bundle of sticks that patent owners are entitled to parse out as they see fit.[53] Thus, patent owners

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[50] *United States v. Univis Lens Co.*, 316 U.S. 241, 252–54 (1942).
[51] *Quanta*, 553 U.S. at 618.
[52] 35 U.S.C. § 261 ("[P]atents shall have the attributes of personal property."); *see also* Adam Mossoff, *A Simple Conveyance Rule for Complex Innovation*, 44 Tulsa L. Rev. 707 (2009).
[53] *Restatement (Second) of Contracts* § 721; Amelia Smith Rinehart, *Contracting Patents: A Modern Patent Exhaustion Doctrine*, 23 Harv. J. L. & Tech. 483, 495 (2010) ("A patent owner also can divide his bundle of rights to exclude others, separating the right to use from the right to sell the patented invention."); Leonard J. Hope, *The Licensed-Foundry Defense in Patent Infringement Cases:*

can sell distinct sticks from their bundle of property interests without including the remainder of their sticks.[54] As the Supreme Court held in *Adams*, patent owners can transfer the right to use or manufacture separately from the right to sell.[55] This allows patentees to grant a limited license of a scope that both parties desire, at a price to which both agree. For example, most purchasers would view a product with a single-use restriction to be worth less to them than the same product with no such restriction. Accordingly, assuming the purchaser was fully aware of the single-use limitation, basic economics would predict that limited license to be factored into the price.[56] Indeed, that was precisely the situation in this case, where purchasers agreed to pay less for printer cartridges they agreed to return.[57]

If valid post-sale restrictions are held incapable of altering the default exhaustion rule, patent rights will lose their attributes akin to real property and

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Time to Take Some of the Steam Out of Patent Exhaustion, 11 Ga. St. Univ. L. Rev. 621, 625 (1994) ("A patent is considered, like other property, to be a bundle of rights.").

[54] *Gen. Elec.*, 272 U.S. at 489–90; *Adams*, 84 U.S. at 456 ("The right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee."); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991) ("[Patent rights are] a bundle of rights which may be divided and assigned, or retained in whole or part.").

[55] *Adams*, 84 U.S. at 456.

[56] *See B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997).

[57] A4–5.

patent owners will lose their long-standing right to contract for the sale of only certain sticks in their bundle of patent rights. If all patent rights are unavoidably conveyed with every sale, it may be necessary for manufacturers to charge higher prices in order to be adequately compensated for the conveyance of the entirety of their patent rights. As a result, hospitals and other health care providers may face increased costs for patent rights they do not want or need.

Further, forcing patentees to convey all of their patent rights in a product at the time of sale will not simplify transactions in the medical device industry.[58] If post-sale restrictions are ineffective to alter the scope of the license conveyed with a sale, more complex licensing structures are likely to be implemented. For example, manufacturers may need to impose contractual penalties to dissuade the transfer of used single-use devices. These complex licensing structures will likely cause hospitals' transaction costs of obtaining medical devices to increase.

Amici have argued that if post-sale restrictions are held unenforceable through patent law, healthcare costs will be saved.[59] To the contrary, if all post-sale restrictions are held ineffective and patent owners are forced to convey all

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[58] Br. of *Amicus Curiae* Licensing Execs. Soc'y (U.S.A. and Canada), Inc. in Support of Neither Party [Dkt. 205] at 15–16 ("The 'simplicity' argument likewise fails to account for contractual restrictions that may still be imparted on goods.").

[59] *See* Br. of the Ass'n of Med. Device Reprocessors at 1–2.

of their rights at the time of sale, prices for patented medical devices will likely increase. In *B. Braun*, this Court explained that in transactions where not all rights are transferred "it is more reasonable to infer that the parties negotiated a price that reflects only the value of the 'use' rights conferred by the patentee."[60] Because medical device manufacturers spend millions on research and development of medical devices, they desire to sell their patented technology at a price to recoup these expenditures.[61] Without valid post-sale restrictions that limit the rights conveyed with the original sale, manufacturers may need to raise their prices to compensate, and hospitals may face higher costs as a result of acquiring patent rights that they have little interest in exercising.[62]

CONCLUSION

Reaffirming the viability of *Mallinckrodt* and its progeny post-*Quanta* is not only mandated by Supreme Court case law, it also enables medical device manufacturers to protect patient safety. Doctors, hospitals, device manufacturers, and especially patients, benefit from the simplicity and flexibility of *Mallinckrodt*'s conditional-sale doctrine. This Court should reverse the

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[60] *B. Braun Med.*, 124 F.3d at 1426.
[61] *See* Br. of Licensing Execs. Soc'y at 10.
[62] *See id.* at 13 ("[T]he acquiring party may be quite willing to surrender future use of the disposable articles in exchange for the lower acquisition cost allowed for by patent exhaustion.").

district court's dismissal of Lexmark's patent-infringement claims under the doctrine of patent exhaustion and reaffirm the conditional-sale doctrine under *Mallinckrodt*.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Date: August 19, 2015

By: */s/ Joseph S. Cianfrani*
Joseph S. Cianfrani
Kent N. Shum

Attorneys for Amicus Curiae
Medical Device Manufacturers Association

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). This brief contains 5,550 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This Brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Date: August 19, 2015

By: */s/ Joseph S. Cianfrani*
Joseph S. Cianfrani

Attorney for Amicus Curiae
Medical Device Manufacturers Association

CERTIFICATE OF SERVICE

In Re: **BRIEF OF AMICUS CURIAE MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF LEXMARK INTERNATIONAL, INC.**
Caption: *Lexmark International, Inc. v. Impression Products, Inc.*, 2014-1614, -1619
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STATE OF CALIFORNIA)
) ss:
COUNTY OF ORANGE)

I am a citizen of the United States and a resident of or employed in the County of Orange; I am over the age of eighteen years and not a party to the within action; my business address is: 2040 Main Street, 14th Floor, Irvine, California 92614. On August 19, 2015, I caused to be served two copies of the above-entitled document on the persons interested in said action by FedEx Priority Overnight sealed envelope addressed as follows:

Timothy Meece
tmeece@bannerwitcoff.com
Audra Heinze
aheinze@bannerwitcoff.com
Bryan Medlock, Jr.
bmedlock@bannerwitcoff.com
Jason Shull
jshull@bannerwitcoff.com
BANNER & WITCOFF, LTD.
Ten South Wacker Drive, Suite 3000
Chicago, IL 60606
Phone: (312)463-5420; Fax: (312)463-5720

Benjamin Beaton
bbeaton@sidley.com
Joshua Fougere
jfougere@sidleny.com
SIDLEY AUSTIN LLP
1501 K Street, NW
Washington, DC 20005
Phone: (202)736-8000; Fax: (202)736-8711

Robert Hochman
rhochman@sidley.com
Constantine Trela
ctrela@sidley.com
SIDLEY AUSTIN LLP
Bank One Plaza
1 South Dearborn Street
Chicago, IL 60603
Phone: (312)853-7000; Fax: (312)853-7036

Steven Loy
Steven.loy@skofirm.com
STOLL, KEENON & PARK LLP
300 West Vine Street, Suite 2100
Lexington, KY 40507
Phone: (859)231-3000; Fax: (859)253-1093

Attorneys for Plaintiff/Cross-Appellant,
LEXMARK INTERNATIONAL, INC.

Edward F. O'Connor
eoconnor@avynolaw.com
AVYNO LAW, P.C.
6345 Balboa Blvd., Suite 190
Encino, CA 91316
Phone: (949)291-2894; Fax: (818)332-4205

Attorney for Defendant/Appellant
IMPRESSION PRODUCTS, INC.

I declare under penalty of perjury that the foregoing is true and correct. Service executed on August 19, 2015, at Irvine, California.



Linda Dunn