2014-1617, -1619

United States Court of Appeals for the Federal Circuit

LEXMARK INTERNATIONAL, INC.,

Plaintiff-Cross-Appellant

v.

IMPRESSION PRODUCTS, INC.,

Defendant-Appellant

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

Defendants.

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

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

ROBERT A. SURRETTE
(*Principal Counsel of Record*)
CHRISTOPHER M. SCHARFF
MCANDREWS, HELD, AND MALLOY, LTD.
500 West Madison Street, Suite 3400
Chicago, Illinois 60661
(312) 775-8000
Counsel for Amicus Curiae, Association of Medical Device Reprocessors

June 19, 2015

CERTIFICATE OF INTEREST

Counsel for amicus curiae Association of Medical Device Reprocessors certifies the following:

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

Association of Medical Device Reprocessors

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

Association of Medical Device Reprocessors

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

None

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

Robert A. Surrette and Christopher M. Scharff

MCANDREWS, HELD & MALLOY, LTD.

Counsel for Association of Medical Device Reprocessors

Dated: June 19, 2015

/s/ Robert A. Surrette

Robert A. Surrette
Principal Counsel of Record

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STATEMENT OF INTEREST

The Association of Medical Device Reprocessors ("AMDR") is a trade organization consisting of member companies engaged in the business of reprocessing medical devices. Member companies clean, repair, and re-sterilize (among other steps) medical devices that can safely be reused pursuant to FDA regulations. The devices that AMDR member companies reprocess include, without limitation, used cardiovascular, non-invasive, general surgery, and orthopedic devices, as well as expired devices or open and unused devices. Ultimately, AMDR member companies provide hospitals with safe and effective reprocessed devices, which save healthcare costs and are environmentally friendly.

Some AMDR member companies are subsidiaries or divisions of various original equipment manufacturers ("OEM") of medical devices. As such, those AMDR members may reprocess their own parent company's medical devices. In addition, however, AMDR members provide hospitals with comprehensive reprocessing and recycling initiatives, including by reprocessing devices made by other OEMs. Some of the medical devices reprocessed by AMDR members, therefore, compete with sales of new medical devices made by other OEMs.

AMDR members that market devices in the U.S. are regulated by the Food and Drug Administration (FDA). Before a reprocessed medical device can be marketed or sold, a third-party reprocessor must demonstrate that the reprocessed

device is substantially equivalent in 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:

- Premarket notification or approval
- Quality system requirements
- Registering reprocessing firms and listing all products
- 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

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 investing in new technologies. 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 eliminate millions of pounds from local landfills per year and help hospitals realize over $400 million per year

in supply cost and waste savings. On average, medical device reprocessing can save a single hospital over 50,000 pounds of medical waste per 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 medical device reprocessing industry is not unique. Other products such as automobiles and auto parts, cell-phones and other electronics, computer printer cartridges, and many others are capable of being repaired, reformatted, or refilled many times. By using such refurbishment services, consumers are able to extend the useful life of these products, thereby helping the environment while saving money.

If, however, an OEM/patentee can avoid patent exhaustion simply by including a "single-use" restriction in a purchase agreement or click-wrap/shrink-wrap agreement, both consumers and refurbishers would risk liability for patent infringement if they reprocess or reuse such patented devices. Consumers, including the hospitals that AMDR members serve, would be forced to dispose of new devices that have only been used a single time, and purchase a new replacement device from the patentee. Healthcare costs would multiply, waste would pile up, and competition would be reduced. Patentees would be legally allowed to tie repair/refurbishment services to the sale of a patented product.

AMDR, therefore, seeks to provide the Court with the perspective of an industry that would be impacted significantly by the decision in this case. AMDR submits this brief pursuant to the Federal Circuit's *en banc* order in this case, inviting interested amici to submit briefs without need of a motion to the Court.

Specifically, AMDR submits this amicus brief in support of Defendant-Appellant Impression Products, Inc., to address the second Question Presented:

> The case involves (i) sales of patented articles to end users under a restriction that they use the articles once and then return them and (ii) sales of the same patented articles to resellers under a restriction that resales take place under the single-use-and-return restriction. Do any of those sales give rise to patent exhaustion? In light of *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), should this court overrule *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), to the extent it ruled that a sale of a patented article, when the sale is made under a restriction that is otherwise lawful and within the scope of the patent grant, does not give rise to patent exhaustion?

For the reasons discussed below, such sales do give rise to patent exhaustion under the test articulated in *Quanta*. Under *Quanta*, <u>any</u> authorized sale, regardless of whether it is accompanied by a tangential "single-use" or "use-and-return" restriction in the sales agreement, triggers patent exhaustion. Any post-sale restrictions on a patented device should not be enforceable through patent law, but instead only through contract law. *Quanta's* holding and reasoning reveals that the Federal Circuit's decision in *Mallinckrodt* was based on a misapprehension of earlier Supreme Court precedent, and is no longer good law.

RULE 29(c)(5) STATEMENT

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, including Stryker Sustainability Solutions, Inc., a wholly-owned subsidiary of Stryker Corporation, contributed money intended to fund preparing or submitting the brief. Stryker Corporation has no parent corporation, and no publicly held company owns ten percent or more of its stock.

SUMMARY OF ARGUMENT

For over 150 years, the Supreme Court has recognized the patent exhaustion doctrine as a defining boundary of the scope of the limited monopoly afforded by a patent. Under the patent exhaustion doctrine, an authorized sale of a product substantially embodying the patented invention exhausts the patent right. Put another way, after title of a patented product passes to a purchaser through a sale authorized by the patentee, the purchaser and any down-stream purchaser or user are free under patent law to use, dispose of, or repair the patented product. The patent exhaustion doctrine has fostered commerce in used and refurbished goods, repair services, and replacement parts. It has resulted in beneficial competition. It has helped reduce costs for consumers, allowing lower-cost access to used patented

technology. And it has helped the environment by reducing waste, allowing durable goods to be recycled and reused

In *Mallinckrodt, Inc. v. Medipart, Inc*., 976 F.2d 700 (Fed. Cir. 1992), the Federal Circuit addressed the impact of "post-sale" restrictions in a purchase agreement, and whether a patentee could escape the patent exhaustion doctrine by "conditioning" the patent license afforded through sale of a patented product. The Federal Circuit interpreted prior Supreme Court precedent as having addressed only post-sale restrictions that ran afoul of antitrust law. Under that reasoning, the Federal Circuit in *Mallinckrodt* held that other post-sale restrictions that are not *per se* illegal under antitrust law could, if reasonably tied to the patent, exempt a patented product from the patent exhaustion doctrine. For example, the Federal Circuit found that a sale subject to a post-sale restriction limiting a patented product to a "single use" did not trigger patent exhaustion.

Subsequently, in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), the Supreme Court revisited the effect of patent exhaustion on sales of patented article subject to a post-sale restriction. Instead of using antitrust law as the test for the propriety of a post-sale restriction, the Supreme Court in *Quanta* applied prior precedent without regard to its treatment of antitrust law, and articulated a broad, bright-line test for patent exhaustion. Under *Quanta*, <u>any</u> authorized sale triggers patent exhaustion. The Supreme Court did not limit patent

exhaustion to authorized and unconditional sales of a patented product. As such, *Quanta* overturned *sub silentio* both the express holding and the underlying rationale of *Mallinckrodt*. In particular, *Quanta's* analysis of prior Supreme Court precedent reveals that the Federal Circuit's decision in *Mallinckrodt* was based on a misapprehension of earlier Supreme Court precedent, and is no longer good law. Under *Quanta*, any authorized sale, even if it is accompanied by a "single-use," "use-and-return," or other tangential restriction, triggers patent exhaustion. Such restrictions can only be enforced through contract law, not patent law. The majority of commentators and lower-court judges agree.

ARGUMENT

I. THE SUPREME COURT IN *QUANTA* REAFFIRMED A BROAD AND SIMPLE STANDARD FOR PATENT EXHAUSTION

A. Under *Quanta*, Any Sale "Authorized" By the Patentee Exhausts the Patent, Notwithstanding the Existence of Tangential Post-Sale Restrictions in the Sales Contract

In *Quanta*, the Supreme Court recognized that a balance is necessary between the rightful exercise of a patent owner to reap the rewards for its invention and the right of the public to engage in commerce around the invention and in the patented invention itself. *See Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (U.S. 2008). One way this balance is realized is through the long-established doctrine of patent exhaustion. As re-affirmed by the Supreme Court in *Quanta*, the patent exhaustion rule is both broad and simple: "[T]he authorized sale of an

article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article." *Id.* at 638 (emphasis added). Put another way, the Court stated that "the longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item." *Id.* at 625 (emphasis added). Accordingly, once the patentee parts with title through an authorized sale, complete title to the device purchased becomes vested in the purchaser.

Notably, the Supreme Court's test in *Quanta* does not require both an authorized and unconditional sale. 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. Nor does the patent exhaustion doctrine depend on antitrust law.

Additionally, the Supreme Court's *Quanta* opinion does not limit its holding to narrow facts or on the specific "conditions" in the agreement between the parties. Rather, the Supreme Court recognized that the patentee (LGE) had licensed a manufacturer (Intel) to manufacture and sell products practicing certain patents. *Id.* at 636. What the patentee argued were "conditions" on the manufacturer's license to sell the products (i.e., a contractual provision that the manufacturer was required to notify any purchasers that they could not combine the patented products with non-Intel components) were found by the Court to be

merely collateral agreements that did not render the sales by Intel "unauthorized." *Id.* When the manufacturer sold the products to a third party (Quanta), "Intel's authorized sale to Quanta thus took its products outside the scope of the patent monopoly" and as a result, the patentee could "no longer assert its patent rights against Quanta." *Id.* at 638 (emphasis added).

The Supreme Court's decision in *Quanta* did not deviate from prior precedent, but rather, reaffirmed what it had long held regarding patent exhaustion. Indeed, the Supreme Court in *Quanta* began its opinion by stating that the "longstanding doctrine of patent exhaustion" it was applying had existed since "19th century cases." For example, the Supreme Court in *Motion Picture Patents Co. v. Universal Film Manufacturing Co.*, long-ago held that post-sale restrictions are ineffective to prevent patent exhaustion. 243 U.S. 502, 518 (1917). In that case, Motion Pictures Patents held a patent on film projectors and granted a license to a third party to manufacture and sell projectors. The licensee was required to affix a plate to the projectors it sold, which imposed a post-sale restriction that the machine could only be used with certain motion pictures, and that removal of the plate "terminates the right to use this machine." *See id.* at 516. Universal Film, who was not a party to any contract with Motion Pictures Patents sold end users of the projectors film reels that were not authorized for use with the machines. Motion Pictures Patents sued Universal Film for patent infringement. *See id.*

In *Motion Picture Patents*, the Supreme Court held that the post-sale restriction was unenforceable—the initial authorized sale of the machines by the licensee exhausted the patents and voided any post-sale restrictions. *See id.* at 516. The Court explained 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." *Id.* at 516. The Supreme Court did not state that its finding was narrow or limited to the fact that the specific post-sale restriction in *Motion Pictures* would have also been a *per se* antitrust violation (i.e., tying). *Id.*

Similarly, in *United States v. Univis Lens Co.*, 316 U.S. 241 (1942), the Supreme Court relied on the patent exhaustion doctrine in again concluding that explicit post-sale restrictions were not within the scope of the patent grant. There, the patent holder had attempted to control retail prices of its patented lenses. In response to Univis' claims that the price restraints were permitted by patent law, the government asserted the patent exhaustion doctrine. *Id.* The Supreme Court agreed and 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 . . . ." *Id.* at 251.

Importantly, in *Univis*, while the Supreme Court held that the specific post-sale restraint in that case also would have been a *per se* antitrust violation (price

fixing), it first and foremost held that the reason why the post-sale restriction was unenforceable was due to patent exhaustion. The Court in *Quanta* confirmed this when, even though the facts in *Quanta* did not deal with price-fixing or any other *per se* antitrust violation, it explicitly found that "*Univis* governs this case." *Quanta*, 553 U.S. at 617.

B. The Supreme Court Specifically Pointed to Contract Law—Not Patent Law—as a Permissible Way for Patentees to Enforce Agreements on Post-Sale Activity

The Supreme Court in *Quanta* also explicitly recognized that post-sale restrictions are something to be enforced, if at all, through contract law, rather than patent law. In a footnote, the Supreme Court stated that:

> We note that the authorized nature of the sale to Quanta does not necessarily limit LGE's other contract rights. LGE's complaint does not include a breach-of-contract claim, and we express no opinion on whether contract damages might be available even though exhaustion operates to eliminate patent damages.

Quanta, 553 U.S. at 636, fn. 7 (emphasis added), *quoting Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666 (1895) ("Whether a patentee may protect himself and his assignees by special contracts brought home to the purchasers is not a question before us, and upon which we express no opinion. It is, however, obvious that such a question would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws."); *see also Motion Picture Patents*, 243 U.S. at 509 ("The extent to which the use of the patented

machine may validly be restricted . . . by special contract between the owner of a patent and the purchaser or licensee is a question outside the patent.")

This approach strikes the proper balance. Under traditional contract law, a patentee and purchaser can agree to whatever otherwise legal use restrictions they wish, no different from any other contract. And just like any other contract, breach would give rise to a claim for contract damages—not potential willful patent infringement, attorneys' fees, or injunction that would be available in a patent case. At the same time, third parties and downstream purchasers, who are not privy to the contract, were not involved in its negotiation, and may not even have knowledge of it or its terms, would not be bound by its restrictions. Again, this is no different than any other contract situation. Further, the enforceability of any post-sale restrictions between the patentee and purchaser would be subject to validity challenges under antitrust law, just as with other contracts.

The patent exhaustion doctrine thus avoids accidental violation by innocent downstream purchasers. It also provides certainty to third parties as to their rights to reuse, resell, or repair a patented product. *See, e.g.*, Herbert Hovenkemp, *Post-Sale Restraints and Competitive Harm: The First Sale Doctrine in Perspective*, 66 N.Y.U. Ann. Surv. Am. L. 487, 542 (2011) ("As a general matter one can be guilty of patent infringement without having any notice whatsoever. If that rule were applied to post-sale restraints, the result could be a significant problem of hold-up,

as innocent subsequent purchasers could be sued for patent infringement for violating conditions they knew nothing about.").

C. *Quanta's* Broad Patent Exhaustion Holding Is Consistent With Earlier Supreme Court Precedent Recognizing that Non-Authorized Sales Do Not Trigger Exhaustion and That Patentees Can Restrict Non-Purchaser Licensees

Quanta's broad holding also clearly delineates the type of conduct that does not trigger patent exhaustion. Specifically, the Supreme Court has long recognized a difference between (a) "post-sale" restrictions and (b) "pre-sale" restrictions when it comes to patent exhaustion.

In a pre-sale restriction situation, the patentee grants a license to a licensee to both make and sell the patented product. The patentee has not sold the product to the licensee and thus there is no "authorized sale" from the patentee to the licensee. Rather, the patentee is allowing the licensee to step into its shoes as the manufacturer and the first seller. In that situation, the patentee can put restrictions on the manufacturer-licensee's ability to sell the product in the first instance as a matter of patent law. For example, the patentee can give the manufacturer-licensee a license to only sell the patented product within a certain geographic space, or only make and use the patented product for certain purposes. These are restrictions on the patented product before it is sold or regarding how it is sold.

In these situations, non-licensed use of the patented technology by the manufacturer/licensee or unauthorized sales by the manufacturer/licensee in

violation of the agreement, are unlicensed and therefore infringing. *See, e.g.*, *General Talking Pictures Corp. v. Western Elec. Co.*, 305 U.S. 124, 127 (1938) (holding that a patentee and manufacturer-licensee can agree to field of use restrictions enforceable via patent law on both the licensee and purchasers with knowledge of the restriction). Once the manufacturer-licensee makes an authorized sale to a customer, however, patent exhaustion is triggered—the exact fact scenario of *Quanta*. *See Quanta*, 553 U.S. at 625.

These cases illustrate that the Supreme Court treats pre-sale restrictions between a patentee and manufacturer-licensee (e.g., as in *General Talking Pictures* and *General Elec.*) very differently from post-sale restrictions between a patentee and purchaser (e.g., as in *Quanta*, *Univis*, and *Motion Picture Patents*). Single-use or use-and-return restrictions on a purchaser of a product cannot be enforced through patent law because they are necessarily the latter type—post-sale restrictions. These cases also all reflect again the consistent standard set by the Supreme Court regarding patent exhaustion—the "authorized sale" test.

II. THE SUPREME COURT'S HOLDING IN *QUANTA* OVERTURNED *MALLINCRODKT'S* CONDITIONAL SALE EXCEPTION TO PATENT EXHAUSTION

A. *Mallinckrodt's* Conditional Sale Doctrine Is Inconsistent With *Quanta's* Holding

The Supreme Court's holding in *Quanta* overturned *sub-silentio* *Mallincrodt's* "conditional sale" exception to patent exhaustion. Even though the

Quanta decision does not directly discuss *Mallinckrodt*, it necessarily rejects the holding of *Mallinckrodt*.

Specifically, *Mallinckrodt* involved a patentee's attempt to use a "single use only" restriction in a purchase agreement to control, via patent law, the post-sale use of the patented device after it was sold by the patent holder. *See Mallinckrodt*, 976 F.2d 700. In other words, the sales at issue in *Mallinckrodt* were, by definition, "authorized" because they were directly from the patentee. The sale itself was not "conditioned" on being effectuated only after the single-use restriction was satisfied, i.e., the single-use restriction was not any sort of condition precedent. The single-use restriction was merely a tangential covenant that was part of the contract, unrelated to the transfer of title. *See id.* at 702-703. Nearly every sale agreement contains some provisions that survive the purchase, such as limitations on warranties, limitations on liability, or the like.

The issue in *Mallinckrodt*, therefore, was primarily whether this tangential single-use contract restriction was even valid under antitrust law. *See id.* The Federal Circuit found that such single-use restrictions were not *per se* illegal under antitrust law and also passed the "rule of reason." *See id*. at 706. Once that issue was decided, however, the Federal Circuit went a step further. The Federal Circuit broadly held that any post-sale restrictions that are reasonably tied to the patent and pass antitrust muster also avoid patent exhaustion. *See id.*

The Supreme Court's decision in *Quanta* directly contradicts this "conditional sales" exception to patent exhaustion articulated in *Mallinckrodt*. *Quanta* broadly and unambiguously holds that patent exhaustion results from any "authorized sale," regardless of whether the sales contract contains any post-sale restrictions. *See Quanta,* 553 U.S. at 625. The Supreme Court directly addressed whether a tangential post-sale restriction in a sales agreement (there, an agreement that the patented product could only be used in Intel products) could exempt the sales from patent exhaustion. *See id.* The Court held that such post-sale restrictions cannot avoid patent exhaustion. *See id.* Further, by holding that the earlier Supreme Court *Univis* decision governed, the *Quanta* decision also recognized that post-sale restrictions are voided by patent exhaustion regardless of their legality under antitrust law. *See id.*

Accordingly, the same reasoning necessarily applies to *Mallinckrodt*. The tangential "single-use" restriction present in the contract in *Mallinckrodt* was no more a "condition" on the sale of the patented product than was the post-sale restriction present in *Quanta*. Both were collateral provisions in the sales contract, and neither were prerequisites to the transfer of title to the patented product. The holding of *Quanta* is, therefore, directly at odds with the holding of *Mallinckrodt*.

Most commentators agree. *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) (claiming *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 ("A careful examination of the manner in which the *Quanta* case was litigated and decided . . . indicates that there is no longer any room for continued adherence to the *Mallinckrodt* line of cases.").

Likewise, numerous lower-court judges, in well-reasoned decisions, have determined that *Quanta* overruled Mallinckodt's conditional sale exception. *See, e.g.*, *Ergowerx Int'l, LLC v. Maxell Corp. of Am.*, 18 F. Supp. 3d 430 (S.D.N.Y. 2014) ("*Quanta* precludes the argument that any failure by a party to abide by any contractual condition in an agreement involving a patented device will revive an otherwise exhausted patent so as to permit the patentholder to sue for infringement, as opposed to, e.g., breach of contract."); *JVC Kenwood Corp. v. Arcsoft, Inc.*, 966 F. Supp. 2d 1003, 1010 n.1 (C.D. Cal. 2013) ("After *Quanta* . . . it is unclear to what extent the *Mallinckrodt* decision applies."); *Lexmark Int'l, Inc. v. Ink Techs. Printer Supplies, LLC*, 2014 WL 1276133, **6-7 (S.D. Ohio Mar. 27, 2014) ("this Court's review of the relevant caselaw does not reflect an endorsement by the

Supreme Court of post-sale use restrictions once goods are placed into the ordinary stream of commerce. . . . Thus, to the extent that *Mallinckrodt* holds that such post-sale use restrictions preclude patent exhaustion after an authorized sale, the Court agrees with the *Static Control II* court that *Mallinckrodt* was overruled by *Quanta* sub silentio."); *Intergraph Hardware Techs. Co. v. Dell, Inc.*, 2009 U.S. WL 166559, *3 (E.D. Tex. Jan. 16, 2009) (concluding that *Quanta* is "new law" that overturned the Federal Circuit's conditional sales doctrine).

B. *Quanta* Also Overturned The Underlying Rationale of *Mallinckrodt*, Showing *Mallinckrodt* Was Premised on an Incorrect Interpretation of Earlier Supreme Court Precedent

The Supreme Court's decision in *Quanta* also renders inapplicable the reasoning behind the Federal Circuit's decision in *Mallinckrodt*. Specifically, the Federal Circuit in *Mallinckrodt* had interpreted the Supreme Court's prior patent exhaustion cases, such as *Motion Picture Patents* and *Univis*, as only establishing that "price-fixing and tying restrictions accompanying the sale of patented goods were *per se* illegal." *Mallinckrodt*, 976 F.2d at 704. As the *Mallinckrodt* court interpreted those cases, *Motion Picture Patents* and *Univis* "did not hold, and it did not follow, that all restrictions accompanying the sale of patented goods were deemed illegal." *Id.* at 708. Rather, the Federal Circuit in *Mallinckrodt* found that the enforceability of a post-sale restriction did not depend on the patent exhaustion

doctrine, but instead on whether the post-sale restriction was illegal under antitrust law. *See id.*

The Supreme Court in *Quanta* did not adopt this standard for patent exhaustion. Indeed, the Supreme Court did not look to antitrust law at all in analyzing the enforceability of the post-sale restriction in *Quanta*. Instead of asking whether it was reasonable under antitrust law for LG to prohibit its patented inventions from being used in non-Intel products, the Supreme Court simply held that because the products had been subject to an "authorized sale," patent exhaustion was triggered, making the legality of the post-sale restrictions moot. *See Quanta*, 553 U.S. at 636-638.

Moreover, by stating that "*Univis* governs," *Quanta* recognized that *Univis* did not turn on whether or not the post-sale restriction was illegal under antitrust laws. Indeed, instead of premising its holding on an analysis of antitrust law, the *Univis* Court had in fact started 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. To answer that question, the Court turned to the patent exhaustion doctrine. *Id.*

In other words, the *Univis* Court found that the post-sale restrictions were illegal under antitrust law only after the Court already had concluded that patent

exhaustion voided the restrictions anyway. *See* Saami Zain, *Quanta Leap or Much Ado About Nothing? An Analysis of the Effect of Quanta vs. LG Electronics*, 20 Alb. J.L. Sci. & Tech. 67 (2010) ("*Mallinckrodt* relied on a narrow interpretation of *Univis*, which is inconsistent with how *Univis* was interpreted by *Quanta*."); 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 5 ("*Mallinckrodt* had distinguished *Univis* on the ground that the latter case's patent-exhaustion holding was dependent on and limited by the Court's conclusion that the restrictions imposed by the patent holder violated the antitrust laws. But that purported distinction reflected a fundamental misunderstanding of the *Univis* Court's reasoning.")

Similarly, the *Mallinckrodt* decision also pointed to Supreme Court dictum in *Mitchell v. Hawley*, 83 U.S. 544 (1872) that referred to sales "without any restrictions" as giving rise to patent exhaustion. From that phrase in *Mitchell*, the Federal Circuit in *Mallinckrodt* reasoned that "conditional" sales therefore do not give rise to patent exhaustion. But *Mallinckrodt* misapprehended that statement in *Mitchell*. At the time of *Mitchell* in 1872, a "conditional sale" of property was one in which title did not pass until a condition-precedent had passed. That is quite different from a contract in which a patentee sells a patented product to a purchaser, where the contract simply includes a provision that the product will be

only used for a single use—there is no "condition" that must occur before title to the patented product passes to the purchaser.

C. The Supreme Court's Failure in *Quanta* to Expressly Address and Overrule *Mallinckrodt* Was Not A Stamp of Approval for *Mallinckrodt's* Conditional Sale Doctrine

Some commentators have suggested that because *Quanta* did not explicitly address or overrule *Mallinckrodt* (even though the issue of *Mallinckrodt's* continued viability was initially a question presented), that *Quanta* somehow approved *Mallinckrodt*. The most likely explanation, however, is simply that the Supreme Court did not address *Mallinckrodt* because neither of the parties ultimately asked it to do so. The former Deputy Solicitor General of the United States, who had filed an amicus brief in *Quanta*, believes that after viewing the briefs filed by Quanta and various amici, LGE simply chose not to defend the judgment below based on *Mallinckrodt*. *See, e.g.*, 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 30 (article by the former Deputy Solicitor General discussing his views on *Quanta*). Rather, LGE focused instead on arguing that method patents were not subject to patent exhaustion, an argument that the Supreme Court ultimately rejected. *Id.*

This explanation is supported by LGE's principal brief in *Quanta*, which

contained only a single footnote regarding *Mallinckrodt*, stating that "[e]ven if this Court firmly believes that the Federal Circuit erred in its specific holding in *Mallinckrodt*, the issue presented there is not the one presented here." *Id.* (quoting LGE's principal brief in *Quanta*). At oral argument, Justice Stevens specifically asked LGE's counsel: "Q: Am I correct in understanding that you do not defend the *Mallinckrodt* decision? A: I do not defend the *Mallinckrodt* decision, Justice Stevens, and clearly I don't believe I have to." *Id.* (quoting the transcript of oral argument in *Quanta*). Accordingly, the simple answer for why the Supreme Court did not expressly overrule *Mallinckrodt* as part of the *Quanta* decision is because the patentee there was not relying on *Mallinckrodt*.

III. A CONTRARY RULING WOULD RESULT IN FAR-RANGING NEGATIVE IMPLICATIONS AND UNCERTAINTY

If this Court nevertheless finds, contrary to *Quanta*, that *Mallinckrodt* is still good law, then the patent exhaustion doctrine would be eviscerated. A patentee could potentially exclude from the patent exhaustion doctrine any and all sales of a patented product, including all down-stream sales, simply by including a post-sale restriction in the purchase agreement. Indeed, if the holding of *Mallinckrodt* is taken to its logical conclusion, a patentee could simply put a provision in every sales contract stating that "THIS SALE DOES NOT TRIGGER PATENT EXHAUSTION." It was this very concern that led to the Supreme Court's holding

in *Quanta*. *See Quanta*, 553 U.S. 617 at 630 ("This case illustrates the danger of allowing such an end-run around exhaustion.") (emphasis added).

In modern commerce, a patentee can include post-sale restrictions in an adhesion contract such as shrink-wrap or electronic click-wrap on goods sold to individual consumers. At the same time, however, consumers today can easily repair, refurbish, or resell their goods through vehicles such as EBay.com or Craigslist. Allowing post-sale restrictions to be enforceable downstream through patent law would chill all of this repair and resale activity. There would be little incentive to invest in products and services that complement patented goods, if doing so would risk patent infringement. And consumers would be left to the mercy of whatever high prices the patentee might demand for repair or replacement of a patented good. Modern commerce is better served by a patent exhaustion standard that does not leave a gaping loophole for avoiding it via post-sale restrictions.

Further, if a single-use restriction can avoid patent exhaustion, then where does one draw the line? Without a bright-line rule on patent exhaustion, creative patent holders will undoubtedly attempt to try even more creative post-sale restrictions. A purchaser or down-stream user will have no way of knowing which restrictions are enforceable, which violate antitrust law, or which could expose it to patent infringement liability.

The Federal Circuit in *Mallinckrodt* took the position that only price-fixing and tying restrictions would be impermissible under antitrust laws, and that all other post-sale restrictions on a patented product would be treated under the "rule of reason." Such an approach, however, results in more questions than it answers. For example, could a patentee legally include a post-sale restriction that any repairs can only be made by the patentee under threat of patent infringement? A defendant accused of violating such a restriction might argue that such a post-sale restriction is an illegal antitrust tying arrangement on repair services. But if restricting repair services to only the patentee constitutes impermissible tying, then logically how can a patentee be permitted to dictate that a patented product can only be used once and then a new product must be purchased from the patentee? Indeed, one could say that a single-use restriction is a form of tying, in that sales of replacement devices are tied to a first sale of a patented device.

As another example, under *Mallinckrodt* it is unclear whether a patentee could legally require a purchaser to only resell a patented device to certain authorized refurbishers, or whether the patentee could prohibit the purchaser from reselling a patented device to a specific competing refurbisher. Any such restrictions would have to be analyzed under antitrust rules.

Allowing post-sale patent restrictions would also turn ordinary commercial disputes into complex patent cases. Disputes between a patentee/manufacturer and

a distributor could transform into patent infringement lawsuits rather than run-of-the-mill contract disputes. For example, if a distributor takes patented products that he or she purchased from the patentee, and resells those products outside of an authorized geographic scope or area of use, that distributor would not just be liable for breach-of-contract damages, but potentially treble damages for willful patent infringement. If any post-sale restriction that passes antitrust muster can avoid patent exhaustion, even minor breaches of a distributor agreement, such as disagreements over payment or shipment, could turn into full-blown patent infringement lawsuits.

The bright-line patent exhaustion doctrine of *Quanta* avoids all of this uncertainty. It relegates contract disputes to their proper place—lawsuits for breach of contract. It prevents patent holders from using the much heavier threat of patent infringement liability to enforce simple contract disputes. It gives repair facilities, refurbishing services, purchasers of second-hand goods, and other downstream entities certainty as to their rights with respect to the use or disposition of a patented product. It encourages a beneficial secondary market for used goods, enhances competition, reduces waste, and fosters good environmental practices. In short, businesses and consumers will benefit from a clear adoption of the Supreme Court's broad patent exhaustion rule in *Quanta*, and from a clear finding that *Mallinckrodt's* conditional sale doctrine is no longer good law.

IV. A CLEAR AND BROAD PATENT EXHAUSTION DOCTRINE IS ESSENTIAL TO ROBUST COMMERCE

A holding that *Quanta* overturned *Mallinckrodt* and that "single-use" or "use-and-return" restrictions cannot avoid patent exhaustion is also best for commerce. Repair and refurbishment companies contribute substantially to the United States economy. For example, according to the Automotive Aftermarket Industry Association, the motor vehicle aftermarket industry totaled approximately $285 billion in sales in 2010, with more than 10,000 companies in the United States rebuilding motor vehicle parts. According to the U.S. Census Bureau, in 2010, consumers spent more than $19 billion for repair and maintenance of electronic equipment, including more than $7 billion for computer and office machine equipment repair and maintenance. Gartner Research estimates that in 2014, 56 million refurbished smartphone units were sold to end users around the world. Gartner reports that in North America and Western Europe alone, the market for refurbished phones is approximately $3 billion per year.

Reuse and repair also promotes environmental conservation. For example, rebuilding automotive parts typically re-uses about 88 percent of the raw material from the original parts, and rebuilding engines consumes 50 percent of the energy required to manufacture a new engine. I-ITC estimates that reconditioning ink and toner cartridges will keep approximately 84,000 tons of industrial-grade plastics and metals out of landfills per year. Acquisition guidelines for federal agencies

include a preference for purchasing refurbished or recycled products. *See, e.g.*, 40 C.F.R. § 247.11 (2012); U.S. Environmental Protection Agency, Comprehensive Procurement Guidelines – Non-Paper Office Products, available at http://www.epa.gov/epawaste/conserve/tools/cpg/products/nonpaperoffice.htm#toner (last visited May 12, 2015).

Reprocessed medical devices in particular are a large industry. About 3,000 of the nation's 5,000 or so hospitals have implemented reprocessing programs. AMDR's members reprocess medical devices for 14 of the 17 hospitals recognized on the *US News & World Report* "Honor Roll," including Mayo Clinic, Cleveland Clinic, Johns Hopkins and many others. The Healthier Hospitals Initiative, an alliance of hospitals and health systems that are seeking to boost sustainability in healthcare, released a report in April 2013 finding that 185 hospitals saved $32 million in 2012 by reprocessing single-use medical devices. 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 June 17, 2015).

Even the Food and Drug Administration ("FDA") has recognized the significant benefits of reprocessed medical devices. The FDA recognizes 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/ReprocessingofSingle-UseDevices/ (last visited May 14, 2015). The FDA ensures that "before medical devices can be reprocessed and reused, a third-party or hospital reprocessor must comply with the same requirements that apply to original equipment manufacturers." *Id*.

The primary reason why some OEMs designate medical devices as "for single use only" is simply that the OEMs choose not to conduct the necessary studies to permit labeling the devices, pursuant to FDA regulations, as "reusable." Indeed, some devices are sold as "single-use" in some countries, while being sold as "reusable" in other countries. These single use restrictions, however, also have the potential to be used by OEMs as a vehicle to force hospitals to purchase new devices from the OEM, at a significantly higher cost.

If OEMs are able to use the threat of patent infringement liability to enforce these single use restrictions, the medical device reprocessing industry would suffer. Patent suits involve complex technical issues of claim construction, infringement, and validity, and are very expensive to litigate compared to a simple breach of

contract case. A 2013 survey conducted by the Association of Intellectual Property Law Associations estimates that patent lawsuits typically cost between $970,000 to $5.9 million depending on the amount in controversy. Further, patent infringement suits would bring with them the threat of treble damages for willful infringement, attorneys' fees, and injunctions that would pose an unacceptable risk for small community hospitals or businesses.

Additionally, if post-sale restrictions can be enforced on third party repair/refurbishment companies, who are not privy to any contract between the patentee/manufacturer and purchaser and who may not even be aware of any post-sale restrictions in that purchase contract, then repair or reprocessing companies would be left guessing as to their rights. A repair or reprocessing company that was part of no arms-length negotiation with the OEM/patentee, could nevertheless be subject to the "conditions" of the sale from the OEM/patentee to the hospital, or else be potentially liable as an infringer.

If post-sale restrictions are allowed to avoid patent exhaustion with respect to downstream purchasers or end-users of refurbished goods, the results could be even more draconian. Today, shrink-wrap and click-wrap purchase agreements are ubiquitous. If, for example, a cellphone manufacturer or other electronics manufacturer can simply include a "single-use only" or other post-sale restriction

in a form or adhesion contract, and thereby avoid patent exhaustion, any reseller or consumer of a refurbished device would potentially be a patent infringer.

That is why leading commentators recognize that single-use restrictions to limit reuse of durable goods are "socially harmful" and "not only prevents the rise of a used goods market but limits the use of each good to a single cycle." *See, e.g.*, Herbert Hovenkemp, *Post-Sale Restraints and Competitive Harm: The First Sale Doctrine in Perspective*, 66 N.Y.U. Ann. Surv. Am. L. 487, 542 (2011).

A clear, bright-line rule—that patent exhaustion occurs with an authorized sale, regardless of any tangential provisions in a sales contract—best serves modern commerce. Sellers and purchasers know exactly what they have the right to repair, resell, purchase, or use, free from the threat of infringement suits.

V. CONCLUSION

For the reasons discussed, the judgment of the District Court should be affirmed, and in view of *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), the *en banc* Federal Circuit should overrule *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), to the extent it ruled that a sale of a patented article, when the sale is made under a restriction that is otherwise lawful and within the scope of the patent grant, does not give rise to patent exhaustion. Under *Quanta*, any authorized sale, even if it is accompanied by a "single-use" or "use-and-return" restriction, triggers patent exhaustion.

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Respectfully Submitted,

/s/ Robert A. Surrette

ROBERT A. SURRETTE
(*Principal Counsel of Record*)
CHRISTOPHER M. SCHARFF
MCANDREWS, HELD, AND MALLOY, LTD.
500 West Madison Street, Suite 3400
Chicago, Illinois 60661
(312) 775-8000

Counsel for Amicus Curiae,
Association of Medical Device Reprocessors

United States Court of Appeals
for the Federal Circuit

Lexmark International, Inc. v. Ink Technologies Printer, 2014-1617, -1619

CERTIFICATE OF SERVICE

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by MCANDREWS, HELD, AND MALLOY, LTD., Attorneys for Amicus Curiae, Association of Medical Device Reprocessors to print this document. I am an employee of Counsel Press.

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Edward F. O'Connor
(principal counsel)
AVYNO LAW P.C.
6345 Balboa Boulevard
Suite 190
Encino, California 91316
(818) 488.8140
Counsel for Appellant

Timothy Colin Meece
(principal counsel)
Auda Carol Eidem Heinze
Bryan Medlock, Jr.
Jason S. Shull
Banner & Witcoff, Ltd.
Ten South Wacker Drive
Chicago, IL 60606
312-463-5420
tmeece@bannerwitcoff.com
aheinze@bannerwitcoff.com
bmedlock@bannerwitcoff.com
jshull@bannerwitcoff.com
Counsel for Cross-Appellant

Steven B. Loy
Stoll, Keenon & Park, LLP
300 West Vine Street, Suite 2100
Lexington, KY 40507-1380
859-231-3000
steven.loy@skofirm.com
Counsel for Cross-Appellant

Constantine L. Trela, Jr.
Sidley Austin LLP
Bank One Plaza
1 South Dearborn Street
Chicago, IL 60603
312-853-7000
ctrela@sidley.com
Counsel for Cross-Appellant

Benjamin Beaton
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005
202-736-8000
bbeaton@sidley.com
Counsel for Cross-Appellant

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June 19, 2015

/s/ Elissa Matias
Counsel Press

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Dated: June 19, 2015

Respectfully Submitted,

/s/ Robert A. Surrette

ROBERT A. SURRETTE
(*Principal Counsel of Record*)
CHRISTOPHER M. SCHARFF
MCANDREWS, HELD, AND MALLOY, LTD.
500 West Madison Street, Suite 3400
Chicago, Illinois 60661
(312) 775-8000

Counsel for Amicus Curiae,
Association of Medical Device Reprocessors