No. 15-1189

IN THE

# Supreme Court of the United States

IMPRESSION PRODUCTS, INC.,
*Petitioner,*

v.

LEXMARK INTERNATIONAL, INC.,
*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## BRIEF FOR MEDTRONIC PLC AND ZIMMER BIOMET HOLDINGS, INC. AS AMICI CURIAE SUPPORTING RESPONDENT

PAIK SABER
MEDTRONIC PLC
710 Medtronic Parkway
Minneapolis, MN 55432

AMY LYDON
MEDTRONIC PLC
60 Middletown Ave.
North Haven, CT 06473

JOSEPH TOPMILLER
ZIMMER BIOMET
345 East Main Street
Warsaw, IN 46580

KATHLEEN A. DALEY
*Counsel of Record*
J. DEREK MCCORQUINDALE
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Ave., NW
Washington, DC 20001
(202) 408-4000
kathleen.daley@finnegan.com

*Counsel for Amici Curiae*

February 23, 2017

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

## INTEREST OF AMICI CURIAE

Amicus Medtronic PLC is the world's largest medical technology company.[1] With over 85,000 employees, Medtronic is transforming healthcare worldwide, improving outcomes, expanding access, and enhancing value. Medtronic is a leading innovator in the medical-device industry and capitalizes on the intellectual property it generates. Medtronic owns over 15,000 issued patents in the United States and files over a thousand original patent applications annually.

Amicus Zimmer Biomet Holdings, Inc. is a medical technology company that, through its subsidiaries, designs, manufactures, and markets innovative orthopedic and other musculoskeletal devices for surgeons around the world. Zimmer Biomet has been a driving force in the musculoskeletal healthcare industry for nearly 90 years and sells its products in 100 countries worldwide. Like Medtronic, Zimmer Biomet holds and practices a significant number of patents in the United States, and that number grows every year.

The first question presented in this case is whether a patentee may invoke patent law to enforce restrictions on the use or resale of a patented article after an authorized conditional sale (with post-sale restrictions) of the article in the United States. As leaders in the medical-device industry, amici Medtronic and Zimmer Biomet file this brief to explain how the

---

[1] Pursuant to Rule 37.6, amici affirm that no counsel for a party authored this brief in whole or in part, no such counsel or a party made a monetary contribution to fund its preparation or submission, and no person other than amici or its counsel made such a monetary contribution. Respondent Lexmark International, Inc., filed a letter of blanket consent to amici. Petitioner Impressions Products, Inc., granted consent on February 22, 2017 by electronic mail, a copy of which is submitted herewith.

availability of patent remedies to enforce single-use restrictions on medical devices promotes patient safety and helps original device makers protect their reputation and goodwill. Amici take no position on the second question presented.

## SUMMARY OF ARGUMENT

In the medical-device industry, devices come in two forms—single-use and reusable. Many crucial medical devices for today's physicians are single-use devices. They are designed and tested only for one use or for use on a single patient during a single procedure, and not for subsequent cleaning, resterilization, and reuse. Although safe when used as recommended by the manufacturer, single-use medical devices may have complex structures that were not designed with repeated cleaning, resterilization, and reprocessing in mind. In addition, single-use medical devices may include components that were not designed to withstand multiple uses.

This is in contrast to reusable medical devices, sometimes called multi-use devices. Reusable medical devices are specifically designed for repeated use. Design choices relating to efficacy, durability, and ease of cleaning, disinfection, and sterilization of various components are selected with reprocessing in mind. Manufacturers include cleaning instructions with reusable medical devices that explain which reprocessing methods will allow the device to be reused without degrading it. Once used, medical providers may send their reusable medical devices to the manufacturer or third-party reprocessing companies, who clean, disinfect, and sterilize the devices according to the manufacturer's instructions.

Although single-use medical devices are not designed for reprocessing, third-party reprocessing companies with no relationship with the original manufacturer nevertheless collect certain used single-use medical devices, reprocess them, and sell them at a cost lower than a new single-use device. The original manufacturers, however, need not provide the Food and Drug Administration (FDA) with procedures for proper resterilization and reuse since single-use medical devices are not designed for reprocessing. As a result, those third-party reprocessors may not have cleaning instructions, complete design specifications, and other guidance from the original manufacturer to determine whether a single-use medical device, though not designed for reuse, would be amenable to reprocessing.

And because single-use medical devices are continually being improved, third-party reprocessors face additional problems when trying to reuse a medical device designed for a single use. For example, manufacturers regularly make design changes, which run the gamut from complete redesigns to minor reengineering of internal components to changes in raw materials or material suppliers. While FDA approval or premarket clearance is required for significant changes, minor changes instead require an internal letter to the file or notification to the FDA after the fact in a periodic report, depending on the device type. See 21 C.F.R. §§ 807.81(a)(3), 814.39. As a result, third parties, such as unauthorized reprocessors, may not know all the design changes made to a single-use medical device.

Even minor design changes may affect whether and how a medical device may safely be reprocessed, and this is especially true for a medical device that was designed for only a single use, such as a surgical vessel

sealer, cardiac catheter, or optical trocar. In addition, single-use restrictions are often used to ensure compatibility between the single-use device and associated medical equipment. Therefore, a third-party reprocessor who has reprocessed a single-use medical device may be unaware of design changes that necessitate a revised reprocessing regime or make reprocessing of that single-use medical device even less feasible, or that impact compatibility with other associated medical equipment.

When there is a problem with a reprocessed single-use medical device, the original manufacturer's reputation is at stake because a reprocessed medical device still retains the original manufacturer's markings and trademarks even though the reprocessor adds an additional mark to the device. As a result, when a reprocessed medical device fails, that problem can be wrongly associated with the original manufacturer in the eye of the customer. Reprocessed medical devices are frequently returned to the original manufacturer despite it not having serviced, validated, or sold the reprocessed devices that failed. This causes confusion in the market as to the source of the reprocessed medical device and tarnishes the original manufacturer's goodwill.

The continued availability of patent remedies to enforce single-use restrictions is important to original manufacturers for guarding against these risks and protecting their reputations. Because patent remedies may deter unauthorized third-party reprocessing, used single-use medical devices can be discarded as intended or funneled back to their original manufacturer. Contract law alone cannot provide the same incentives, because the manufacturer and reprocessor ordinarily lack contractual privity. Removing the

protection that patent law provides to enforce clearly conveyed, single-use restrictions on medical devices would likely cause reprocessing of single-use medical devices to increase, leading to more confusion in the marketplace and potentially eroding the original manufacturer's reputation and goodwill.

Concern that the availability of patent remedies to enforce single-use restrictions on medical devices will end the reprocessing industry is overstated. Manufacturers have provided medical devices on the condition they be limited to a single use for decades, and these restrictions have been enforceable under the patent laws for a quarter of a century. Yet during that time, the market for reprocessing multi-use medical devices has flourished. Allowing manufacturers to continue to enforce single-use restrictions under the patent laws incentivizes reprocessors to keep their efforts focused on medical devices intended to be reusable.

While third-party reprocessors argue that reprocessing could provide a lower-cost alternative to purchasing brand-new single-use medical devices, the overall costs and benefits associated with reusable and single-use medical devices are more complicated than that. A market exists for both single-use and reusable medical devices, and can adjust for the existence of single-use restrictions by devaluing products that have such restrictions. There is no reason to remove available patent remedies for single-use medical devices simply to achieve a perceived lower-cost alternative. The market can already dictate those terms under the current system. In other words, the market for single-use and reusable medical devices is robust and functioning without the need for this Court to intervene and restructure the reprocessing industry, which by its own account has been booming.

## ARGUMENT

### THE AVAILABILITY OF PATENT REMEDIES TO ENFORCE SINGLE-USE RESTRICTIONS ON MEDICAL DEVICES BENEFITS PATIENTS AND HELPS TO PROTECT THE ORIGINAL MANUFACTURER'S REPUTATION AND GOODWILL

#### A. Increasing Unauthorized Reprocessing of Single-Use Medical Devices Could Risk Patient Harm

1. Some medical devices are specifically designed to be reprocessed and reused. These are referred to as reusable or multi-use devices. Medical providers and hospitals often contract with third-party reprocessing businesses to clean their reusable medical devices.

The development process for reusable medical devices "often includes multiple redesigns and compromises" related to "the functionality and dimensions" in an effort to produce a device that "can be reprocessed, where possible with automated processes." Eucomed, *White Paper on the Reuse of Single Use Devices* 12 (2009) (Eucomed White Paper), <tinyurl.com/eucomed whitepaper>. The FDA notes that "[m]anufacturers of reusable devices should consider device designs that facilitate easy and effective cleaning, as well as any necessary disinfection or sterilization by the users." FDA, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* 4 (2015).

Manufacturers are cautioned that, "[f]rom the earliest stages of device design and engineering, [they] should consider alternative designs to facilitate effective reprocessing (e.g., replace features that are challenging to reprocess with single-use parts; include flush ports; specify and/or provide dedicated cleaning

accessories)." *Id.* The manufacturer must also develop cleaning instructions to accompany the reusable medical device. *Id.* at 4-22. As a result, in order to facilitate effective subsequent cleaning and resterilization, the design process for reusable devices can be complicated as well as time consuming and costly.

2. In contrast to reusable devices, a single-use medical device is intended by the original manufacturer for one use or on a single patient during a single medical procedure. The product packaging for a medical device will typically state whether the device is designated for a single use, and the device itself may carry a label to that effect too. Medical-device manufacturers are responsible for making that designation, which depends primarily on whether the device was designed and validated to be reprocessed for multiple uses (i.e., the cleaning, disinfecting, and sterilizing of a used device).

For single-use medical devices, because manufacturers need not focus on facilitating reprocessing, they can develop complex devices that may not lend themselves to repeated use or easy cleaning after the initial use. And the manufacturer need not develop a protocol for cleaning and reprocessing a single-use medical device, or provide dedicated cleaning accessories. Instead, the manufacturer can focus its design efforts solely on optimizing the safety and effectiveness of the device for the intended single use. As a result, single-use medical devices are safe, "reliable," "enable technically complex operations to be performed," and may be "easier to use" than their reusable counterparts. Zvi Fireman, *Biopsy Forceps: Reusable or Disposable?*, 21 J. Gastroenterology & Hepatology 1089, 1090 (2006); A.W. van Drongelen & A.C.P. de Bruijn, Dutch Nat'l Inst. for Pub. Health & the Env't, *Reprocessing of*

*Medical Devices* 9 (2008) (Dutch Report), <tinyurl.com/dutchreprocessingreport>. Many surgeries "could not be performed or would be considerably more invasive and riskier" without the availability of single-use medical devices. Dutch Report at 9.

Despite the differences between reusable and single-use medical devices, third-party reprocessors collect and clean certain used single-use devices and sell them for reuse. These reprocessors must seek premarket clearance from the FDA in the form of a "510(k)" premarket notification submission or a report seeking premarket approval containing, among other information, validation data to distribute reprocessed single-use medical devices. The FDA considers such reprocessors to be "manufacturers" of those cleared or approved reprocessed devices, subject to the traditional regulatory framework applicable to medical-device manufacturers, including the requirement to register their facilities and list the devices they distribute with the FDA, 21 C.F.R. Part 807; properly label the device, 21 C.F.R. Part 801; develop and implement a quality system, 21 C.F.R. Part 820; comply with medical-device reporting obligations, 21 C.F.R. Part 803; and report certain corrections and removals of previously distributed devices to the FDA, 21 C.F.R. Part 806.

Even with the FDA regulating reprocessed single-use medical devices, there could still be gaps in the process that introduce risk because third-party reprocessors of single-use devices often do not have full access to all design changes made by the original manufacturer. Manufacturers are continually innovating medical devices and regularly making design changes, ranging from complete redesigns to the minor reengineering of internal components, or changing

raw materials or material suppliers. In doing so, manufacturers must follow strict quality system regulation requirements to evaluate planned changes (including through appropriate testing), document those changes in a design history file, and maintain that file for future reference as well as FDA inspection. See 21 C.F.R. §§ 820.30, 820.180.

While significant changes require FDA clearance through the premarket notification 510(k) process or premarket approval, minor changes instead require an internal letter to the file or submission to the FDA in a periodic report. See FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff* (1997); FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device: Draft Guidance for Industry and Food and Drug Administration Staff* (2016); see also 21 C.F.R. § 814.39. Reprocessors may thus be unaware of some design changes made to a single-use medical device. For example, a manufacturer may change a component material or a surfacing process that, while not impacting the device in a single use context, may have different implications when subject to repeated use or reprocessing techniques such as sterilization. And because even a minor change may affect whether and how a medical device may be safely reprocessed, reprocessors cleared or approved to reprocess a single-use medical device may be unaware of all of the changes that could affect the reprocessing regime.

Amici have faced this problem first-hand. In 2016, Medtronic issued a routine software update for one of its medical generators used to power single-use surgical tools. After that update, certain older tools became incompatible with the generator. But an

unauthorized third-party reprocessor, unaware of the software update, continued to sell those older tools for use with the generator and eventually was forced to recall them. See Health Canada, *Recalls & alerts: LigaSure Blunt Tip Laparascopic and Impact Open Sealer/Divider* (Dec. 13, 2016), <tinyurl.com/stryker ligasurerecall>. If that problem had been encountered during a surgical procedure, complications could have ensued, such as the surgeon being forced to wait for a new vessel-sealing instrument while the patient was on the surgical table and at risk for infection.

Even for design changes that require 510(k) clearance or premarket approval by the manufacturer, which are therefore publicly disclosed by the FDA, unauthorized reprocessors typically will not have access to detailed information about the change. The FDA 510(k) Premarket Notification and PMA Databases only show limited information relating to changes made to devices cleared through the 510(k) process or approved through a supplemental premarket approval. In order for the reprocessor to obtain more information relating to the changes made, the reprocessor must complete a full Freedom of Information Act request, which may take months or years. See FDA Freedom of Information Annual Report 2014. Even when the unauthorized third-party reprocessor eventually receives the 510(k) submission or report seeking premarket approval, the 510(k) or premarket approval report will typically be redacted to protect the original manufacturer's confidential commercial and trade-secret information.

Reprocessors with no relationship to the original manufacturer face additional hurdles when seeking to reprocess a single-use medical device. They have little insight into the design features and intent of the

medical-device manufacturer other than what is available from physical inspection of the device and the FDA 510(k) Premarket Notification and PMA Databases. Medical-device manufacturers design their single-use product with specifications, materials, and validated manufacturing processes that provide a reasonable assurance of the device's safety and effectiveness. Without that product-specific information, these third-party reprocessors may be forced to disassemble and reverse-engineer the device as best they can to determine whether and how a given single-use medical device can be reprocessed. Lacking the manufacturer's design knowledge, a third-party reprocessor may fail to recognize all of the places where debris and potential contaminants may collect on the device. See Michelle R. Tinkham, *Reprocessing of Single-Use Devices: Do the Benefits Outweigh the Potential Dangers?*, 5 Perioperative Nursing Clinics 377, 379 (2010) (Tinkham) ("This information may be difficult to acquire because many OEM [original equipment manufacturer] companies claim that reprocessors do not have access to their proprietary product specifications.").

It has also been recognized that single-use medical devices may have structural features that complicate effective reprocessing. Those devices can be "more delicate and physically complex than reusable devices." K. Roth et al., *Specific Hygiene Issues Relating to Reprocessing and Reuse of Single-Use Devices for Laparoscopic Surgery*, 16 Surgical Endoscopy 1091, 1091 (2002). Medical devices with sharp angles, hinges, coils, or long or narrow cavities may create particular challenges for reprocessing. See U.K. Meds. and Healthcare Prods. Reg. Agency, *Single-Use Medical Devices: Implications and Consequences of Reuse* 7 (2013), <tinyurl.com/gwnznv8>. These are just some of

the challenges to reprocessing a single-use medical device so that it is safe and effective.

The original manufacturer, with its specific knowledge of the product, remains in the best position to know the extent to which a single-use device is amenable to reprocessing. Diluting or eliminating a manufacturer's ability to enforce single-use restrictions could exacerbate the risks posed by third-party reprocessing of single-use medical devices.

### B. The Original Manufacturer's Reputation and Goodwill Are Compromised When an Unauthorized Reprocessor Reprocesses and Resells a Single-Use Device

When problems arise with reprocessed medical devices, the reputation of the original manufacturer may be injured despite not having designed the product for multiple uses or reprocessing and not having approved of the method of reprocessing. And although reprocessors are required to place their own mark on the reprocessed device, the reprocessed device still retains the mark of the original manufacturer as well, leading to confusion in the market and reputational injury. 21 U.S.C. § 352(u) (2012); FDA, *Compliance with Section 301 of the Medical Device User Fee and Modernization Action of 2002—as amended*, <tiny url.com/ j4jt79w>. The Federal Circuit identified similar facts underlying its *Mallinckrodt* decision twenty-five years ago. *Mallinckrodt, Inc.* v. *Medipart, Inc.*, 976 F.2d 700, 702 (Fed. Cir. 1992) (after unauthorized reprocessing by Medipart, the devices were "shipped back to the hospitals," but "still bear[ing] the inscription 'Single Use Only' and the trademarks 'Mallinckrodt' and 'UltraVent'").

The confusion in the market as to the source of reprocessed single-use medical devices is demonstrated by the fact that if third-party reprocessed devices fail during procedures, they are often returned to the original manufacturer instead of to the unauthorized reprocessor that last serviced it. Such a situation leaves the customer with the mistaken impression that the failure is due to a problem with the originally manufactured device when, in fact, the problems may have arisen through reprocessing or repeated use. This confusion inevitably harms the goodwill that an original manufacturer has developed over time and damages its reputation with customers.

Original manufacturers are also frequently asked to investigate problems with their marked devices, only to determine that the devices in question were reprocessed by third parties not authorized by the original manufacturer. Oftentimes, a device failure is reported to the original manufacturer, but it is difficult to investigate since the reprocessed device has not been returned and cannot be tracked down. As a result, it is not always possible to properly link a patient injury to a reprocessed device. See Tinkham at 379-80 (noting that many original device manufacturers "have performed testing of reprocessed versions of their products and have found many issues," and that "[d]ue to poor tracking and reporting processes within [healthcare] facilities, . . . some patient injuries may not be linked to a reprocessed item"). This leaves the original device manufacturer compromised because it cannot evaluate whether the problem was attributable to its device or a third-party reprocessor.

Also, in order to obtain clearance from the FDA, a reprocessor has to show that the reprocessed single-

use device is "substantially equivalent" to the originally manufactured device or "any device of that type." FDA, *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices* 4, 9 (2006); 21 C.F.R. § 807.87. But a reprocessed device that the FDA has determined to be substantially equivalent to the original single-use device may still not meet the full spectrum of the original manufacturer's requirements.

For example, a manufacturer may have a requirement that a knife or cutting edge have a particular degree of sharpness. That sharpness could degrade with reprocessing. And while the blade may still be substantially equivalent to the original device, it may not meet the manufacturer's very high standard. As another example, a manufacturer may provide a specific nano-coating on the jaws of a single-use surgical instrument, which improves, but is not integral to, the performance of the instrument. The nano-coating cannot withstand reprocessing. As a result, when that instrument is reprocessed, the improved performance resulting from the nano-coating may not be maintained. Or, a manufacturer may have requirements regarding the finish on a handle. That finish could become blemished or discolored after reprocessing. This may not be something that affects the safety and effectiveness of a product but does impact the manufacturer's brand and reputation for a certain quality product. Thus, the reprocessed device, while cleared by the FDA, may not perform in every respect as the original manufacturer intended. This leads to further problems for the original manufacturer since that reprocessed device is being sold with its markings still on the device.

The reputational harm resulting from this practice led a trade group of many original manufacturers to file a Citizen Petition with the FDA to stop it. The trade group sought to have the FDA require third-party reprocessors of single-use medical devices to remove identifying marks of the original device manufacturer, including any references in the label. But the FDA denied the request. See FDA, *Medical Devices; Guidance on Labeling of Reprocessed Single Use Devices; Request for Comments and Information* (2001), <tinyurl.com/zsdh3rd>. So FDA regulations alone do not eliminate the potential for market confusion based on a third-party reprocessor's actions.

Removing protections that a patent provides in enforcing clearly conveyed single-use restrictions would only increase these harms to an original device manufacturer's reputation. If the "long-settled view [is] that the essence of a patent grant is the right to exclude others," *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980), then, as the Federal Circuit noted, the ability to do so in order to safeguard a company's reputation is "hardly unrelated to the interests protected by the patent law," *Lexmark Int'l, Inc.* v. *Impression Prods., Inc.*, 816 F.3d 721, 752 (Fed. Cir. 2016) (en banc), *cert. granted*, 137 S. Ct. 546 (2016). The Federal Circuit acknowledged this legitimate concern facing original device manufacturers and recognized the right to exclude in this context, particularly because it touches on reliability and patient safety. *Id.* ("A medical supplier in Mallinckrodt's position plausibly may have similar reason to believe that reuse, when not under its own control, carries a significant risk of poor or even medically harmful performance, to the detriment of its customers and its own reputation."). FDA regulations lack the necessary provisions to protect these reputational interests, and

contract law alone cannot provide relief because the manufacturer and reprocessor ordinarily lack privity. Single-use restrictions are critical to helping original manufacturers prevent marketplace confusion and the resulting damage to reputation.

### C. The Enforceability of Single-Use Restrictions on Medical Devices Has Not Destroyed the Reprocessing Industry and Is Good for the Healthcare Industry

1. Various amici supporting petitioner, including the Association of Medical Device Reprocessors Association (AMDR), AMDR Br. 16-21, argue that the availability of patent remedies to enforce single-use restrictions will spell the end of secondary markets for used products. That has certainly not been the case with medical devices.

In fact, the AMDR boasts that reprocessing medical devices is a successful industry in the United States, AMDR Br. 9-10, notwithstanding that the Federal Circuit's conditional-sale doctrine in patent cases has been binding precedent dating back to *Mallinckrodt*. It cannot be that the *Mallinckrodt* decision was simply ignored all those years, as AMDR suggests, AMDR Br. 5, 14; on the contrary, it was heavily cited and frequently reaffirmed. *E.g.*, *Princo Corp. v. ITC*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (en banc); *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1298 (Fed. Cir. 2002), *cert. denied*, 537 U.S. 1232 (2003); *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997). So the Federal Circuit's recent *Lexmark* decision is not likely to suddenly "erase medical device reprocessing," as the AMDR claims, AMDR Br. 3, because it merely "reaffirm[s] the principles of [its] earlier decisions" that have been the controlling law for decades. See *Lexmark*, 816 F.3d at 726. The *Mallinckrodt* era

coincides with a period of growth for reprocessors. See AMDR Br. 3, 9-10.

2. There is a good reason why reprocessors generally have been able to thrive alongside the conditional-sale doctrine: medical providers want at least some products they can reuse or resell. In other words, there is market demand for *both* reusable and single-use medical devices. That demand naturally drives original manufacturers to supply reusable medical devices in the first instance, in addition to single-use medical devices. And that in turn opens the door for the reprocessing industry to service reusable medical devices.

What is more, the fact that medical providers desire some reusable medical devices demonstrates that the market places some value on reusability. Presumably, then, the market adjusts to the existence of single-use restrictions by devaluing products so restricted. Indeed, that is exactly what happened with respondent's ink cartridges: the reusable version fetches a price "roughly 20 percent" higher than the single-use version. Pet. App. 10a. In the medical device space, a similar phenomenon has been documented. See Eucomed White Paper at 6 ("Multiple use devices would normally command a significant premium over single use devices . . . ."). The touted efficiency and environmental benefits to reprocessing, moreover, must be weighed against the considerable resources consumed to make devices reusable. Compare *id.* at 7 ("[A]nalyses of the environmental impact of single use devices should also consider the significant resources (e.g. chemicals) needed and the energy consumed during the refurbishment of devices."), with AMDR Br. 3, 5. See also Philip Jacobs et al., *Economic Analysis of Reprocessing Single-Use Medical Devices: A Systematic Literature Review*, 29 Infection Control and Hospital

Epidemiology 297, 301 (2008) (surveying economic literature to assess the costs and benefits of reusing single-use medical devices and concluding that "[o]ur review indicates that the cost-effectiveness of reusing single-use medical devices is not established").

Enforceable single-use restrictions ensure that both single-use and reusable medical devices are available in the market. Absent patent remedies, contract law and FDA regulations alone do not fully address all potential harms created by unauthorized reprocessing of single-use devices. Overturning the line of authority subjecting unauthorized single-use reprocessors to liability under 35 U.S.C. § 271 will undoubtedly increase the frequency of such activities. The status quo permitting enforceable single-use restrictions provides a net social benefit. It provides ready access to affordable medical devices while minimizing risk to patient safety. At the same time, it maintains the current functioning market and incentivizes the reprocessing industry to focus its efforts on those reusable devices that are designed for reprocessing.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

PAIK SABER
MEDTRONIC PLC
710 Medtronic Parkway
Minneapolis, MN 55432

AMY LYDON
MEDTRONIC PLC
60 Middletown Ave.
North Haven, CT 06473

JOSEPH TOPMILLER
ZIMMER BIOMET
345 East Main Street
Warsaw, IN 46580

KATHLEEN A. DALEY
*Counsel of Record*
J. DEREK MCCORQUINDALE
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Ave., NW
Washington, DC 20001
(202) 408-4000
kathleen.daley@finnegan.com

*Counsel for Amici Curiae*

February 23, 2017