Legal Backgrounder

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# DOES REPROCESSING MEDICAL DEVICES TREAD ON TRADEMARK RIGHTS?

by

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Imagine you go for an angioplasty to repair a clogged artery. Shortly before the procedure, a nurse appears with a consent form on a clipboard. The nurse explains that the catheter and balloon that your cardiologist will be using have been previously used on one or more patients, but that these devices have been carefully reprocessed after each use. This, the nurse explains, is highly cost-effective, and your signature on the consent form is needed just to show that you understand the catheter and balloon have been previously used.

"Is this safe?" you ask, a little nervously. "Hey, are you by any chance a lawyer?" the nurse asks. "If you are, you don't need to sign the form. We just go ahead and use new catheters and balloons on all lawyers."

The most important fact about the reprocessing of medical devices is that, in reality, scenes like this do not take place. Patients (and sometimes even physicians) are not always advised that the medical devices used in procedures like angioplasty have been previously used on other patients and then "reprocessed" by third-party vendors for use on other patients. Many of these devices are labeled by the original manufacturer for "single-use only" and are often called "SUDs."

The third-party reprocessing industry appears to be growing rapidly. In June 2000, the General Accounting Office estimated that 20% to 30% of hospitals reused SUDs on multiple patients but cautioned that this estimate may be low. GAO, "Single-Use Medical Devices," No. HEHS-00-123, at 10 (June 2000). Commonly reprocessed SUDs include cardiovascular and urethral catheters, orthopedic blades, saws, and fixation devices, and various endoscopic devices.

Manufacturers often label devices as "single use only" because to market these devices for multiple use requires the manufacturer to prove to the U.S. Food & Drug Administration ("FDA") that the device can be reused and still be the equivalent of a new device in terms of safety and efficacy. It is always expensive, and often difficult or impossible, to prove to FDA's satisfaction that a device can be safely and effectively

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reused, even after "reprocessing." When a device is labeled "for single-use only," this means that the necessary studies to prove its safety and effectiveness for multiple reuses either have not been conducted or, in some cases, could not be conducted.

Does the reprocessing of a medical device, especially one labeled for single-use only, by a third-party vendor infringe the trademark of the original manufacturer of the device? The courts have split on this question, even on essentially identical facts.[1] If the courts eventually reach a consensus that third-party reprocessing of SUDs generally does infringe the trademark of the original manufacturer, then reprocessing of SUDs, except by hospitals themselves or the original manufacturers, would effectively be at an end. Consequently, this question has vital importance both to original manufacturers and the third-party reprocessors.

Trademarks play an unusually important role in the context of critical medical devices used by physicians and nurses. The consistent high quality of those devices is more important than with most run-of the-mill goods. Also, the emergency nature of some medical procedures, plus the often harried pace of medicine in general, puts a premium on the quick and confident recognition of a particular manufacturer's product. Not surprisingly, original manufacturers usually place their trademarks directly on their devices.

When a hospital decides to reprocess a SUD, rather than discard it, the hospital collects the used SUD and gives it ─ often in a simple bucket with other used SUDs ─ to a third-party reprocessor. The reprocessor then cleans, repairs, resterilizes, repackages, and returns the SUD to the hospital for use on another patient. The "repair" of the device may include sharpening a blade or replacing critical components. Sometimes the reprocessor etches its own tracking number on the device, but more often the reprocessor has no reliable means of tracking how many times (or "turns," in the lingo of reprocessors) the device has been used. The new package should display the reprocessor's name, but usually the reprocessor does not put its own trademark on the device or deface the trademark of the original manufacturer.

Thus, once a reprocessed SUD is removed from its new package by a hospital technician, there may be no easy way for a scrub nurse or a surgeon to determine that the device is reprocessed rather than new. The hospital at some level may be aware that reprocessed SUDs are being used on its patients, but the "end users" ─ nurses, surgeons, and, not least, the patients themselves ─ may not.

Against the backdrop of the growing trend toward third-party reprocessing of SUDs, Congress in 2002 imposed a specific labeling requirement for devices reprocessed by a third-party reprocessor. Each such SUD must "conspicuously" bear the statement "Reprocessed device for single use. Reprocessed by [name of the third-party reprocessor]." Medical Device User Fee & Modernization Act of 2002, Pub. L. No. 107-250, § 302(a) (codified as amended at 21 U.S.C. 352 (2002)). Congress, however, did not address, or even consider, the trademark issues raised by reprocessing of trademarked medical devices. (Congress also imposed requirements that third-party reprocessors, in certain instances, provide FDA with "validation" data to prove that their cleaning and resterilization produce consistently acceptable results.)

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[1] *Compare Karl-Storz Endoscopy-Am., Inc. v. Fiber Tech Med., Inc.*, No. 00-1032, 2001 WL 94739 (4th Cir. Feb. 5, 2001) (unpublished) (holding rebuilding of endoscopes by third-party at request of hospital is not trademark infringement because trademark is not used in commerce), *with Karl Storz Endoscopy-Am., Inc. v. Surgical Tech., Inc.*, 285 F.3d 848 (9th Cir. 2002) (holding third-party's reprocessing at request of hospital to be used in commerce of trademark; most important factor is confusion of end-users of device).

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Trademark infringement is the use of a trademark in commerce on goods in a way that is likely to cause confusion. These two elements ─ use in commerce, and likelihood of confusion ─ both apply to the reprocessing of SUDs in distinctive ways.

The root principle of trademark law that is implicated by the third-party reprocessing of SUDs is the "first sale rule," which provides that the mere resale of a trademarked product by a purchaser of that product does *not* constitute trademark infringement. This is why we can place a classified advertisement in the newspaper offering to sell our old Mustang convertible without fear of receiving a frosty letter from the Ford Motor Company legal department.

The first sale rule, however, does not by itself answer two important collateral questions. The first of these questions has bedeviled trademark law for decades, but the second is relatively new and belongs almost entirely to the context of reprocessed medical devices.

The first question is whether it constitutes trademark infringement to sell a trademarked product that has been substantially altered. The courts, with their typical precision, have answered this question with, "It depends." (Some of these cases, for example, have arisen in the context of retailers of expensive wristwatches, who have undertaken to make these already fancy watches even fancier, by, for example, encrusting them with diamonds.) The courts in these cases have focused on the extent of the changes to the trademarked product ─ the more extensive the changes, the more likely the trademark will be found to have been infringed. Often lurking just below the surface of these cases is a more fundamental consideration: is the end user of the altered product confused or misled by the display of the original trademark on the product? After all, most people, and probably all teenagers, know a used Mustang convertible when they see one. *See Ford Motor Co. v. Ultra Coachbuilders, Inc.*, No. EDCV 00-00243-VA, 2000 WL 33256536 (C.D. Cal.), *aff'd*, 238 F.3d 428 (9th Cir. 2000) (unpublished table decision) (display of Ford trademark on stretch limousine not infringement because modifications were apparent).

The second question is whether a trademark is being used in commerce where the device is not "sold" (at least not technically). The Lanham Trademark Act provides that a trademark is infringed only if the putative infringing use takes place "in commerce." Congress has defined "in commerce" to mean that the product bearing the trademark is "sold or transported in commerce." 15 U.S.C. § 1127 (1998 & Supp. 2003). Third-party reprocessors argue that their reprocessing of SUDs bearing the original manufacturer's trademark does not qualify as a "use in commerce" because they do not buy the used SUDs from hospitals. Instead, they collect SUDs from a hospital and return the same SUDs after reprocessing to the same hospital. Title does not pass, as we used to say in law school, and hence there is no "use in commerce" of the original manufacturer's trademark. *E.g., U.S. Surgical Corp. v. Orris*, Inc., 5 F. Supp. 2d 1201, 1208-09 (D. Kan. 1998), *aff'd*, 185 F.3d 885 (Fed. Cir. 1999) (unpublished table decision).

It is not reassuring to learn that a surgeon's right to know the most recent source of the catheter placed in her hand in the operating room depends on the property law of passing title, but for some courts that is the case.

The Ninth Circuit, however, has put forward a far more realistic view of reprocessed devices, which also more accurately reflects the statutory text. In *Karl Storz*, that court reversed summary judgment in favor of a defendant reprocessor. 285 F.3d 848. The district court held that defendant's "repair and refurbishment" for hospitals of endoscopes originally manufactured by plaintiff did not constitute trademark infringement. The Ninth Circuit reversed and held that "[w]here the repair is done by an outside contractor, as is the case here, the question is whether the trademarked product is so altered that the substance of the transaction is a sale, and it would be misleading to sell the product without noting the alterations." *Id*. at

856. The court noted that the statutory definition of "use in commerce" includes situations where a device is either "sold *or transported* in commerce." *Id.* at 855 (citing 15 U.S.C. § 1127, emphasis added) quoting 15 U.S.C. § 1127).

The Ninth Circuit in *Karl Storz* recognized that there is no "brightline test" for whether a company that repairs goods while retaining the original manufacturer's trademark on them is "using the trademark in commerce," but it did state that the most important factor is "whether *end users* of the product are likely to be misled as to the party responsible for the composition of the product." *Id.* at 856-57 (emphasis added).

The Ninth Circuit's *Karl Storz* decision represents a more real-world approach to the question of trademark infringement in the context of reprocessing of SUDs. In particular, the court emphasized that "Storz submitted evidence of actual confusion on the part of surgeons as to whether malfunctioning Storz endoscopes were original Storz scopes or had been repaired or rebuilt by someone other than Storz." *Id.* at 855.

The key to whether a third-party reprocessor of critical medical devices has infringed the trademark of the original manufacturer should be whether the "end users" of the device are likely to be confused as to the most recent source of the device. The absence of a "sale" or of "passing title" should be irrelevant to the question of infringement.

A label on the repackaging applied by the reprocessor will not prevent surgeons, nurses, or patients from being misled as to whether the device is new or reprocessed, because in most instances the repackaging is removed from the reprocessed device by hospital technicians before any nurse or surgeon sees the device in the operating room. The recent congressionally-imposed requirement that the reprocessor's name appear on the package will do little or nothing to avoid confusion in the operating room.

Some courts in the medical device reprocessing context have focused too heavily on the extent of the repairs to the medical device. While this approach may make sense in the context of, for example, used golf balls,[2] it is inappropriate for SUDs. The critical nature of many medical devices, and the ease with which "end users" of these devices may be confused, makes this approach inappropriate. Instead, the courts should focus on the practical question whether nurses, surgeons, and patients understand that the medical devices in question have been "reprocessed" by a company other than the owner of the trademark displayed on the device.

Where there is no likelihood of confusion of these end users, then there may be no trademark infringement. This, however, would appear to be the exceptional case. In general, where the medical device bears the trademark of the original manufacturer, and is labeled for only a single-use, then ─ absent special circumstances ─ the courts should apply a presumption that reprocessing of the device for multiple uses infringes the original manufacturer's trademark.

[2] *Nitro Leisure Prods., LLC v. Acushnet Co.*, 341 F.3d 1356, 1362 (Fed. Cir. 2003) (affirming denial of preliminary injunction against refurbisher of golf balls clearly marked as "used" and recognizing that "consumers of new goods have different expectations than consumers of used goods").

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