

Medical Devices: New License Issues For Single-Use Devices

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On October 26, 2002, President Bush signed into law the Medical Device User Fee and Modernization Act (the "Act"). Many of its parameters have been discussed and debated in the industry for years, such as the user fee. This article explores licensing issues, particularly those related to single-use medical device refurbishing, in light of intellectual property and provisions of the Act. Initially, it can be pointed out that the Food and Drug Administration ("FDA") has published a very good summary of the Act on its web site.¹

Patent law doctrine of "Permissible repair" vs. "Impermissible reconstruction," and How This Affects Licensing of Single-Use Medical Devices

Patent laws and licensing practice in the United States, as it has developed over the years inside and outside of the medical device industry, follows fairly understandable rules. While the Act has added some requirements, it is useful to review briefly the history. In the area of repairs of patented devices, the general rule today is that, absent an agreement to the contrary at the time of purchase of the device, a patent owner exhausts all rights in that particular device.² Stated differently, the laws of the United States allow a purchaser of a patented device to repair and replace worn or broken parts, but replacement that amounts

to a second creation of the patented device is not permissible without a license and is considered patent infringement.³

In the medical device industry, questions usually arise when the purchaser, say a hospital, purchases a patented medical device, either from the patent owner or a manufacturer licensed to make and sell the device, and then seeks to have the device repaired or refurbished by a service contractor of the hospital. Early cases recognized that if the patent owner/seller somehow attached notice to the device that the device was "licensed to use once only," or similar language, then a suit for patent infringement could be maintained against those who refurbished the devices for reuse.⁴ A medical device case on point is *The Kendall Co. v. Progressive Medical Technology Inc.*, 38 USPQ2d 1917 (Fed. Cir. 1996). In this case, a customer's replacement, after each use, of pressure sleeves purchased from defendant for use with a patented device for applying compressive pressure to a patient's limbs constituted permissible repair, even though the pressure sleeves could theoretically be used for three years or more before they physically wore out, since an element of a patented device is effectively spent when its continued use is neither practical nor feasible. Since reuse of the pressure sleeves

would not be feasible due to risk of contamination between patients, this was enough to find that the sleeves were spent after each use. Note that the patent claims covered a device for supplying compressive pressure against a patient's limb, where the sleeves were only one element of the patented device.

It is convenient for management of medical device reproducers and OEMs alike, and their licensing counsel, to break down the possible scenarios into three primary fact settings for patented devices:

1. A part is not spent but is replaced to enable the device to perform a different function;
2. A spent part is replaced;
3. The entire patented device is spent and reconstruction is required to make the device useable again (of course "useable" probably connotes safe and effective in the medical device field).

The first situation, which might be termed off-label⁵ use, does not arise often, but has been termed a situation "kin to repair," and thus is permissible without a license. The second situation constitutes a permissible repair when the spent part is not separately patented, and thus no license is required (No matter how critical the part is to the patented device and no matter how costly or difficult replacement may be). The third situation would constitute an infringing reconstruction,

1. www.fda.gov, see for example "Summary of the Medical Device User Fee and Modernization Act of 2002," November 7, 2002, Center for Devices and Radiological Health.
2. *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659 (1895).

3. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961).
4. *American Cotton-Tie Co. v. Simmons*, 106 U.S. 89 (1882). A medical device case on point is *The Kendall Co. v. Progressive Medical Technology Inc.*, 38 USPQ2d 1917 (Fed. Cir. 1996).

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unless permitted through an appropriately drafted license agreement.

Note also that the FDA does not regulate off-label uses of drugs or devices, and the FDA does not regulate the practice of medical physicians. Rather, it is the common law of informed consent, medical malpractice, and product liability that govern these situations. It is thus important to note that private parties are able to contract (formulate a license agreement), even for off-label uses of medical devices, provided that no law is violated thereby. Regarding situation 1 (different function), it is entirely feasible that private parties sign a license agreement whereby a patent owner/licensor authorizes the licensee to make, use, or sell only an off-label use. This practice has been upheld by US courts as a proper extension of the patent monopoly.⁶

The Karl Storz Case

Unless there is a “complete recreation” of a “spent” patented device, it is likely that a claim of patent infringement will be easily defeated. Also, due to the expense of obtaining and maintaining medical device patents, medical device OEMs may not be as ambitious in their patenting.

5. “Off-label” has more accurately been termed “extra label” use. See James M. Beck and Elizabeth D. Azari, “FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,” 53 FOOD & DRUG L.J. 71 (1998). As noted in this article, “It means only that a product is used for a condition or in a way not appearing on its FDA-regulated labeling, not that the agency has judged the use adversely. See, e.g., *Washington Legal Found. v. Kessler*, 880 F. Supp. 26, 28 n.1 (D.D.C. 1995). Off-label can mean many things. “[U]sing an approved drug to treat a disease that is not indicated on its label, but is closely related to an indicated disease, treating unrelated, unindicated diseases, and treating the indicated disease but varying from the indicated dosage, regimen, or patient population may all be considered off-label use.” William L. Christopher, Off-Label Drug Prescription: Filling the Regulatory Vacuum, 48 FOOD & DRUG L.J. 247, 248 (1993) (footnotes omitted).”

6. See, e.g., *General Talking Pictures v. Western Electric Co.*, 304 U.S. 175, reh’g denied, 305 U.S. 675 (1938); *Mallinckrodt, Inc. v. Medipart, Inc.* 976 F.2d 700 (Fed. Cir. 1992).

Trademark and unfair competition law has seen renewed interest, as exemplified by the *Karl Storz*⁷ rigid endoscope case. In what may become more commonplace, especially for expensive medical devices such as these, Storz sued Surgi-Tech on trademark infringement claims. Surgi-Tech was repairing broken endoscopes received directly from hospitals and doctors and receiving payment.⁸ In about 20% of the cases, Surgi-Tech was performing a “complete rebuild,” replacing everything but a main block, which had the Karl Storz trademarks thereon. Furthermore, since the devices had to be sterile, no other source indicators were apparent to the ultimate users, surgeons, who were complaining back to Storz of receiving faulty devices. The court in this instance found that Karl Storz had a valid complaint, stating that the law recognizes “post-purchase confusion” (i.e. the surgeons, who did not purchase the devices, but as the ultimate users, were confused as to the source, thinking that the refurbished endoscopes were purchased directly from Karl Storz).

As we will see, the Act addresses post-purchase confusion, and requires reproducers to take certain measures to avoid it.

New US Regulatory Requirements for Reprocessed Single-Use Devices

Prior to delving into the Act and its requirements, some definitions from the Act are presented.

Single-use device means a device that is intended for one use, or on a single patient during a single procedure.

Reprocessed, with respect to a single-use device, means an original device that has previously been used

on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition. A single-use device that meets this definition shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term ‘recycled’ rather than the term ‘reprocessed.’

Original device means a new, unused single-use device.

Critical reprocessed single-use device means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

Semi-critical reprocessed single-use device means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

Before passage of the Act, the regulatory requirements for manufacturers of reprocessed single-use devices (the persons who are reprocessing the device) basically depended upon the class of the device. Manufacturers of reprocessed class I and II single-use devices were required to have a 510(k)⁹, unless the device was exempt from 510(k). Reprocessors of class III devices were required to obtain premarket approval.

Under the Act, reprocessors of some exempt devices will no longer be exempt from the 510(k) submission requirements but rather will need to submit 510(k)s that include validation data. Validation data will

7. *Karl Storz Endoscopy-America v. Surgical Technologies Inc.*, 62 USPQ2d 1273 (CA 9 2002).

8. The court noted that in 1984, Surgi-Tech was the only company repairing endoscopes, other than the OEMs. Eventually, Surgi-Tech was joined by more than 50 other independent surgical instrument repair companies.

9. 510(k) = premarket notification, and refers to the part of the FDA regulations dealing with medical devices that are substantially similar to devices that are already being legally marketed. It is a much less rigorous and less costly review. The statutory citation is Title 21, Section 510(k) of the FD&C Act, and Regulatory citation is 21 CFR Section 807.

also be required for many reproprocessors of single-use devices that are currently the subject of cleared 510(k)s. Finally, reproprocessors of class III devices will need to submit a premarket report (a new type of premarket application).

What does this mean for medical device OEMs and reproprocessors in terms of licensing? It means that a license addressing the right to use validation data (e.g. obtained from third party test vendors) is now an important consideration. Some critical and semi-critical devices, which were previously exempt from 510(k), will have their exemptions terminated by FDA, and must now include validation data (as described below), and must be submitted within 15 months of publication of the termination. Reprocessed single-use devices not included on either the critical or semi-critical device lists may continue to be marketed without submission of a 510(k).

Validation Data

Validation data will be required from reproprocessors of single-use devices that the FDA decides requires such data. Validation data comprises:

1. Data regarding “cleaning and sterilization,” and
2. Data regarding “functional performance” to show that the reprocessed device “will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended” by the person who submits the 510(k).

For licensing purposes this presents several questions: How much data will be required for cleaning, sterilization, and functional performance? What exactly is meant by “substantially equivalent” when speaking of functional performance? As this term is undefined in the regulations, it would be wise for the parties to any data license agreement to define “substantially equivalent.” The user of the validation data will want a statement to the effect that “the user of the data (data licensee) will determine, in conjunction with the appropriate regulatory agency, the amount of data required, and validation data provider shall work

reasonably with validation data user until validation data satisfactory to the regulatory agency is supplied.”

Nine-month Time Frame

Since under the Act, marketing must cease if validation data has not been submitted for a device that already has a cleared 510(k), time provisions should be provided for in the data license agreement. Under the Act, the validation data must be submitted within nine months of the date the FDA includes the device on the list of devices for which validation data is required. To be safe, the data licensor should require the validation data no later than eight months after the date the FDA lists the device.

Device Labeling Requirements, Pre-market Reports and Licensing Considerations

Any reprocessed single-use devices introduced into US interstate commerce after January 25, 2004 must use new labeling as follows, which must appear “prominently and conspicuously” on the device itself:

Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device].

The FDA states “this provision will make it easier for patients and health care professionals to know when they

are using a reprocessed device.” For device reproprocessors, this will obviously add expense to the reprocessing cycle. A licensed reproprocessor should attempt to shift all or a portion of this financial burden back to the OEM in the license agreement.

The Act creates a new category of premarket submission, the premarket report. A premarket report must be submitted for a Class III reprocessed single-use device that previously required a PMA.¹⁰ The FDA has specified the contents of a premarket report. A full listing is beyond this article, but includes “the device name, including both the trade or proprietary name and the common or usual name,” and “proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.” Also required are “full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective,” and “any additional data and information . . . that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.” Also required, as mentioned herein, is “validation data . . . that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended . . .” As noted below, much of the benefit of this activity, which is now required of the reproprocessors, will accrue to the benefit of the OEMs and their trademarked medical devices. Therefore, it seems reasonable to have a clause in the license agreement whereby the OEM assists the reproprocessor with payments and the acquisition of validation data.

Licensing Between Reproprocessors

Obviously, the requirement of the Act that reproprocessors of Class III devices must submit premarket reports is a benefit to original device manufacturers, since any activity that supports and perhaps enhances

10. PMA = premarket approval, which is required by the FDA to market “new” medical devices, in other words devices that are not substantially equivalent to devices that have already been marketed. Premarket approval is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III pre-amendment devices may require a Class III 510(k). The US statute citation is Title 21, Section 515 of the FD&C Act, and the regulations are at 21 CFR Section 814.

having higher quality products in the field will enhance the goodwill associated with the original device's trademark(s). Surely, some reproprocessors will no doubt find the Act and its implementing regulations too burdensome to continue a prosperous business. It will be interesting to see if reproprocessors are able to survive through licensing. As will be seen, however, the Act could be interpreted to restrict this practice.

License Agreements Now Need to Specify Who Pays User Fees

The Act calls for user fees, which have been long resisted; however, the industry is protected somewhat in that fees are reduced substantially for small businesses (defined as those having gross receipts or sales less than \$30 million, including all affiliates, partners, and parent firms). The dollar figure was originally \$10 million. If the reproprocessors attempt to cross-license the use of validation data, it will be vital to disavow that the parties are affiliates, partners, or that one firm is a parent of the other.

Licenses Can be Restricted to Single Use

It is instructive to compare the 1992 *Mallinckrodt*¹¹ case with the Act. The patented device was an apparatus for delivery of radioactive or therapeutic material in aerosol mist form to the lungs of a patient, for diagnostic and treatment of pulmonary disease. Radioactive material is delivered primarily for image scanning in diagnosis of lung conditions. Therapeutic agents may be administered to patients suffering various lung diseases. The device was manufactured by Mallinckrodt, who sold it to hospitals as a unitary kit that consisted of a "nebulizer" which generates a mist of the radioactive materials or the prescribed drug, a "manifold" that directs the flow of oxygen or air and the active materials, a filter, tubing, a mouthpiece, and a nose clip. In use, the radioactive

materials or drug is placed in the nebulizer, is atomized, and the patient inhales and exhales through the closed system. The device fits into a lead-shielded container that is provided by Mallinckrodt to minimize exposure to radiation and for safe disposal after use.

The device was marked with the appropriate patent numbers, and bears the trademarks "Mallinckrodt" and "UltraVent" and the inscription "Single Use Only". The package insert provided with each unit stated "For Single Patient Use Only" and instructed that the entire contaminated apparatus be disposed of in accordance with procedures for the disposal of biohazardous waste. The hospital was instructed to seal the used apparatus in the radiation-shield container prior to proper disposal. The hospitals whose activities led to the lawsuit did not dispose of the UltraVent apparatus, or limit it to a single use.

Instead, the hospitals shipped the used manifold/nebulizer assemblies to Medipart, Inc. Medipart in turn packaged the assemblies and sent them to Radiation Sterilizers Inc., who exposed the packages to at least 2.5 megarads of gamma radiation, and returned them to Medipart. Medipart personnel then checked each assembly for damage and leaks, and placed the assembly in a plastic bag together with a new filter, tubing, mouthpiece, and nose clip. The "reconditioned" units, as Medipart called them, were shipped back to the hospitals from whence they came. Neither Radiation Sterilizers nor Medipart tested the reconditioned units for any residual biological activity or for radioactivity. The assemblies still bore the inscription "Single Use Only" and the trademarks "Mallinckrodt" and "UltraVent."

The court held, among other things, that the lower court was wrong in holding that the restriction on use was, as a matter of law, unenforceable under the patent law. Furthermore, if the sale of the UltraVent device was determined to be accompanied by a valid restriction to single patient use, the

"reconditioned" units, even if only repaired (not recreated) were an infringement of the patents and required a license.

Several points can be made in regards to the Act. The Act supports Mallinckrodt in the definition of "reprocessed," where it does not matter what the remanufacturing party calls the unit. In terms of a single use device, "recycled" and "reconditioned" are equivalent to "reprocessed."

Note that in *Mallinckrodt*, the "reconditioned" device itself was still marked with the original manufacturer's trademarks and the "Single Use Only" inscription, but apparently no marks or other indications that the units were not in fact from Mallinckrodt. The Act specifically addresses labeling of reprocessed units by the reproprocessor. Note the original device in *Mallinckrodt* was packaged with instructions on how to dispose of the device, but that neither Medipart nor Radiation Sterilizers tested the reconditioned units for safety or efficacy. The Act calls for reproprocessors to supply "full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective," and "any additional data and information . . . that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device." These reports will have to be financed, so again, it will be up to the skilled license negotiators to craft an agreement whereby some of the costs incurred by the reproprocessors are defrayed. Perhaps the OEMs will license reproprocessors the use of "information, published or known" regarding investigations into the safety and efficacy of their device. Certainly these will not always be available to the reproprocessors other than through competently drafted license agreements. OEMs will have to be careful to avoid anti-competitive practices in these respects (such as providing data to some reproprocessors but withholding from others, creating an unbalanced,

11. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992).

anti-competitive information cartel). Finally, note that in a situation such as in Mallinckrodt, validation data would now be required that would demonstrate that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended.

Conclusion

Licensing provisions will be necessary to deal not only with explicit provisions of the Act, but with uncertainties in those provisions. This is a natural and reasonable area where licensing professionals can be of service. Possible license scenarios are between OEMs and reproprocessors; between reproprocessors; and between reproprocessors and validation test data vendors. Some of the issues that will need to be addressed, depending on the situation, include:

- Marking their devices (OEMs and reproprocessors)
- Granting of patent and trademark licenses with reasonable terms
 - Financial support for premarket report generation, validation data, inspections, etc.
 - Use restrictions, as in Mallinckrodt. (on the device, in the package inserts, and perhaps a written agreement with the hospitals)
- Who will pay FDA user fees

Unfortunately, there are many issues that will have to be sorted out, such as the specifics of the labeling requirements, and the amount of validation data that is required. Perhaps these issues were to be left to the development of the law by the courts, but perhaps it was also hoped that private parties (original device manufacturers and reproprocessors) would be able to work out reasonable solutions themselves through creative licenses and other agreements. The user fees will bring a new dynamic, potentially pushing parties to work together to pool resources, and perhaps along the way avoid conflicts in open court.