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Afterthoughts

Consulting with counsel and design engineers before launching your new device can help protect aftermarket sales.

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In this economy, it is critical to squeeze every drop of value out of your intellectual property. You can be sure that your competitors are wringing every last drop out of theirs. One area that is sometimes overlooked in the medical device arena is the aftermarket for disposable or consumable components. Many devices are systems or assemblies that include both a reusable component and one or more disposable or consumable components. For example, a biopsy system may include disposable needles or cannulae that come into contact with patient tissues and bodily fluids as well as reusable components such as motors and gears that do not. Patenting efforts often focus on the broader system, i.e., the combination of reusable and disposable components. This is especially true if the combination—and not any one component—appears to be what is new and worthy of patent protection. In such cases, it can be difficult to obtain patent claims[1] that cover individual components, or claims that cover them broadly.

The aftermarket for disposables and consumables can be substantial. A sound patenting strategy involves considering whether to protect them separately and, if so, how to do it. If you do not separately protect these potential post-sale revenue sources, you can expect aftermarket competition to quickly arise, especially if the patented system is successful. This article discusses the legal landscape for protecting disposables and consumables and provides strategies for protecting them.

Hurdling the 'Repair Doctrine'

The "repair doctrine," which is a term used in patent cases, is a significant hurdle to protecting disposables and consumables. The doctrine comes into play when a company sells a patented system that includes disposable components, and its customers obtain the disposables from other suppliers.

At the outset, if your patent covers an entire system (e.g., the entire biopsy system with the motors and the needles), you should *not* assume that it will separately protect the disposables. Patents that claim only a complete system or assembly will often provide no protection for unpatented components that are part of the system or assembly. Once a consumer purchases the system from the patent holder, the patent rights in the system are deemed to be "exhausted," and the consumer has the right to repair the system to the extent necessary to use it. A consumer is not allowed to "make" the patented invention, and to do so constitutes patent infringement. However, the U.S. courts distinguish between "reconstructing" a patented system—which is impermissible—and "repairing" a patented system—which is permissible.

The distinction between impermissible reconstruction and permissible repair often turns on, one, whether the unpatented components have a useful life that is less than that of the entire system and, two, whether the components are intended to be replaced. Buyers of a patented system have the right to repair it by purchasing unpatented replacement components from suppliers other than the system patent holder. By definition, disposables and consumables are expected to have a useful life that is less than that of the system with which they are used. Thus, unless the disposables or consumables are separately patented, the repair doctrine allows competitors to freely supply them to purchasers of the patented system.

Several court cases illustrate the problems that the repair doctrine presents to medical device manufacturers. In one case, a company obtained a patent for a device that applies compressive pressure to a patient's limbs in order to increase blood flow and treat or prevent deep vein thrombosis.[2] The patent claimed a combination of

two replaceable pressure sleeves that attached to the patient's limbs with three sets of connecting conduits.[3] Both the patent and the patent holder's commercial literature indicated that the pressure sleeves were intended to be replaced in order to avoid contaminating patients with bodily fluids or excretions from other patients. As a result, the court held that a competitor was free to supply the pressure sleeves and that purchasers of the patented system were free to use them to replace the sleeves supplied with the system. The court reasoned that the sale of the patented system conveyed an "implied license" allowing the buyer to purchase replacement pressure sleeves from others.[4]

In another case, a manufacturer of a sharps disposal system obtained a patent for the system.[5] The patent claimed the combination of a fixed, wall-mounted outer enclosure and a removable inner enclosure. The manufacturer contended that more than half the hospitals in the United States used the patented system, and therefore the market for the removable inner enclosure was significant. Unsurprisingly, a competitor had begun supplying competing inner enclosures, and the manufacturer attempted to stop the competitor by asserting its patent rights to the overall sharps disposal system. Both the patent and the patent holder's commercial literature stated that the inner enclosure was intended to be replaced once it was filled with sharps. Therefore, the court held that purchasers of the patented system were free to replace the inner enclosures with those provided by the competitor.

Protecting Your Disposable Aftermarket

The foregoing discussion raises the obvious question: "How do I protect my disposable aftermarket?" There is no single, definitive answer, and in some cases, aftermarket protection for disposables may be unattainable. However, before launching any new product a manufacturer should determine whether it can secure aftermarket protection and find out to what extent it can obtain this protection.

Here are some tips:

First, separately evaluate the patentability of the disposable component by performing a patent search directed to it.[6] If the disposable component is known in the art, you may not be able to separately patent it. However, some disposable components may have a unique feature, such as a one-of-a-kind connector that facilitates interaction with the larger system. In such cases, you should separately patent the disposables.

For example, in one case a patent holder developed a "needle-in-a-needle" biopsy gun.[7] Although the patent included claims to the gun, it also included claims directed to the replaceable needle-in-a-needle assembly. In order to distinguish the needles from those that were known in previous patents, the device manufacturer claimed the features that allowed the needles to connect to "slides" in the gun housing. By including such claims in its patent, the patent holder was able to capture the replacement needle aftermarket for its device.

Second, if the disposable component lacks unique features that allow it to interact with the system, consider designing such features into the component so that it can be separately patented. Ideally, the features will promote and enhance the overall operation of the system. It is especially helpful to design features in the disposable components that interact with the novel features of the reusable component. In our biopsy needle example, the needles included flanged heads that facilitated their connection to two slides in the biopsy gun housing.

Third, to separately patent the disposables you may have to narrowly tailor your patent claims to distinguish known disposables. While the system claims may describe the disposables in broader terms (e.g., "a needle"), the disposable patent claims may need to describe them in much greater detail (e.g., a "needle with a flanged head").

Consult with Counsel and Engineers

Consult with patent counsel and your engineering staff during the design process. With their assistance, design the commercial system so that the features described in the patent claims for the disposables are necessary for the disposables to connect or interact with the system. Otherwise, a clever competitor may be able to design a replacement disposable that circumvents the disposable patent claims while still functioning as a suitable replacement with the overall system.

Even if the system cannot be designed in this manner, you should still try to pursue patent protection—however narrow—for the disposables alone. Narrow claims will still prevent competitors from selling exact copies of your disposables, which will help preserve your share of the disposable aftermarket. Customers may be inclined to buy replacement disposables that have the identical appearance of those supplied with the original system. Therefore, narrow patent claims may have value. Alternatively, you may be able to design a unique aesthetic feature into the disposables and obtain a design patent for the disposables. Again, this will provide some

protection against exact knockoffs and may help preserve your share of the aftermarket.[8]

Conclusion

At this point you may be thinking: “Can we simply require customers for my patented system to buy their disposables from us?” After all, the repair doctrine is premised on an *unconditioned* sale of a patented system that includes the unpatented disposable. Then you may ask yourself: “What if we condition the initial sale on the purchase of disposables from us?” However, such post-sale restraints can violate antitrust laws or may constitute patent misuse if not drafted properly or if not warranted by the relevant circumstances.

The courts have upheld “single-use” restrictions on certain devices with consumable components.[9] Such restrictions apply as long as they are clearly communicated as conditions of the sale and not mere statements of the seller’s intention.[10] However, in light of the antitrust implications, counsel should be consulted before drafting any such post-sale restrictions.

In summary, careful planning is required to protect the aftermarket for a new medical device. Patent counsel and the design staff should work together to try to develop a strategy for separately protecting disposable or consumable components. Otherwise, a significant source of revenue may end up in the hands of opportunistic competitors.

References

1. “Claims” are the numbered paragraphs at the end of a patent that define the scope of the property right, i.e., the scope of the right to exclude others from making, using, selling, offering to sell, or importing the claimed invention. They are akin to a deed for real property.

2. *The Kendall Co. v Progressive Medical Technology*, 85F.3d 1570, 1571 (Fed. Cir. 1996).

3. *Id.; see also* U.S Patent No. 4,253,449 (Claim 1 at column 10).

4. *Kendall Co.*, 85 F.3d at 1573.

5. *Sage Products v Devon Industries*, 45 F.3d 1575, 1576 (Fed. Cir. 1995); *see also* U.S. Patent No. Re 33,413 (Claim 1 at column 4).

6. In a patentability search, patents, patent applications, and possibly other sources such as journal articles are searched and reviewed to determine to what extent they disclose an invention. Such sources are called “prior art.” To be patentable, an invention must be “novel” (not disclosed by a single prior art reference) and non-obvious (not obtainable by modifying a reference or by combining references in a manner suggested by the prior art).

7. *C.R. Bard, Inc. v M3 Systems, Inc.*, 157 F.3d 1340, 1348-1349 (Fed. Cir. 1998); *see also* U.S. Patent No. Re 34,056 (Claim 21 at column 10).

8. A “design patent” protects the ornamental design of an article of manufacture. The “claim” of a design patent is its drawings. In contrast, a “utility patent” is used to protect inventions such as the structure of the medical device or the operation of the device or both.

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

10. *Hewlett-Packard v Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445 (Fed. Cir. 1997).

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