Looking at Intellectual Property From an Engineer’s Perspective

Medical device engineers work in a world characterized by innovation and invention, but it is also a land run by legal truths and consequences. This article provides an overview of patent and trademark law to help engineers traverse the legal terrain.

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By Miriam Beezy and Gerald Swiss

To maximize profitability and perfect your company's rights in yourdesigns, your innovations must be patentable, obtain regulatory approval, andbe identifiable with your company through the use of trademarks and distinctiveproduct design. Unfortunately, engineers are not trained typically to navigate the complex legal issues that go hand in hand with invention. The good news, however, is that your legal counsel can help guide you through the maze. The purpose of this article is to provide an overview of intellectual property issues in both patent and trademark law so that you can interact effectively with your intellectual property counsel.

Requirements of Patentability

The most fundamental patent question to be addressed by the engineer is whether the innovation is patentable. In the U.S., a patentable invention requires that (1) the innovation be a new and useful process, machine, manufacture, or composition of matter or any new and useful improvements thereof and that (2) the innovation must further be non-obvious over the prior art at the time the invention was made. Most new medical devices fall into at least two categories for patentability. First, they are machines that can be used in a specific process, typically treating humans. Accordingly, patent coverage can be obtained on the device itself and on its use in

such treatment, assuming that both the device and its use meet the requirements of patentability articulated above. Still further, if the medical device is used in combination with another element such as a component to be delivered into the body, patent coverage on this combination, typically in the form of a kit of parts, can be obtained.
You should recognize that each category of patentable inventions is independent of the others. For example, a new use for a device is potentially patentable even if the device itself is known. Likewise, a kit of parts can be potentially patentable even if the individual components were known&#151provided that their combination was not known.

The "Novelty" of Innovation

The novelty of any innovation in the U.S. is governed by statute. First, any patentable innovation must not be disclosed per se in the prior art. (Prior art is a law term for publications, patents, and other public disclosures that occur prior to an invention.) If it is already disclosed, it is not novel. For this purpose, a single prior art reference must disclose all the elements of your innovation. Recitation of all but one element of your innovation is insufficient to be novelty defeating.
Second, let's assume that there is publication of your innovation after your date of invention but before you have filed a patent application. In such cases, the U.S. provides a one-year grace period for filing a patent application. Accordingly, if you or your company published your innovation (whether intentionally or unintentionally) or, for that matter, a third party publishes it, you have one year from that date to file a patent application in the U.S. and seek patent protection. Often, the engineer does not appreciate this and wrongfully determines that upon publication, patentability of the innovation in the U.S. is lost.
As a corollary to this, any prior art that describes your invention and that has been published for more than a year serves as an absolute bar to the patentability of your innovation.
Two common activities that will prevent patenting of an innovation in the U.S. are (1) if the medical device was sold or offered for sale in the U.S. more than one year prior to the date the patent application is filed with the U.S. Patent and Trademark Office (USPTO) and (2) if the innovation was in public use for more than one year prior to the date the patent application is filed with the USPTO. *See* "*Case in Point: Sales Offer.*" *article at end.*
While there are other more esoteric caveats in the law that limit patentability of an innovation, the two activities listed above are those that occur most often. If you are aware of either one occurring, you must immediately convey this to your intellectual property counsel so that a proper analysis can be made as to whether the innovation is still patentable and, if so, what is the date by which the patent application must be filed in the USPTO.

Non-Obviousness

The third requirement of patentability of your innovation is that your innovation must be non-obvious over the prior art at the time of your invention. This requirement recognizes the one-year grace period set forth above. Careful attention must be paid to when the publication occurred and when your innovation was

invented.
It is the responsibility of the USPTO to establish that your innovation is obvious under the law. If the USPTO is unable to do so, the innovation is deemed to be non-obvious.
Obviousness is determined by reference to the mythical person of ordinary skill in the relevant art having knowledge of all available prior art. Accordingly, the USPTO typically relies upon one or more prior art references to assert that your innovation is obvious. In most cases, the obviousness or non-obviousness of your innovation is the ultimate yardstick as to whether a patent will be granted. As such, the courts have established legal guidelines to determine whether your innovation is obvious or not.
These guidelines include (1) whether the person of ordinary skill would be motivated to modify the prior art to arrive at your innovation and (2) whether there is a reasonable basis for the person of ordinary skill to predict success in the device arrived at by making these modifications to the prior art.
If the USPTO successfully asserts that your innovation is obvious in view of the principles articulated above, such an assertion is not determinative of the issue. As noted above, the USPTO has the burden of establishing the obviousness of the innovation. Once that burden has been met, then the onus shifts to the engineer and intellectual property counsel to establish the patentability of the innovation. If they are unable to do so, then the innovation is deemed obvious.
You may be able to establish patentability of your innovation by demonstrating that the innovation possesses surprising and unexpected results relative to the prior art. *See article at end* "*Case in Point: New Polymer.*"
The determination of obviousness or non-obviousness of an innovation is a legal&#151not a technical&#151determination. Hence, as an engineer, you should never determine that your innovation is obvious and unpatentable without consulting your intellectual property counsel.
If you have considered whether your innovation meets the tests for patentability outlined above, you will be prepared to meet with intellectual property counsel and will be conversant with the questions often asked by such counsel.

Trademarks: Branding

Assuming your company has commercialized your innovation, its success in the marketplace can be significantly enhanced by the development and protection of a distinctive and legally available trademark and trade dress.
Trademarks, also known as brand names, are terms that identify the products and services of a business and distinguish them from those of others. Trade dress involves product shape and configuration and how the product is packaged. Copyright rights in product shape and packaging may also be acquired. A strong brand or trademark and distinctive trade dress can result in increased sales with proper use.
Choose a distinctive legally available mark and logo. The best marks are not descriptive of the product but are coined or do not describe the product. Your company should conduct an extensive trademark search before adopting a name or mark. Searches are important to determine whether use of your proposed mark will infringe on the rights of others. At least one court has recently interpreted a medical device manufacturer's failure to conduct a trademark search as weighing against a

finding of good faith. Such a finding can lead to an assessment of willful infringement, punitive damages, and attorneys fees against your company.
A preliminary computer search of U.S. Federal and State Trademark Office records for word and design marks may reveal potentially problematic federal and state trademark registrations and applications, but it cannot reveal unregistered users of the mark who may have developed prior rights under the common law. However, as an early screening tool, preliminary searches can provide a valuable, fast indication of whether the same or similar mark is already filed or registered.
A more comprehensive search can be obtained through an outside search firm. Such a search reviews U.S. Federal and State Office Registers and certain common law sources, including U.S. domain names, and provides up-to-date commercial use of trademarks.
A comprehensive search is strongly preferred in determining legal availability as it improves the chances of discovering a non-registered user of the mark who may have acquired rights under the common law. Information on unregistered, common law users is vital because such users may be able to prevent your company from using the mark and may be able to cancel any federal registration of the mark your company ultimately obtains. Trademark counsel should be consulted regarding the best type of search for your company's needs.

Trademarks: Protection

If a manufacturer of a new medical device is the first one to market, it should protect its mark by applying for trademark registration at the earliest opportunity. A trademark registration protecting your company's brand can be a valuable business asset and should be carefully preserved and protected in order to maintain its value.
Applications are generally based on two types of use: actual use and intent to use. Use made in interstate commerce (between U.S. states or between the U.S. and foreign countries) is actual use. If your company has an intention to use a mark, an application may be filed on that basis. The filing of an intent-to-use application is useful where your company wants to reserve trademark rights in a name for use in connection with products or services that are in development.
The U.S. Trademark Office allows an applicant to file extensions of time in which to show use of the mark. If the proper extensions are filed, your company has approximately three years to use the mark in connection with the relevant products or services. The required use of your mark can be made by your company or a licensee. Furthermore, the trademark should be used consistently in all the manufacturer's promotional literature to maintain protection.
The prosecution process or review process by the U.S. Trademark Office can either be an examination that results in a simple office action and early publication for opposition or a complicated process where the examining attorney issues Office Actions refusing registration based on any number of reasons. Obtaining registration without opposition by others typically is an 18-month to two-year process.

More on Trade Dress

As for trade dress, only the non-functional aspects of the appearance of your

medical device qualify for trade dress protection. Generally, design features that are essential to the purpose of the device and affect its cost or quality are considered functional, whereas those features that are solely ornamental and distinctive are protectable trade dress.
Your medical device may only qualify for trade dress protection if consumers have come to associate its non-functional design elements uniquely with its source. Accordingly, the more unique and identifiable your product design, the better the chances for long-term trade dress protection.

Case in Point: Sales Offer

The selling or the offering for sale of a medical device more than one year prior to the date the patent application is filed with the U.S. Patent and Trademark Office can prevent the patenting of an innovation. For example, a sales rep's offer to sell starts can initiate the tolling of the one-year grace period even if the engineer is unaware of the arrangement. A similar problem arises if the innovation was in public use for more than one year prior to the date the patent application is filed. This is often the case when the device is used in a patient for more than one year prior to seeking patent protection in the U.S.

Case in Point: New Polymer

You may be able to establish patentability of your innovation by demonstrating that the innovation possesses surprising and unexpected results relative to the prior art. For example, let's assume that the innovation comprises the use of a new polymer in place of polyethylene in a catheter component. Let's further assume that this new polymer provides an unexpected enhancement in the flexibility of the catheter relative to the catheter using polyethylene. If the U.S. Patent and Trademark Office asserts that the use of the new polymer is obvious over polyethylene, the unexpected enhanced flexibility can be used as a basis to establish the patentability of the invention.