## MDT Medical Design Technology TM

## **Protecting Your Inventions**

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For engineers and designers of medical devices, familiarity with U.S. patent rights is necessary to protect inventions. Before filing an application, it is important to distinguish "prior-art" from "novel" inventions.

In the crowded field of medical devices, it can be difficult to protect inventions through patents. However, it is essential for a company to be competitive, and receiving a patent is the first step. A patent does not grant the owner the right to sell the patented invention; in fact, it only prevents competitors from selling it. Thus, obtaining a patent is an essential first-step in protecting the owner's rights.

A key to patenting an invention is establishing "novelty," which means that an invention is new in that it is not already disclosed or part of the public domain. An invention may be qualified as novel when it has not appeared in "prior art," including other patents, publications, trade brochures, and advertisements on sale or otherwise available to the public.

Accordingly, if a medical device designer creates an invention which is not in the prior art, the invention is novel. Also, depending on where patent protection is sought, "novel" means the inventor may not disclose the invention to others outside of his or her company before filing a patent application. Prior-art patents and published patent applications in the U.S. can be located by searching the U.S. Patent and Trademark Office website. A list of patent documents is available from a simple keyword search in the "abstract and title" fields, and the documents are certainly worth studying. A more thorough search can be performed with knowledge of the USPTO's elaborate patent classification system.

Patents are grouped into categories known as "classes or subclasses," which are based on the subject matter of the patent. Relevant classes and subclasses can be identified by reviewing the front page of patents with similar subject matter, such as patents from competitors. If a patent is found that reveals a person's "invention," it is not actually "novel" and patent protection is not available.

The public use or display of an invention, at a trade show or public forum, for example, or the publication of a technical paper discussing the invention, are within the inventor's control or the control of the inventor's company. If public displays or publications occur prior to the filing of a patent application they will cause an invention to lose its "novelty." It is important to be aware that the U.S. gives inventors a full year to file a patent application after any such public disclosure or publication. However, most foreign countries do not offer the one year window, making it important to file a U.S. patent application prior to public disclosure in order to protect one's foreign patent rights.

Patent rights can also be lost if the inventor and his company abandon the invention. Abandonment may occur when work on an invention is completed, but is put on hold for a length of time without promptly filing a patent application. There are different reasons for abandonment. For instance, in the context of a large company, an employee decides the invention is not feasible due to cost, lack of customer interest, or production issues. If a competitor then files a patent application to the same invention, he will receive the patent although he conceived of the invention later. In addition, failure to meet deadlines set by the USPTO will result in abandonment of a patent application.

An inventor's prior-filed foreign patent application can also result in the loss of U.S. patent rights. Typically, the happens when the foreign application becomes a patent or is published before the U.S. patent application is filed.

To reiterate, obtaining a patent does not give a person the right to sell the patented invention. A patent only prevents others from making, using, or selling, the invention. A person should also consider that patents are often improvements on other inventions, meaning the improved product includes the original invention. For that reason, companies should perform freedom-to-operate studies on intended products prior to marketing them, regardless of whether the new product is covered by its own patent.

Freedom-to-operate studies involve locating relevant U.S. patents and determining whether those patents cover the new product. Since a U.S. patent can be enforced twenty years from its application filing date, studies need to look at relevant patents filed less than twenty years earlier. In other words, expired patents cannot be infringed.

Overall, it is essential that engineers and designers of medical devices file U.S. patent applications as soon as an invention is fully developed in order to protect patent rights. In addition, patents owned by the competition should be carefully checked before developing and marketing a new product.

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