Introduction to patent strategies for medical device inventions

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THE MEDICAL DEVICE INDUSTRY STORY of Gary Michelson, MD, is well known. As an orthopedic surgeon, Dr Michelson developed numerous surgical tools for various spinal and orthopedic procedures, building an extensive patent portfolio totaling more than 340 United States (US) patents and more than 950 issued or pending patent applications worldwide.[1] In 2005, Dr Michelson resolved a contentious litigation dispute with industry giant Medtronic, Inc, which agreed to pay $1.35 billion in exchange for access to Dr Michelson's patented inventions.[2] Dr Michelson's story vividly illustrates the tremendous importance and benefits that can result from developing and executing an effective patent strategy for medical device inventions.

This article provides an introductory, high-level overview of the basic concepts and components of a comprehensive patent strategy, including the pursuit of patent protection for offensive and defensive use against competitors, available measures for avoiding and/or challenging competitors' patents, and the roles that experienced patent counsel typically perform in helping clients make use of the patent system to achieve their specific business objectives.

IMPORTANCE OF A SUCCESSFUL PATENT STRATEGY

Patents confer a right to exclude others from practicing a patented invention. Contrary to popular belief, patents do not provide the affirmative right to practice an invention, because there may be additional third-party patents that also cover a particular product or device. A strong and diverse patent portfolio can provide numerous benefits in a variety of contexts. In the litigation context, patents can be used offensively to recover monetary damages and exclude competitors from operating in a particular market. Conversely, patents also can be used defensively as a valuable deterrent or countermeasure to avoid or resolve litigation brought by competitors, particularly where the opportunity for cross-licensing is attractive to both sides.

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Patents also confer monetary benefits even if never asserted in litigation. For example, an extensive patent portfolio can provide the basis for a licensing program that generates valuable revenue streams; it can pre-emptively discourage competitors from developing similar, competing products; and it can greatly enhance a company's overall reputation and valuation in the eyes of potential investors or buyers. Thus, an effective patent strategy should be viewed as an important tool for achieving various business and financial objectives.

PATENT DOCUMENT

There are a number of different types of patents available in the United States, including utility patents, design patents, and plant patents. Utility patents protect the useful or functional aspects of an invention and comprise approximately 90% of all patents issued by the US Patent and Trademark Office each year. Design patents protect the ornamental design or appearance of an article but not the functional aspects. In addition, patent protection is territorial, with different countries having their own unique patent systems. In general, inventors must seek patent protection in each country or geographic region in which patent protection is desired. This article is limited to a discussion of US utility patents.

Although patents vary in terms of the specific subject matter they disclose and claim, every patent document shares a common overall structure. The patent cover page provides a compilation of various clerical information, including patent number, date of issue, date of filing, identification of related patents and patent applications, a list of named inventors, and other related information.

The major component of the patent consists of the "specification" or "written description," which describes and explains the patented invention in detail, and typically includes a discussion of various topics, such as the background of the invention, the problem(s) solved by the invention, and specific examples illustrating the function and operation of the invention.

Listed at the end of every patent are one or more numbered sentences called "claims," which define the legal scope or boundaries of protection covered by the patent. Every patent claim is considered a separate invention. The claims of a patent often are compared with a fence at the edge of a property or the boundary lines on a deed, because they define the outer reaches of the invention protected by the patent. A patent owner can exclude others from making, using, selling, offering to sell, or importing subject matter falling within the scope of the patent claims for the duration of the patent.

Separate from, but related to, the patent document itself is the "prosecution history,"—the compiled record of exchanges between a patent applicant and the patent office generated in the course of applying for and obtaining a patent. Among other things, the file history can play an important role in determining the scope of the patent claims during subsequent litigation and patent office proceedings.

PATENTABILITY REQUIREMENTS

Patent protection only is available to inventions that meet certain legal requirements. These requirements are initially the focus of examination during patent prosecution before the patent office as well as in any subsequent litigation that may arise in connection with an issued patent. A brief conceptual overview of these various patent law requirements is provided below.

Utility and patent-eligible subject matter: 35 U.S.C. § 101. By statute, patent protection is available for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[3] In general, this means that an invention must have "utility"—ie, it must have a practical or specific use. Moreover, patent protection only is available for certain categories of patent-eligible subject matter—ie, a process, machine, manufacture, composition of matter, or improvements thereof. Laws of nature, natural phenomenon, mathematical formulas, and abstract ideas generally are not eligible for patent protection.

In practice, the utility requirement rarely presents an obstacle to patentability. In recent years, however, patent eligibility has become a more significant hurdle to obtaining patent protection after a string of recent Supreme Court decisions that have more narrowly interpreted the scope of patent-eligible subject matter.[4]

Novelty and anticipation: 35 U.S.C. § 102. An invention must be novel to receive patent protection. If a claimed invention was disclosed or described previously, either expressly or inherently, in a single prior art reference, it is not novel, is considered to be "anticipated," and cannot be patented. The specific statutory provisions defining various categories of prior art are complex and beyond the scope of this article and were altered significantly by statutory amendments that