



## Strategic patents can strengthen your innovation



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**In today's innovation economy**, a medical device company's success depends on the strength and value of its patent portfolio. Recent statistics from the U.S. Patent & Trademark Office (USPTO) show the issue rate for new medical device patents is exploding. In fact, the number of medical device patents issued by the USPTO has increased each year since 2009. While the number of issued patents is increasing across all technology sectors, the issuance of medical device patents is increasing at a much faster rate. According to Thomson Reuters, medical devices exhibited the strongest patent growth rate among 12 key technology areas. Indeed, medtech companies need to stake their claims in the medical device patent gold rush.

### Patents Fuel Company Growth

A strategic patent portfolio is crucial to a medtech company's growth and survival and can provide numerous business advantages. Patents are extremely important for medical device companies in all life stages. For early-stage companies, patents are often the only way for investors to place a value on a company's technology, as sales usually cannot begin until after regulatory approval from the U.S. Food & Drug Administration (FDA) or the European Medicines Agency (EMA). In this way, patents make up a significantly greater portion of enterprise value for early-stage medical technology companies than other startups. As a medtech company grows, patents become the currency to secure financing through venture capital or private equity investment. Patents can also lead to collaborations, joint ventures, and licenses with strategic partners.

Patents are equally important for later-stage companies that are generating revenue. Experts estimate that the

average medical device and drug patent can have a net present value of almost \$200,000. Simply put, patents are a source of enterprise value that medical device companies cannot afford to ignore.

In addition to their monetary value, medical device patents also hold great strategic value. A strategic patent portfolio can be used both offensively as a sword to strike out at competitors, and defensively as a shield to avoid competitor attacks. Offensively, patents can prevent competitors from making, using, or selling the patented invention. Defensively, patents can serve as bargaining chips against a competitor who threatens to sue for patent infringement of one of the competitor's patents.

### Develop a Strategic Patent Portfolio

Developing a strong portfolio first requires comprehensive patent coverage for the company's core technology. Companies should file one or a series of patent applications providing the broadest possible patent protection to cover the core technology. To obtain broad patent protection, a medtech company should consider both current and future business objectives and contemplate ways that competitors may attempt to design around the patents. Where applicable, patent claims should be directed to the entire device, key components, disposables, methods of manufacturing, methods of treatment, therapeutic uses, combination therapies, and any other aspects of the invention. As the core technology evolves, incremental improvements should be patented to form a "picket fence" of patent protection around the core technology. By filing patent applications covering incremental improvements, medtech companies will continue to expand their presence in the marketplace.



### Impact of Patent Reform

Patent reform has recently swept across the United States and Europe, and medtech companies must adapt their patent strategies to maximize intellectual property (IP) protection. In 2013, multiple new provisions of the America Invents Act (AIA), the first major reform to patent United States law in 60 years, changed the United States patent system from "first-to-invent" to "first inventor-to-file." Thus, medical device developers should file patent applications early in the development process before any public disclosure. The dramatic revisions of the AIA along with Europe's recent proposals for a Unitary European Patent and Unified European Patent Court are closing the gap between the two regions' patent laws. Such fundamental alterations in IP protection have medtech companies reevaluating how to best protect and enforce medical device innovations. Developers of medical technologies should work with strategic patent counsel early in the development process to maximize patent protection in the United States and around the world.

### File International Patent Applications


Filing international patent applications further strengthens a patent portfolio and expands a company's presence in the global marketplace. While foreign patent applications can be expensive, filing in strategic countries can be critical to the commercial success of a product. A company should consider filing in specific countries with a large target market for the product, countries where competitors' manufacturing facilities are located, and countries that export medical products to other regions through distribution channels. While the United States, Europe, and Japan have historically been top patent filing countries, China and Brazil are rising up the list.

### Watch Out for Patent Trolls

With the growing success of new medical technologies, the unwanted attention of patent trolls will not be far behind. Also known as patent assertion entities or nonpracticing entities (NPEs), patent trolls are businesses that acquire patents for the purpose of collecting royalties from companies

whose products or practices allegedly infringe patents owned by the NPE. In 2013, patent trolls invaded the medical technology industry by filing numerous patent infringement lawsuits against medical device companies. As the funding and profits in the medical technology sector increase, so will the undesirable activity of patent trolls. By taking careful steps to protect medical technology innovations through patents, companies can reap the financial and legal rewards of a successful strategy, and minimize the potential losses caused by patent trolls.

### Conclusion

In the wake of a shifting medtech market and changing patent legal landscape, tactical medical device developers would be wise to review and assess their research and development programs and patenting goals. By working with strategic patent counsel, medical device makers can take advantage of the changing patent landscape to stake bigger claims in the medical device patent gold rush. 



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