

Patents and the FDA: Four Critical Considerations Medical Device Companies Must Know to Successfully Introduce New Products into the Market



July 16, 2025
By Gregory Grissett

The intersection of patent strategy and FDA regulatory strategy is a critical consideration for medical device companies. A well-integrated approach can create powerful barriers to entry, strengthen intellectual property (IP) portfolios, reduce risk, and attract investors. This article explores key issues and strategies to ensure your patent and FDA efforts work together effectively.

An integrated patent and FDA strategy adds significant value to the business. Many companies focus solely on regulatory approval, overlooking how FDA submissions might affect their patent portfolio or vice versa. A coordinated approach between patent strategy and FDA strategy offers significant benefits to the business: stronger patent protection combined with FDA exclusivity creates complementary barriers to entry for competitors. This enhances your ability to protect innovations and ensures your patent strategy is embedded within the regulatory framework for the product that will be sold. Value for investors or later strategic acquirers is a direct result of an integrated patent and FDA strategy.

Four areas where medical device regulation and patent law overlap that must be implemented carefully include: patent coverage in view of FDA submissions, Freedom-To-Operate (FTO) risk, product Labeling and Patent Marking, and patent term extension (PTE).

Patent Coverage and FDA Submissions

Regulatory submissions often include technical details that can affect patent protection. To avoid premature disclosures and ensure alignment, file patents before submitting your regulatory documents to the FDA. While you may have filed for protection early during the product development process, reassessing the product just before submission is an important step to ensure your patents cover what you are seeking to market in the United States. Patent counsel should certainly have the opportunity to consider the filing documents, in ALL of their detail, to consider new patent filings to augment your patent strategy.

This strategy also serves other important purposes, like preventing premature public disclosures (e.g., in 510(k) summaries) that could compromise patent rights. Well-crafted summaries and filing documents could limit the usefulness of the confidential FDA data obtainable via Freedom of Information Act (FOIA) requests. Importantly, this key action ensures consistency between FDA filings and patent claims, avoiding statements that could lead to unenforceability due to inequitable conduct. In other words, saying one thing to the FDA that is inconsistent or contrary to the position you are taking regarding prior art can lead (it has) to a finding by the Court that patents are unenforceable. In addition, products evolve, certainly during

development, but even after market introduction. A robust use of continuation patent applications can help maintain adequate protection as the product evolves. There are numerous benefits to considering FDA filings in light of the patent strategy and not doing this simple task is a wasteful use of resources. Talk to your patent counsel!

Third-Party Patent Risk and Freedom to Operate (FTO)

Patent litigation is prevalent in the medical device industry, and failure to consider your products' freedom to operate can destroy business value. Before submitting a device for FDA approval, conduct FTO studies to identify potential infringement risks. These should include an analysis of IP related to predicate devices, especially for 510(k) submissions. In addition, understanding patents that cover competitive products is another key step in this process. Avoid using language in FDA submissions that could serve as a roadmap for infringement, such as instructions for use or device descriptions. Carefully drafting these documents is a viable way to limit risk and minimize the disclosure of otherwise proprietary information that is not germane to the purpose of the FDA submission but might otherwise be important in the third-party patent context.

Update FTO studies at key milestones, such as before submitting an investigation device exemption, 510(k), or PMA submissions. This is the best way to minimize patent risk once the product is approved, and the ever-important sales begin. Conducting this analysis based on what your business is authorized to sell in the U.S. is a critical consideration because patent risk only flows from making, selling, using, and importing into the U.S. a product that infringes a valid claim of a U.S. patent. Understanding the patent landscape related to the products that have high revenue generation potential is a required but pragmatic business practice to implement.

Product Labeling, Patent Marking and Maximizing Damages

Patent marking plays a crucial role in infringement cases. Generally, a patent owner is entitled to damages only after the infringer has been notified—either through a cease-and-desist letter, a lawsuit, or compliance with the patent marking statute.

Because the FDA regulates product labeling, companies can implement their patent marking during regulatory submission, and in particular, where product labels are concerned. The U.S. allows for virtual patent marking, where a URL (e.g., mycompany.com/patents) is included on the product label. Once the product receives market clearance with this label, damages can accrue from that point forward.

Failing to implement this strategy could delay damage accrual until after a lawsuit or cease-and-desist letter is issued. This can be potentially years after market introduction. A simple URL on a label, submitted with your FDA documents, can make a significant financial difference in your patent infringement case, should you need to file one later. There is no simpler way to increase patent value than to implement patent marking on product labels during the FDA approval process.

Patent Term Extension (PTE) for FDA-Regulated Products

Patents last 20 years from the date a non-provisional U.S. application is filed. During that time, the patent owner has exclusive rights to the patented invention. Once expired, however, others may freely use the invention. However, certain devices, and Pre-Market Approval (PMA) products specifically, can qualify for up to an additional five years of patent term extension. To be eligible for PTE, the product must have undergone a regulatory review period before it can be commercially marketed. The patent must not have been previously extended, and the application for PTE must be filed within a specific timeframe (typically 60 days) after the product receives regulatory approval. This extended exclusivity can significantly impact revenue. Companies should therefore actively monitor regulatory timelines to ensure the timely filing of patent term extension requests. Carefully consider the most valuable patent for extension because there is only one extension per regulatory approval allowed under the law. And finally, avoid delays during prosecution, such as taking extensions of time to file a response, as each extension of time can reduce the potential extension period.

In summary, four things that can maximize business value for your medical device are:

- Align patent filings with FDA submissions to ensure broad, enforceable claims. Conduct and update FTO studies throughout the product lifecycle.

- Share FDA submission materials with patent counsel to avoid inconsistencies.
- Incorporate virtual patent marking into FDA labeling at the earliest possible instance.
- File for patent term extension when available.

A successful medical device launch requires a great deal from a business. A robust patent strategy, integrated with the FDA framework, can only support a successful launch; it will not hinder it. By proactively aligning regulatory and patent efforts, companies can secure stronger protection, reduce risk, and enhance business value.