Smarter Patent Strategy in the Age of AI

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Patents are the currency of the medical technology industry and fundamental to commercial success. A well-planned intellectual property (IP) strategy bridges pre-clinical research, regulatory approval, and commercialization to create value and help secure market exclusivity.

Artificial intelligence (AI) is now changing IP strategy. The U.S. Patent and Trademark Office (USPTO) is integrating AI into patent examination to make the process faster, more consistent, and more reliable. USPTO leadership has announced that AI-based application review is being incorporated into USPTO workflows, though human patent examiners remain responsible for final examination decisions.

The underlying patent laws have not changed, and patent examination standards remain the same. However, AI is changing how quickly and consistently patent applications are analyzed. The USPTO is focusing on using AI-assisted workflows to support core patent examination tasks, including claim interpretation, priority analysis, prior-art searching and mapping, and analysis under existing patent laws.

For medtech innovators, this means that investing more time and effort before filing may reduce the total cost of obtaining valuable patent protection. Prudent medtech companies should update their patent strategy to adapt to the USPTO's changing examination approach.

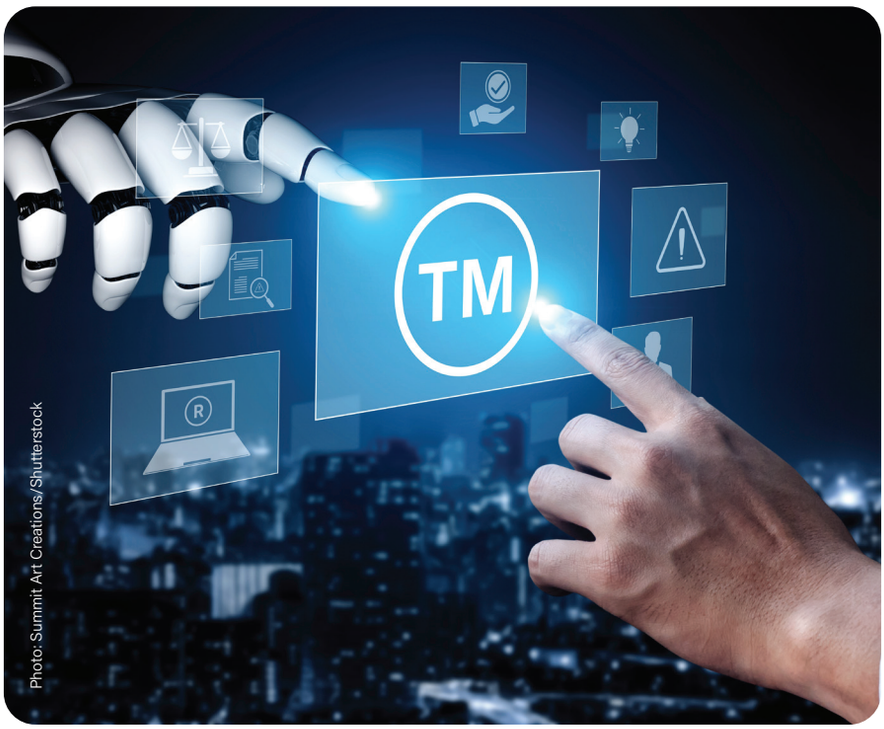


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Invest in the First Patent Application

Since AI-assisted examination rewards consistency, technical coherence, and precise terminology, medtech companies should treat drafting the initial patent application as the most important stage of patent prosecution, not merely the starting point. The USPTO's evolving AI approach can identify key claim terms, locate definitions in the specification, and align terminology between claims and disclosure. Ambiguous language can therefore create problems that may influence multiple areas of examination.

Before filing, medtech companies and their patent attorney(s) should pressure-test the patent application by asking whether it can withstand AI-assisted examination. Key questions include: Are important terms used consistently? Does the specification clearly support each claim term? Does the application describe alternative embodiments or potential design-arounds?

Addressing these questions early may increase front-end costs, but reduces the need to explain, amend, or repair the application later during examination. The goal should not be filing the least expensive application, but rather delivering the most cost-effective path to commercially meaningful protection.

The "Fix It During Prosecution" Strategy Will Become More Expensive

Historically, patent applicants often had room to refine their positions during USPTO examination. An applicant might file relatively broad patent claims and use exchanges with the examiner to survey the prior art, amend the claims, clarify terminology, and gradually distinguish the invention.

AI-assisted patent examination significantly changes that dynamic, though. Claim interpretation, invention framing, priority review, and claim-to-prior-art mapping happen early and feed into later statutory analyses. An examiner's initial interpretation is more likely to carry through prosecution, so weaknesses in the original application surface sooner and persist longer.

That makes a "fix it later" approach increasingly costly. Reactive amendments may narrow claims one issue at a time,

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while early concessions and interpretations become part of the examination record and impact continuation applications. The result may be more USPTO actions, additional attorney time, unnecessary continuations, and ultimately narrower patent protection.

A more cost-effective approach is to move key work upstream: invest earlier in understanding the invention, assessing the patent landscape, and drafting a stronger application before filing, thereby strategically reducing overall prosecution costs.

Use Continuations Strategically, Not Automatically

Continuation applications build valuable layers of protection, but AI-assisted examination makes strategic continuation planning essential. Early narrowing or admissions in the initial application may limit later efforts to pursue broader protection. Companies should therefore plan continuation strategy deliberately: identify the claim scope worth pursuing, decide what features have commercial value, and reserve continuation applications for technologies that justify the additional cost. For example, the initial patent application may focus on narrow claims, while a later-filed continuation application may contain broader claims. This proactive patenting approach can reduce unnecessary filings and attorney fees while preserving continuation practice for the technologies and claim scope with the most commercial value.

Be Selective About International Patents

For products with global commercial potential, medtech companies should also consider international patent protection. The higher cost of international filings should limit international patent protections to a company's key markets, manufacturing risks, and enforcement priorities.

The Patent Cooperation Treaty (PCT) allows the filing of a single international application covering 157 countries, including the United States and foreign medtech markets. A PCT patent application can delay filing costs in specific countries for 18 months.

To optimize international patent protection, medtech companies should consider filing in countries with large product markets, as well as countries where competitors' manufacturing facilities may be located. Key jurisdictions for medtech companies include the United States, Europe, China, and Japan. Brazil, India, Canada, Mexico, Australia, and South Korea may also be appropriate depending on budget and commercial priorities. Because many foreign countries restrict patenting methods of treatment or diagnostics, companies should consider claim drafting strategy before filing individual foreign applications. Patents in foreign countries can help protect a company against potential infringers who may make, use, or sell the company's invention in markets worldwide.

Prevent Expensive Problems Before They Occur

One of the most important ways to protect IP is to avoid inadvertent public disclosure. Releasing an invention into the public domain—through publication, presentation, website posting, blogging, or discussions with investors, customers or suppliers—before filing a patent application can forfeit patent rights and erode competitive advantage.

In the United States only, an inventor has up to one year from the first public disclosure to file a patent application. In all other countries, absolute novelty means patent applications must be filed before any public disclosure. Thus, file patent applications before any public disclosure, or risk losing patent rights.

Several basic documents should be in place to protect IP ownership and confidentiality:

Invention Assignment Agreements: Should state that all ownership rights in work product by an employee or consultant are automatically assigned to the company. Use present tense language such as "hereby assigns" to avoid ownership disputes.

Non-Disclosure Agreements (NDA): Use NDAs when confidential information must be shared with third parties for legitimate business reasons, including seeking financing, evaluating vendors, or obtaining advisor input. Sensitive information should not be disclosed until after an NDA is signed.

Employee Handbooks: Useful for setting out employment expectations, including the expectation that the company's IP should not be shared, disseminated, or misappropriated under any circumstances.

Conclusion

Patents remain fundamental assets for medtech companies, as they are capable of supporting investment, licensing, partnerships, market exclusivity, M&A, and IPOs. Strategic planning with a patent attorney in the R&D stage can help streamline patent application preparation and examination while increasing the likelihood of obtaining commercially meaningful protection.

As the USPTO adopts AI and becomes more technologically sophisticated, medtech companies should do the same. In the age of AI-assisted examination, smart patent strategy puts the strongest possible patent application in front of the examiner from the first day. ❖

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