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Insight

AI-Enabled Tech Faces Dual Hurdles in FDA Regulation, Patent Law

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Artificial intelligence is reshaping health care by powering medical devices and diagnostic tools that are increasingly precise, adaptive, and data driven. Yet innovators face two distinct but interconnected challenges.

The Food and Drug Administration is modernizing its regulatory framework to ensure patient safety while enabling innovation. Meanwhile, US patent law grapples with questions of inventorship and subject matter eligibility as algorithms and diagnostics adapt to evolving standards for patentability.

Attorneys should understand the intersection of these hurdles, the reasons behind FDA oversight and patent law, the effect of last year's FDA guidance, and how intellectual property barriers influence protection of AI-enabled technologies. There also are ways that innovators can overcome these challenges.

Different Goals

While FDA oversight and patent law often affect the same technology, they serve fundamentally different purposes. FDA oversight protects patients and public health by ensuring medical technologies are safe, effective, and reliable before they reach the market. This includes rigorous premarket evaluation; post-market monitoring; and ongoing assessments of risk, transparency, and clinical performance.

Patent law, by contrast, incentivizes innovation. Under the US patent system, inventors gain a limited monopoly in exchange for public disclosure of their invention. To qualify, inventions must be new, non-obvious, adequately described, and fall within the bounds of patentable subject matter.

As a result, FDA oversight and patent law approach AI-enabled technologies from different angles: One safeguards public health, while the other rewards and encourages technological advancement.

FDA's Latest Guidance

AI-enabled technologies, particularly those using machine learning or adaptive algorithms, pose challenges that traditional FDA frameworks didn't anticipate. Unlike static medical devices, AI models can evolve as they process new data, raising concerns about transparency, bias, and safety if their performance changes after deployment.

To address these issues, the FDA issued guidance last year on predetermined change control plans, or PCCPs, and total product lifecycle oversight for AI-enabled medical devices. PCCPs enable developers to pre-specify how future software updates will be validated and monitored. Doing so avoids the need for a new submission each time an AI model changes—as long as updates remain within FDA-approved parameters.

The guidance also emphasizes transparency in algorithmic decision-making, bias mitigation to ensure performance across diverse populations, and post-market monitoring to track the technology's real-world safety and effectiveness.

By clarifying approval pathways, the FDA aims to balance innovation with accountability, providing developers with greater regulatory predictability while ensuring that adaptive AI technologies remain safe throughout their lifecycle.

Patent Law Challenges

Even if a company successfully navigates FDA approval, intellectual property obstacles remain—especially those related to inventorship and subject matter eligibility.

US patent law requires that only natural persons can be inventors. Courts have rejected attempts to name AI systems as inventors, as in *Thaler v. Vidal*. This creates uncertainty when AI contributes to the "inventive step," such as discovering a novel biomarker during training on clinical data. Companies must carefully document human involvement to preserve patent rights.

Under *Alice Corp. Pty. v. CLS Bank International* and *Mayo Collaborative Services v. Prometheus Labs, Inc.*, algorithms and diagnostic methods risk being deemed unpatentable as abstract ideas or laws of nature, unless claims include something more, such as unconventional technical steps or specific machine implementations.

Many AI-driven diagnostics rely on correlations between biological markers and disease states, which face heightened scrutiny unless tied to novel data processing or system-level improvements.

A Hypothetical Example

Consider an AI platform that analyzes hospital admissions, staffing, and equipment data to forecast demand for Intensive Care Unit beds and surgical resources, then recommends real-time scheduling changes to improve patient care.

Because its recommendations would affect patient care decisions, the platform likely would fall under the FDA's "software as a medical device" framework. The FDA would require clinical validation, bias mitigation, and post-market monitoring to ensure safety and effectiveness. If the AI model retrains on new data, a PCCP could pre-authorize updates without requiring a new submission each time.

Even if FDA-cleared, the platform would face patent hurdles under *Alice*. A claim simply reciting "collecting and analyzing data to optimize scheduling," for example, risks being deemed an abstract idea on a generic computer.

To be patent-eligible, claims likely would need to recite a novel algorithm or system architecture that provides a specific technical improvement beyond routine data processing.

Best Practices

While FDA approval governs whether a product can be marketed, patents govern who can market it. For companies developing AI-enabled health-care technologies, the most effective approach is to treat regulatory and IP strategies as parallel, coordinated efforts rather than sequential steps.

Best practices include:

- Engaging regulators early to align on safety, efficacy, and post-market monitoring requirements before product launch
- Designing PCCPs proactively so adaptive AI models can be updated efficiently while staying within FDA-approved parameters
- Coordinating patent strategy with regulatory timelines to ensure that claims emphasize technical improvements and human-directed innovation while preserving flexibility for future product iterations

By integrating these efforts from the outset, innovators can accelerate time to market while strengthening both regulatory compliance and IP protection.

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