# *AI-Powered Medical Devices Bring Patent and Regulatory Pitfalls*

Published in Bloomberg Law (August 5, 2024) by Alexis Cohen, Gilbert Smolenski and Xanadu Halkias

- WilmerHale attorneys explain challenges facing developers
- Disclosing too much to FDA may threaten IP protection efforts

Artificial intelligence and machine learning are transforming the medical device industry. Simultaneously, companies are working to gain Food and Drug Administration approval and obtain intellectual property protection for this technology.

As these changes take place and newer guidance emerges, IP practitioners need to help clients navigate these complicated areas without jeopardizing investment into AI or machine learning-enabled technology.

Companies should evaluate how using AI to create software as a medical device may affect their ability to obtain patent or copyright protection for core aspects of their software or design. The Copyright Office and the US Patent and Trademark Office each issued guidance for when AI-enabled activities qualify for IP protection.

**Regulatory Considerations**

Software as a medical device has existed for decades. But recent advances have led to a new generation of such devices that typically use collected data to train complex models that can classify, predict, diagnose, or treat various conditions.

Medical devices using AI and machine learning may have significant clinical benefits and lead to better patient outcomes. For example, some FDA-approved software programs purport to use AI to automate and improve various aspects of medical image analysis

But if such devices aren't properly designed or trained, there could be negative patient outcomes, such as if the same AI-enabled medical image analysis provides the incorrect output. Given the need to balance benefits and risks, the FDA and Congress have been implementing various changes to the regulatory framework for AI or machine learning-enabled medical devices.

AI and machine learning-enabled devices typically have used one of two processes to obtain US regulatory approval. The premarket approval process is the most stringent and can take several years. The 510(k) process is shorter and simpler, relying on a showing of substantial

equivalence to a previously approved device to demonstrate the new device is safe and effective.

As part of this regulatory review process,

Developers must explain to the FDA how their enabled models work. This may include characterizing how the model compares to earlier ones and whether the new model uses existing computer functionality.

Assuming an AI or machine learning-enabled software obtains approval, if a developer wishes to make software changes, such as introducing a model trained on new data, the developer likely will have to make a new process submission. This encourages the approved software to remain static.

Recognizing that technological advances can happen more quickly than the regulatory approval process allows—including in real time for dynamic or self-taught models—the FDA and Congress have been working toward a new regulatory framework that attempts to account for such advances.

In 2022, the FDA completed a software pre-cert pilot program to evaluate a lifecycle monitoring approach for AI or machine learning-enabled software as medical devices. In late 2022, President Joe Biden signed into law the Food and Drug Omnibus Reform Act of 2022, which includes a provision where the FDA can implement a Predetermined Change Control Plan for certain software as a medical device that will exempt some planned changes from the regulatory approval process.

The FDA has issued draft guidance and regulations to implement these plans. The regulations may mean that the government will not need to approve every update to a particular model or newly used set of training data for AI-enabled medical devices.

During the initial review process, developers can submit a plan for how they intend to manage, and control potential risks from, implementing those modifications. This process would expedite when modifications can be made available for commercial use

**IP Considerations**

For each regulatory clearance pathway, a developer must provide the FDA information about the software models, testing, training, and validation data and any other pertinent materials featured in the medical device. This raises several IP considerations.

When explaining how their models obtained FDA approval, developers should carefully consider how those statements affect copyright authorship and patent inventorship.

Sometimes software is ineligible for patent protection under Section 101 of the Patent Act. If SaMD developers pursue patent protection, they should evaluate how to draft their applications and patent claims to mitigate the risk of future patent eligibility challenges.

Developers may want to protect key aspects of their AI or machine learning-enabled software through trade secrets instead of patents. Under the previous approval process, developers would submit information to the FDA as part of the process, which sometimes includes trade secrets.

Under the proposed framework that requires the FDA to analyze the software developer's model and training practices, even more proprietary data may be required during the initial

approval process. Companies must ensure they exercise appropriate cautions when submitting information to the FDA to ensure it remains a secret. Otherwise, they risk losing trade secret protection over critical aspects of their devices.

Department of Commerce guidance issued in 2022 reminded companies that statements to the USPTO "that are inconsistent with statements submitted to the FDA and other governmental agencies" violate an applicant's duty of candor and good faith and fair dealing to the patent agency.

Developers must consider whether their regulatory statements about the design and functionality of their devices are consistent with representations they made to the USPTO, such as inventorship or key aspects of the design. Otherwise, the patent holder risks that their patents will be declared unenforceable.

*This article does not necessarily reflect the opinion of Bloomberg Industry Group, Inc., the publisher of Bloomberg Law and Bloomberg Tax, or its owners.*

**Subhead**

- bullet
- bullet