

## MEDCITY INFLUENCERS

# The patent protection conundrum facing producers of AI-enabled software as medical devices

Some courts have invalidated AI-related patents where the claims and specification of the patent lacked sufficient specificity regarding the invention.

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**E**arlier this year, the FDA released a discussion paper entitled Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Devices (SaMD), which proposes a regulatory framework for governing medical devices that incorporate artificial intelligence.

In the discussion paper, the FDA recognized that AI-based medical devices may have potentially significant benefits. The FDA highlighted AI's "ability to learn from real-world use and experience, and its capability to improve its performance," for example as the AI tools learn from new data over time. The FDA also predicted that "AI/ML-based SaMD will deliver safe and effective software functionality that

improves the quality of care that patients receive."

The proposed regulatory framework for AI devices includes a "Total Product Lifecycle" regulatory approach. This entails regulation of both the medical device and the protocols that control the way the algorithm may change over time (as the AI processes new data and adapts).

Given the potential benefits of AI-based medical devices, companies will surely want to protect their AI-based innovations in the medical device field. Trade secrets and copyright law can protect the specific computer code used in programming the AI software for a medical device, but patents can offer a broader protection for the functionality of an AI-based medical device.

A key issue when considering patent protection is the "abstract idea" exception. The Supreme Court has held that patent claims on inventions that are directed to an abstract idea and that lack an inventive concept are patent ineligible under Section 101 of the patent laws. *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014).

The abstract idea exception has been used to invalidate patents relating to both data analysis and medical processes—the two core concepts joined together in AI-based medical devices. For example, the Federal Circuit has invalidated patents directed at "collecting information, analyzing it, and display-

ing certain results.” *Elec. Power Group v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). The abstract idea exception has also been used to invalidate claims directed at medical processes that apply natural correlations. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 80 (2012).

The abstract idea exception will be a significant consideration for patents relating to AI-based medical devices. Companies will need to be careful in drafting their patent claims to ensure their best chances at surviving a patent eligibility challenge.

One argument available for patent owners is that their claims provide a technical improvement to the technology in question (e.g. the computer or medical device). If a patent claim “improve[s] computer functionality,” it may survive invalidation even if the claim relates to an abstract idea. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370 (Fed. Cir. 2018). In the context of AI-based medical devices, patent owners may be able to argue that their invention improves the functioning of the computer/medical device or improves the efficacy of the medical treatment/procedure in which the device is used.

There is currently little case law specifically addressing AI-related inventions, but at least one court has suggested that AI-related inventions may be patent eligible: “To the extent artificial intelligence inventions...involve an inventive concept, they could be patentable even if they have, at their core, an abstract concept.” *Blue Spike, LLC v. Google Inc.*, Case No. 14-cv-01650-YGR, 2015 WL 5260506, \*6 (N.D. Cal. Sep. 8, 2015).

Other courts, however, have invalidated AI-related patents where the claims and specification of the patent lacked sufficient specificity regarding the invention. For example, in a decision recently affirmed by the Federal Circuit, one district court held that a patent merely recited the concept of “predictive analytics” without more and was therefore invalid. *PurePredictive, Inc. v. H2O.AI, Inc.*, Case No. 17-cv-03049-WHO, 2017 WL 321480, \*7 (N.D. Cal. Aug. 29, 2017). In that case, the patent owner argued its claims used AI to “generate a predictive ensemble in an automated manner’ with ‘little or no input from a user or expert.” But the court held that the patent “‘merely recite[d] the abstract idea of’ predictive analytics” and lacked “specificity” ( for example,

it did not “describe specific system architecture”). The court also held that there was no significance to the fact that an AI system could process “millions of learned functions,” which would be “impossible for a human”—the claim was still invalid.

One key lesson for those looking to protect their AI-based medical devices with patents is to note the importance of describing the AI-based system with sufficient specificity in the patent. Fortunately, this corresponds to aspects of the FDA’s proposed regulatory framework, which requires disclosure of details of the AI system. For example, the FDA’s discussion paper notes the importance of the “Appropriate level of transparency (clarity) of the output and the algorithm.” The FDA also emphasized that the protocols governing changes to the algorithm should include “a step-by-step delineation of the data and procedures to be followed so that the modification achieves its goals and the device remains safe and effective.”

Another potentially helpful guide to the type of specificity that may ensure patent eligibility is the Patent Office’s 2019 Revised Patent Subject Matter Eligibility Guidance. Although these guidelines lack the force of law, they provide helpful identifications of the type of benefit which—if claimed and described in the patent—may be sufficient to avoid invalidation under the abstract idea exception. Examples including identification of an “improvement in the functioning of a computer...[or] other technology or technical field” or use of an invention “to effect a particular treatment or prophylaxis for a disease or medical condition.” These, and other potential improvements, might plausibly be recited by patents directed toward AI-based medical devices.

As AI-based medical devices become more prominent, it will be important to consider the “abstract idea” exception and define the system with sufficient specificity to attain patent protection on those devices.

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