

David McCombs, Vincent Shier, Eugene Goryunov, Dina Blikshteyn, Jamie Raju, Brooke Cohen in Med Device Online: ‘How to Navigate Patent Eligibility of AI-Driven Diagnostics’

August 2, 2022 David McCombs, Dina Blikshteyn, Jamie Raju, Brooke Parker

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[David McCombs](#), Vincent Shier, [Eugene Goryunov](#), [Dina Blikshteyn](#), [Jamie Raju](#), and [Brooke Cohen](#) authored an article in *Med Device Online*. Read an excerpt below:

In an attempt to formalize the law on patent eligibility under 35 U.S.C. § 101, the U.S. Supreme Court issued two major decisions outlining a two-part test: *Mayo v. Prometheus* and *Alice v. CLS Bank*. Instead of bringing clarity, however, *Mayo* and *Alice* spawned discord among various district courts and, as a result, increased the uncertainty in § 101 jurisprudence. The U.S. Supreme Court had the opportunity to clarify the state of the law in *American Axle*, but declined to do so, denying the certiorari petition.

The uncertainty in patent eligibility has had a particularly chilling effect on patenting life sciences and computer software inventions. AI-driven innovations that lie at the intersection of these two fields face particular difficulty in satisfying the judicially created requirements under § 101.

The prevailing concern for many life sciences companies is that they give the quid, but never see the quo that the patent system is supposed to provide. Given the publication of patent applications and the current challenges of obtaining and defending the patent protection arising, in large part, from the patent eligibility challenges, many life sciences companies are considering forgoing patent protection altogether. This decision is short-sighted. First, AI is transforming the life sciences industry and companies should strive to invest in and protect these game-changing inventions. Second, there are effective patent-drafting and claim strategies that increase the likelihood of passing muster under § 101 during prosecution and, subsequently, withstanding patent challenges in district courts.

[In an article for Drug Discovery Online](#), we discussed how practitioners can navigate the uncertain area of inventorship in the area of AI-assisted drug discovery. In this article, we focus on patent eligibility of AI programs for disease diagnosis.

Excerpted from *Med Device Online*. To read the full article, click [here](#), or read an earlier article in the series [here](#).