Nimalka Wickramasekera Examines the FDA's AI Regulatory Framework

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Intellectual Property Litigator Nimalka Wickramasekera was quoted in BioWorld MedTech's April 10 article "FDA's AI Paper Draws Cheers, But Agency Expected to Resist Calls for Legislation." The article addresses the FDA's draft framework for unlocked artificial intelligence (AI).

Companies trying to wedge their way into the artificial intelligence space might be wrapped up in concerns regarding FDA regulation, but developers might have a few intellectual property issues to deal with as well, which may revolve around the question of subject matter eligibility under Section 101 of Title 35 of the Federal Code, Nimalka explains.

"I think that we are definitely going to see Section 101 being raised as an issue," with regard to AI patents, she said. The concerns that have plagued software patents since the 2014 Supreme Court decision in *Alice Corp. v. CLS Bank* will almost certainly dog patents for AI as well.

Companies that want to bullet-proof their patents post-Alice should move away from claims that describe what the result is to how the innovation actually achieved that result. Claims that are broad—such as those describing data gathering and what the algorithm might do with the data—will be more vulnerable on the 101 front. Conversely, explaining how the claims achieve the intended effect will make those claims less susceptible to the Section 101 challenge.

The iterative, learning algorithm implied in the AI space is in some ways different from a fixed algorithm where regulations are concerned, but a learning algorithm generally faces the same types of challenges that traditional software patents face. The only difference might be in seeing how these claims are shaping up in patents that have been drafted since Alice, and whether they present any challenges we haven't already seen. It will be interesting to see how the adaptive nature of some of these AI articles is manifested in patent claims, she notes.

On the other hand, it is difficult to rule out the possibility that the adaptive nature of AI could unexpectedly trip some intellectual property wires once on the market, given the prospect that an adaptive algorithm could stray into territory that already enjoys patent protection. This could become an especially interesting consideration for AI algorithms that are sold or licensed to a second party, at which point multiple defendants will be forced to argue whether they are liable for any purported infringement.

Nimalka notes that while the case law for AI has yet to develop in any robust fashion, the developer may still have protection if your device adapts and has a new result or functionality, but uses the same type of rule in getting to that result.

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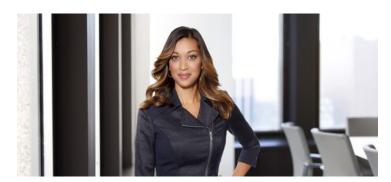Intellectual Property   Patent Litigation   Technology, Media & Telecommunications

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