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New Patent Bill Could Boost Diagnostics, But Needs Work

By **Ryan Davis**

Law360 (August 12, 2022, 10:03 PM EDT) -- Patents on medical diagnostics have been repeatedly struck down under current patent eligibility standards, and while a new bill may help turn the tide if enacted, it needs revisions to ensure that methods of diagnosing disease can be patented, attorneys say.

The office of Sen. Thom Tillis, R-N.C., has said that one of the goals of the Patent Eligibility Restoration Act he introduced this month is to ensure that diagnostics inventions can be patented, after numerous decisions invalidating them over the past decade.

However, the word "diagnostics" does not specifically appear in the bill. Attorneys said that other provisions could have the effect of permitting patents on those inventions, but they leave enough open questions that companies seeking patents on diagnostic methods would still face uncertainty if the measure passed as drafted.

The language in the bill aimed at shielding diagnostic patents from eligibility challenges "doesn't clearly jump off the page," according to Vincent Shier of Haynes and Boone LLP, who added he found it "a little jarring at first" that the measure wasn't more explicit on that point.

The language of the bill is "maybe not as clear as we'd like," but "the concept is here, and I do think it protects and restores patent eligibility in the diagnostic space," he said.

Carla Ji-Eun Kim of Sterne Kessler Goldstein & Fox PLLC said that under the wording of the bill, many diagnostic methods would be patent eligible, although "it may not necessarily eliminate future litigation on diagnostic methods, and it will have to be clarified even more."

"I think the bill can definitely improve," she said. "But I do welcome this attempt and think it's a great starting point."

Potential Fixes

Since the U.S. Supreme Court's 2012 decision in Mayo v. Prometheus finding a method of determining the proper drug dosage to treat autoimmune diseases ineligible for patenting, nearly all diagnostic patents that have been reviewed by the courts have met the same fate.

The courts have established certain categories of subject matter that are not patent eligible, including laws of nature and natural phenomena. Those are typically cited in cases involving diagnostics, in which

diseases are detected using newly discovered biological phenomena, like a gene being associated with a higher risk of a certain disorder.

The new bill seeks to bring more clarity to the patent eligibility analysis by discarding the broad categories of ineligible material established by the courts, and instead setting out a narrower list of specific subject matter that can't be patented.

Particularly relevant to the diagnostics field is the bill's statement that a process that "occurs in nature wholly independent of, and prior to, any human activity" is not patent-eligible. Since most diagnostic inventions involve some human activity, like acquiring a blood sample and processing it or isolating a metabolite, the bill's wording could keep such patents from being found ineligible, Shier said.

If the patent includes steps that involve human intervention, "at least in the draft, that's where the language clearly gets us to diagnostics and gets us around where the Supreme Court in Mayo … really kind of damaged that whole sector," he said.

Another provision of the bill that could be helpful for diagnostics is a section stating that an unmodified natural material as it exists in nature would not be patent-eligible, but a material that is altered by human activity, or is "otherwise employed in a useful invention or discovery, shall not be considered to be unmodified" and could thus be patented.

It could be argued that diagnostic methods involve natural material employed in a useful invention or discovery, and therefore should be patent-eligible under the bill, so "I think that's the cryptic assist to medical diagnostics," said Peter J. Butch III of Fox Rothschild LLP.

"It's saying you can measure something in a human and apply it in a useful invention, namely a medical diagnostic, and you've got it," he said. "This is what they're trying to accomplish here, and they may succeed."

Potential Problems

Despite the intent of the those who drafted the legislation to protect diagnostic patents, "you really have to read between the lines of this bill," Butch said. He added that it would be helpful to patent applicants if, during eventual debate over the bill in Congress, lawmakers clearly stated in the congressional record that the provisions are intended to protect diagnostic patents, since that's not readily apparent from the text.

Warren Woessner of Schwegman Lundberg & Woessner PA said that, given the wording about human activity and useful discoveries, "you could probably shoehorn in diagnostic methods with all those various qualifiers."

"But that's clunky. I mean, we shouldn't have to do that kind of struggling," he said.

According to Shier, "one of the big concerns comes from whether or not the language achieves the intended goal when it comes to medical diagnostic processes."

He said he saw the potential for courts to broadly read the bill's wording that processes occurring in nature "wholly independent" of human activity are not patent-eligible to still exclude diagnostics, by

discounting the human intervention in the method, and finding that the claim really just covers a natural process.

"That would be where I think we'd see a litigation battleground for interpretation on the diagnostic front," Shier said. "If the courts are hellbent on maintaining an interpretation that's consistent with the outcome in Mayo, then that would be where I think they would go."

Kim pointed out that some simple diagnostic methods may involve limited human activity and just involve observing a natural phenomenon that is discovered to be associated with a disease, and patents on such methods would still have trouble securing protection under the bill.

Potential Revisions

Tillis has indicated that the bill is intended as a starting point, and that potentially years of debate and revisions are expected before it ever becomes law. So attorneys had suggestions for how the bill could more clearly protect diagnostic patents.

Kim noted that the bill specifically states unmodified human genes and mathematical formulas are not eligible for patents, so it could do the same to explicitly state what is eligible.

"In one way, I think this can be a lot more simple," she said. "If the human gene section remains the way it is, I do think that specifically mentioning diagnostics would help."

Woessner suggested the bill could state that processes involving the recognition of the utility of a naturally occurring correlation are patent eligible. That would make clear that the patent doesn't cover the correlation itself, but what it indicates about a patient's health, he said.

"If we're going to do a legislative fix, let's fix it, instead of having to work within some framework of very general information that doesn't mention processes or diagnostics," Woessner said.

Years of court decisions that methods of diagnosing disease are not patent-eligible have hindered the incentive for companies to pursue that research, and they instead focus more on new drugs and other technologies that can be patented, Kim said.

"I do file diagnostics method applications," she said. "But I think that we would have filed a lot more, and we would have developed a lot more, if the patent protection was strong."

Shier said he continues to advise clients to seek patents on diagnostics, because even if they aren't valid under current standards, the law could change while the application is pending, as a result of court rulings or through legislation like the new bill.

But until that happens, the current eligibility landscape has had what he called "a dramatic impact on the medical diagnostic community, and ultimately what it creates impediments to is the development of potential life-saving technologies."

--Editing by Emily Kokoll & Dave Trumbore.
