

Vincent Shier in Law360: 'New Patent Bill Could Boost Diagnostics, But Needs Work'

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Haynes Boone Partner Vincent Shier was quoted extensively in a *Law360* article. Below is an excerpt:

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 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 Boone, 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. ...

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. ...

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." ...

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."

Excerpted from *Law360*. To read the full article, click [here](#).