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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Fed. Circ. Pleads For Patent Eligibility Clarity: What Now?

By **Ryan Davis**

Law360 (July 10, 2019, 9:13 PM EDT) -- In a 7-5 decision, the Federal Circuit declined last week to sit en banc to address the contentious issue of patent eligibility, yet the judges all called for Congress or the U.S. Supreme Court to clarify the law. Here's what could happen following the court's unusual plea for help.

All 12 judges on the Federal Circuit appeared to agree that an Athena Diagnostics test for an autoimmune disease should be patent-eligible, but they were deeply divided on whether it actually is under high court precedent. The majority said they felt legally bound to rule the test was invalid for claiming an ineligible law of nature, a conclusion the dissenters said read prior decisions too broadly.

The court's divergent views on whether the Supreme Court's key 2012 decision in Mayo v. Prometheus mandated the invalidation of Athena's patent, illustrated by the eight separate opinions in the 86-page order, crystallized the confusion attorneys say is pervasive about what makes an invention patent-eligible, particularly in the field of medical diagnostics.

"It seems no two judges can apply Mayo the same way, and if that isn't a cry for help, I don't know what is," said Bridget Smith of Knobbe Martens.

Judge Kimberly Moore suggested in her opinion that there is no more the Federal Circuit can do to provide clarity, advising litigants that "your only hope lies with the Supreme Court or Congress," a view echoed by several of her colleagues.

The prospect of lawmakers or the justices taking up the mantle of patent eligibility reform holds both promise and risk, attorneys say, but the fractured outcome at the Federal Circuit is sure to add to calls for action.

"It's certainly a motivation for people going to Congress and people going to the Supreme Court. It's not going to calm things down, that's for sure," said former U.S. Patent and Trademark Office solicitor Nathan Kelley of Perkins Coie LLP.

The Supreme Court could refine its past rulings, while legislation to redefine what is patent-eligible could come from Congress. Failing that, the Federal Circuit could keep grappling with the issue on its own. The divided ruling could affect each possible outcome in different ways.

Legislation

Passing patent legislation is a struggle, but the Federal Circuit's call to clarify patent eligibility comes as Congress is working on a bill to do just that. The measure, expected to be **introduced this summer**, would overrule Supreme Court decisions, including Mayo, that established subject matter that is ineligible for patents, like laws of nature, natural phenomena and abstract ideas.

Since the Supreme Court seems to have made clear where it wants the law to go, the Federal Circuit's pleas seem to be best directed to Capitol Hill, said Michael Abernathy of Morgan Lewis & Bockius LLP.

"In light of the proposed legislation, I think this decision probably is some sort of push for Congress to intervene," he said.

The Federal Circuit's decision caught the attention of Sens. Thom Tillis, R-N.C., and Chris Coons, D-Del., who are drafting the bill. They said in a Monday statement that the outcome shows legislative action "is both urgent and critical."

"Life-saving technologies like medical diagnostics are now being excluded from the patent system despite the judges themselves agreeing that these innovations should be eligible for patents," they said, adding that the decision sends a message to Congress that "America's patent laws are stifling innovation."

That was welcomed by proponents of legislation, like David Suter of Harness Dickey & Pierce PLC, who said he was pleased the lawmakers' reaction was "message received."

"I think the fix does have to come from Congress," he said. "We'll see what happens, but at least it looks like there's some momentum."

If Congress were to pass a law discarding the Supreme Court's prohibition on patents directed to laws of nature, it would sweep away the often confusing body of law on what meets that description. That could make Federal Circuit judges comfortable upholding patents they believe are deserving of protection, like Athena's diagnostic test.

U.S. Circuit Judge Alan Lourie wrote in his opinion that "if I could write on a clean slate," only natural laws themselves like $E=mc^2$ would be ineligible, not inventions that detect natural laws, like diagnostics. Smith said that "to some extent, having this new legislation might give them the ability to write on a clean slate."

Yet congressional action comes with risks, Kelley said, since a new law is going to require the Federal Circuit to spend years interpreting and applying it to determine what passes muster.

"The danger is that if Congress writes a law, then we're going to have go through the motions of figuring out what the law means through case after case after case," he said.

But even the Federal Circuit's call for help may not be enough to clear the hurdles any legislation faces in gaining enough support to become law.

"We're coming into an election cycle, and would anyone be willing to work to get this legislation up to Trump for signature? I think at the end of the day, it's doubtful in this environment," Abernathy said.

Another Look by the High Court

Some Federal Circuit judges suggested that the justices are best suited to clarify what can be patented under Mayo. U.S. Circuit Judge Timothy Dyk wrote that while he believes diagnostic tests like Athena's should be patent-eligible, they mostly cannot be under current high court precedent, so "it is the Supreme Court, not this court, that must reconsider the breadth of Mayo."

If new legislation isn't in the cards, the Supreme Court could take up the Athena case or another one to recalibrate its patent-eligibility standard to widen patent protection on things like diagnostic tests, Kelley said.

"If we can get where people think we need to get with a Supreme Court opinion, that's a much cleaner thing for the Federal Circuit to deal with," he said. He noted that some Federal Circuit judges seemed to be speaking directly to the justices to entice them to get involved.

In their opinions, those judges pointed out what they described as flaws in past high court patent-eligibility rulings. For instance, Judge Dyk said the Mayo decision that inventions directed to laws of nature can't be patented is difficult to square with the subsequent 2013 Myriad decision, which suggested discoveries of such laws with a diagnostic purpose may be patent-eligible.

Likewise, U.S. Circuit Judge Raymond Chen suggested that Mayo "is in considerable tension" with the high court's 1981 Diamond v. Diehr decision that patent eligibility must be determined by looking at patent claims as a whole, not by dissecting them into elements to be considered individually, as the court appeared to require in Mayo.

Those opinions are "both about actual concrete problems with Supreme Court case law as it exists today, and the Federal Circuit's inability to resolve that," Kelley said. "I think that's the kind of thing that could actually move the Supreme Court to take a case."

Others questioned whether the high court, which has denied dozen of petitions involving patent eligibility standards, would wade into the issue again, especially since Congress could moot the issue through legislation.

"If there is a cert petition, I'm wondering if it will be denied just because of the timing of these proposed legislative changes," Smith said.

Even if the Supreme Court were to take a case, it likely could only make incremental changes that build on past decisions, which the Federal Circuit would then have to interpret. Suter said he believes the better approach is for Congress to overhaul the law.

"Who knows what's going to come out of the legislative sausage-making, but I have no faith that the Supreme Court is going to do anything with this. They created the problem," he said.

More Federal Circuit Action

The decision seemed to be the last word from the Federal Circuit on the patent eligibility of diagnostic tests, but there may be some wiggle room for the court to sit en banc in another case, attorneys said.

A rehearing request framed as a general dissatisfaction at the state of the law is unlikely to be granted,

but a concrete argument about why a particular patent should be eligible could catch the court's eye and give it a chance to expound further on patent eligibility, Kelley said.

"Yes, this was a denial, but five judges voted for rehearing. All you need is one or two other judges," he said. "So if you've got a compelling case and you can convince one of those other judges that my case is a little bit different and here's why, that might work."

Attorneys said they'll also be watching for whether a future Federal Circuit panel might find a medical diagnostic patent to be eligible, something that hasn't happened since Mayo. Because five judges said they would have upheld Athena's patent, having two of them on the same panel in the future could lead to such a result.

That may be a long shot after the fractured opinion, but "there could be the right case with some decently constructed claims, and there's an argument to be made that maybe you'd get it through," Suter said.

Then the question would be whether the full court would review such a decision and overturn it with a breakdown similar to last week's ruling. But the variety of views among the judges shows how difficult it is to predict the outcome of any patent eligibility case and why someone other than the Federal Circuit may need to get involved.

"I don't think this uncertainty is helping anybody. This kind of ambiguous status quo is going to continue until the Supreme Court or Congress does something," Smith said.

The case is Athena Diagnostics Inc. et al. v. Mayo Collaborative Services LLC, case number 17-2508, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Philip Shea and Alanna Weissman.