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

Fed. Circ. Ruling Shows Limits Of USPTO Eligibility Guidance

By **Ryan Davis**

Law360 (April 3, 2019, 8:59 PM EDT) -- By emphasizing that it isn't bound by U.S. Patent and Trademark Office guidance on patent eligibility, the Federal Circuit has given a stark reminder that patent owners can't rely on the office's views about what can be patented, and patents the office issues may be at risk in court.

The appeals court on Monday invalidated two Cleveland Clinic patents on cardiovascular disease tests, finding they claim a patent-ineligible natural law. The court rejected the clinic's argument that the agency's eligibility guidance indicates its patents are valid, writing that "while we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance."

The USPTO has issued several guidance memos to examiners on the contentious issue of what types of inventions are eligible for patents, some of which have been widely viewed as making more things eligible. But the Federal Circuit has now made clear the office does not have the last word on eligibility, and that patents issued under its guidelines are subject to scrutiny and invalidation in court.

"For companies seeking patent protection, the Cleveland Clinic decision means that the USPTO, following its own guidance, may be issuing invalid patents," said Kia Freeman of McCarter & English LLP, adding that it shows the office "will not be allowed to lead the way out of the eligibility quagmire."

The ruling illustrates that "PTO guidance is not a safe harbor for patent owners when it comes to district court litigation," said Mark Remus of Brinks Gilson & Lione.

Courts will analyze patents based on their own precedent, and the USPTO's guidance may be taken into account if judges feel it is on point, but it will not control the outcome, he said. That means that "there is a big difference between the patents you can get and the patents you can enforce," he noted.

"Patent applicants need to be mindful of the fact that this guidance may be helpful in determining what patents they're able to get from the patent office, but just because you've survived the patent office under that guidance, that certainly does not mean that you will have a strong case for enforcing those patents when it comes to district court litigation," Remus said.

Since the U.S. Supreme Court's 2012 decision in Mayo v. Prometheus that natural laws can't be patented under Section 101 of the Patent Act, courts, applicants and attorneys have struggled to

determine what inventions pass eligibility muster. Since Director Andrei Iancu took office last year, the USPTO has attempted to bring more clarity on the issue, but the ruling shows it cannot do that alone.

"Some people might have viewed the guidelines as a potential panacea to what's wrong with Section 101. And it's clear to us now that that's not going to be the case," said Gonzalo Merino, vice president and chief intellectual property counsel at Regeneron Pharmaceuticals Inc. "The U.S. patent office might issue a patent, but it might be declared invalid later in litigation. And that's not a good thing."

The USPTO's guidance is a step in the right direction, but it can't by itself fix the eligibility issues, since the court has said it is not obligated to follow the agency's lead, he said.

"The most important point is that it's clear this is not going to fix the 101 issues. Something more is needed: for example, a legislative fix," Merino said.

He has participated in a series of roundtables with industry groups organized in recent months by U.S. Sens. Thom Tillis, R-N.C., and Chris Coons, D-Del., to discuss possible legislation to overhaul Section 101. Tillis has said they hope to have a draft bill by early summer and "want to make progress very seriously this year."

"I'm optimistic in that it's remarkable that we have this opportunity and I'm not sure that this opportunity will easily come up again: having the bipartisan attention of two senators that are willing to conduct regular roundtables to discuss the issues for hours and come up with some truly innovative legislation," Merino said.

Unless and until the patent eligibility statute is overhauled by Congress, patent applicants and attorneys will have to contend with the potential that differing views on patent eligibility between the USPTO and the courts could cast a cloud on the viability of certain patents.

"I think that's the clear struggle that we all find ourselves in now as we prosecute patents," said Jeremiah Frueauf of Sterne Kessler Goldstein & Fox PLLC. "We're trying to figure out the line between the case law that is constantly evolving and the PTO's efforts to provide some sort of guidance."

Patent applicants need to balance the USPTO's guidance and the case law, he said. That may mean pursuing patents at the office that "walk the line," while being ready to argue in court that the patents are analogous to those that have survived Federal Circuit eligibility challenges.

The Cleveland Clinic case dealt specifically with an example found in patent eligibility guidance the USPTO issued in 2016. The example described a hypothetical invention using "conventional" techniques to detect a protein that naturally occurs in people with a fictional autoimmune disease called "julitis," and stated such an invention should be patent-eligible.

Cleveland Clinic said its patents, which deal with measuring a protein tied to an increased risk of heart disease using conventional methods, should be found eligible as well. The Federal Circuit disagreed, saying the USPTO's hypothetical example was "strikingly similar" to a prenatal DNA test patent that was found ineligible in a 2015 Federal Circuit decision, known as Ariosa v. Sequenom, and concluding that decision controls.

That outcome "seems like it's a death knell" for any further attempts by applicants to rely on that specific USPTO example to argue for patent eligibility, and it remains to be seen whether the office will

keep it on the books given the Federal Circuit's view, said Kevin O'Connor of Neal Gerber & Eisenberg LLP.

The decision was actually in line with the views of many observers who have said the "julitis" example may not comport with the Federal Circuit's Ariosa holding, including attorneys who **spoke to Law360** the day after the guidance was issued.

The Cleveland Clinic ruling doesn't suggest the Federal Circuit is rejecting all of the USPTO's guidance, O'Connor said, though it may suggest to patent owners that it's not really worth the effort to make arguments in court that are based on what the office had to say.

"I don't really ever think it's the best argument to put forward in district court that the outcome is dictated in any way by the agency's interpretation," he said, since "the answer could always be, 'We're not bound by it.'"

Other attorneys said the guidance could still be a useful part of arguments in court that a patent should be found eligible.

"I wouldn't shy away from citing to PTO guidance, even if it's not binding on the courts. They can be persuasive," said Thomas Hedemann of Axinn Veltrop & Harkrider LLP. "Of course, they weren't persuasive in this case, but that doesn't mean that other courts in other circumstance won't at least consider what the PTO has said about something."

The decision is really the first time the Federal Circuit has taken a hard look at an eligibility argument in litigation that was based on the USPTO's guidance, so attorneys said it was worth the effort on the part of Cleveland Clinic.

"I thought it was a good try," said Freeman of McCarter & English. "Sometimes the Federal Circuit is inclined to give deference to the USPTO, but obviously not here."

The case is Cleveland Clinic Foundation et al. v. True Health Diagnostics LLC, case number 2018-1218, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Breda Lund and Aaron Pelc.