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

USPTO Patent Guidelines Give Hope To Life Sciences Cos.

By **Ryan Davis**

Law360, New York (May 6, 2016, 9:44 PM ET) -- New U.S. Patent and Trademark Office guidance to examiners on patent eligibility may offer a lifeline to applicants seeking protection for medical diagnostic tests and other life sciences inventions, attorneys say, providing a road map for avoiding ineligibility under the Supreme Court's Mayo and Myriad decisions.

The patent office issued a memo to examiners on Thursday instructing them to give more detailed explanations when they reject applications on subject-matter eligibility grounds. The memo was accompanied by a 31-page list of hypothetical life sciences inventions and explanations of why they are or are not patent-eligible, to which examiners can refer when evaluating applications.

The list is notable because it includes examples of claims referring to detecting diseases and administering treatments that the USPTO deemed to be patent-eligible. In the wake of the U.S. Supreme Court's ruling in Mayo Collaborative Services v. Prometheus Laboratories Inc., declaring a diagnostic test to be ineligible for a patent, and its ruling in Association of Molecular Pathology et al. v. Myriad Genetics Inc., saying the same about human genes, many applications have been rejected under earlier USPTO guidelines for applying those decisions.

But the new examples could start to turn the tide, attorneys say.

“The guidance provides hope for diagnostic companies and their patent claims,” said Maria Laccotripe Zacharakis of McCarter & English LLP. “The diagnostics industry was decimated by earlier guidelines, which were largely informed by Supreme Court case law. … This new guidance means that tests to diagnose illness, or to predict how a patient will respond to a given treatment, are now eligible for patent — a potentially life-saving development for people who suffer from cancer and other dread diseases.”

The guidance “is useful in that it gives you a road map to getting a patent,” but the comfort life sciences companies may take from the examples comes with an important caveat, said Courtenay Brinckerhoff of Foley & Lardner LLP.

The USPTO's statement that some of the hypothetical examples are patent-eligible appears to be inconsistent with recent Federal Circuit decisions invalidating life sciences patents, including one involving Sequenom Inc.'s patent on a prenatal DNA tests.

As a result, the guidance “puts applicants in the tricky position of obtaining claims that the Federal

Circuit might not uphold," Brinckerhoff said.

She suggested that the USPTO may have deliberately written its examples that way in order to advance the discussion about patent-eligibility. Sequenom is appealing the decision on its patent to the Supreme Court, and if the justices take the case, it could be a key opportunity for them to reconsider the law on patent-eligibility for life sciences inventions.

"The patent office did not follow the Federal Circuit's decision, and maybe they were trying to show how perhaps the decision was not correct and lay the groundwork for the solicitor general or the Supreme Court to have an alternative to look at," Brinckerhoff said.

The Mayo decision in 2012 and Myriad in 2013 held that laws of nature and natural products are not patent-eligible under Section 101 of the Patent Act, and numerous patents related to life sciences, particularly diagnostics methods, have been invalidated under those decisions since.

The USPTO included several examples of hypothetical inventions, but one in particular attracted the attention of attorneys who reviewed the document. It describes several claims related to diagnosing and treating a fictional disease called "julitis" that causes chronic skin inflammation. The office described seven related claims and deemed six to be patent-eligible.

The hypothetical applicant in the example has discovered that that the presence of a protein known as "JUL-1" in a person's plasma and skin indicates that they have julitis. The application describes detecting the protein either through a biopsy or by bringing a sample from the patient into contact with an antibody of the protein taken from humans or pigs.

Claim 1 in the example describes obtaining a plasma sample from a patient and detecting whether JUL-1 is present by using an antibody. The USPTO said that claim would be patent-eligible because administering a drug and determining the result is not by itself an ineligible natural law.

However, Claim 2 in the example, which includes the same two steps and adds a third in which the patient is diagnosed with julitis as a result of the test, would not be patent-eligible, the office said. The correlation between the presence of the protein and a diagnosis of julitis is the result of natural process, which cannot be patented, the office said.

The examples include several other related claims that include a step of diagnosing the disease and then treating it in various ways, all which the office said would be patent-eligible because they involve novel methods of detection or treatment.

The guidance indicates that someone who discovers a protein or other biomarker correlated with a disease can obtain a claim on simply detecting the biomarker. However, using the correlation between the biomarker and the disease to make a diagnosis is not patent-eligible unless the claims include additional steps like administering a treatment, the example suggests.

"I think that the example provided here once again opens a path for life sciences and biotech companies to obtain patent protection for these very important inventions, which we have not been able to do after the Mayo and Myriad decisions," Laccotripe Zacharakis said.

Nevertheless, attorneys found the USPTO's reasoning in the example to be confusing and said it might not be persuasive to a court.

The fact that Claim 1 in the example was deemed to be patent-eligible, while Claim 2, which involved diagnosis of the disease, was not, doesn't seem to follow rationally and "raises a lot of questions," said Michelle Holoubek of Sterne Kessler Goldstein & Fox PLLC.

"How can a narrower claim not be eligible but a broader claim can be eligible?" she said.

In addition, Claim 1, on simply detecting the presence of a protein, which the USPTO found to be eligible, appears to be similar to the Sequenom's patent on testing a fetus for diseases using plasma from the mother, which the Federal Circuit said was not patent-eligible, Brinckerhoff said.

Moreover, even if Claim 1 may be eligible under the USPTO's interpretation, it is so broad that it is open to being invalidated on obviousness or anticipation grounds, attorneys say.

For all those reasons, seeking diagnostic patents by following the USPTO's examples could be perilous and applicants would be advised to also include additional claims that are more limited in scope, Brinckerhoff said.

"You need to be careful with this strategy and let the client know the claims may not be upheld," she said. "I wouldn't not get them, but I would not put all my eggs in that basket."

However, given the extreme difficulty in obtaining patents for diagnostic and life sciences patents since Mayo and Myriad, applicants should be encouraged by the USPTO's examples, Laccotripe Zacharakis said.

"If you understand patent law, the distinction between Claim 1 and Claim 2 doesn't really make sense," she said. "But since it's a path to patent-eligibility on these types of claims, I'm happy to take it on behalf of my clients."

--Editing by Mark Lebetkin and Patricia K. Cole.