

USPTO Patent Guidelines Give Hope To Life Sciences Cos.

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Maria Laccotripe Zacharakis, PhD

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 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."

"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.

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."