ARTICLE 09

FINDING A CURE FOR MEDICAL DIAGNOSTIC PATENTABILITY

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Finding a Cure for Medical Diagnostic Patentability

Anyone considering a therapeutic drug regimen for a medical condition wants to know they need that drug. Medical professionals also want to accurately diagnose a disease to ensure the right therapy is prescribed or to know that a patient is responding positively. Symptoms alone may not be specific enough to provide an accurate diagnosis of the underlying disease.

Medical diagnostics companies are developing diagnostic assays that allow medical professionals to accurately diagnose medical conditions and determine a patient's responsiveness to therapy.

But because of a line of United States Supreme Court cases, including *Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Alice Corp. v. CLS Bank International,* courts are invalidating patents directed to diagnostic methods. Exacerbating the problem, the United States Patent and Trademark Office is rarely issuing patents directed to diagnostic methods.

Patenting allows companies to recoup some of the research and development costs associated with identifying biomarkers associated with disease, developing diagnostic assays, obtaining regulatory approval and bringing diagnostic kits to market. These court cases and the USPTO's response to the cases have left enforcement of existing diagnostic patents and patenting of new diagnostics uncertain.

The courts and USPTO are finding diagnostic method claims invalid as being directed to exceptions to patent-eligible subject matter under 35 U.S.C. § 101. Patent-eligible subject matter is defined as "… any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof…." Laws of nature (e.g., diagnostic methods), abstract ideas (e.g., mathematical algorithms), and natural phenomena (e.g., wind) make up a judicially established set of exceptions to the broad categories of patent-eligible subject matter. These judicial exceptions are considered by courts to be the basic tools of scientific and technological work, so their patenting may impede innovation more than it would promote it.

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Patent-eligible? Examining the Impact of *Mayo and Alice*

In *Mayo,* the Supreme Court established a new test to evaluate whether a claim is directed to patent-eligible subject matter. At issue in *Mayo* was whether a claim directed to a method of testing a patient's blood for metabolites of a therapeutic and adjusting the amount administered based on the amount of metabolite to reach a specific range of the metabolite was patent-eligible subject matter. The Supreme Court held the patent invalid as being directed to non-patentable subject matter because the correlation between the naturally produced metabolites and therapeutic efficacy and toxicity was an unpatentable "natural law" and the other steps of the method were well-understood, routine, conventional activity previously engaged in by scientists in the field.

Application of *Alice* to diagnostic method claims occurs when claim terms such as "determining," "calculating," "comparing" and "diagnosing," which are typically used in diagnostic method claims, are considered abstract ideas as mental steps. Although diagnostic patents have survived some challenges at the district courts following *Mayo* and *Alice,* the federal circuit has yet to affirm the eligibility of a single challenged diagnostic claim. The USPTO has taken the *Mayo* analysis as far as the courts, and routinely rejects diagnostic method claims as being directed to non-patentable subject matter.

Where does this leave those developing diagnostic methods and assays?

For now, courts and the USPTO are applying a strict standard to diagnostic method claims. As existing patents with diagnostic method claims expire or are invalidated when challenged, new applications require more detail, novel components and/or reagents, and supporting information and data to counter the well-understood, routine and conventional activity argument.

As with computer software technologies where courts are finding certain claims valid under *Alice,* diagnostic method patents and applications need guidance from the courts as to what types of diagnostic method claims qualify as patent-eligible under § 101 following *Mayo* and *Alice.*

While we wait for positive action by the courts and the USPTO, seeking patent protection for diagnostic method claims should continue. If tolerable, applicants can file multiple narrow claims that have proved successful in the computer arts facing *Alice* scrutiny.

Applications and claims should also contain detailed information describing the types of assays, the steps involved and the types of reagents used. Particularly useful limitations include novel reagents, which arguably would pass the current *Mayo* analysis based on their novelty. Other useful limitations include novel steps and novel uses of prior reagents.

Applicants should also consider adding treatment steps to diagnosing claims. A method of treatment claim format might include a step of receiving identification that a subject has a particular biomarker and a step of treating the subject. This claim format requires actions by a single entity and possibly avoids the divided infringement problem.

Be Practical in Your Pursuit of Patenting

If you are exploring patenting a diagnostic method, it will serve you well to understand the uncertainty surrounding such claims as well as the potential to pursue narrow diagnostic claims.

For more information about medical diagnostic patenting, contact one of the authors.

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