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IP FRONTIERS

High Court rules on diagnostic method patent claims

While patent practitioners anxiously await the U.S. Supreme Court's decision in *Assoc. of Molecular Pathologists v. Myriad*, as to whether or not genes are patentable in the U.S, many practitioners are just beginning to grapple with the court's earlier pronouncement in *Mayo v. Prometheus*, which reduced the scope of coverage for diagnostic method patents by eliminating claims that recite "a natural law" or "phenomenon of nature" rather than an "application" thereof.

By KATHY SMITH DIAS
Daily Record Columnist

In the wake of *Mayo* (also referred to as *Prometheus*), concerns abound that the loss of patent protection for diagnostic patent claims will be a disincentive to test developers, thereby derailing the trend toward personalized medicine. Others view the decision as a positive outcome necessary to prevent patents from tying up the use of laws of nature thereby stifling innovation.

Diagnostic methods are typically based on an observation that a patient having a specified disease or condition has an elevated or abnormally low amount of a particular biomolecule, for example, protein X, compared to healthy individuals; in other words, altered levels of protein X correlate with disease or condition Y. The measurement of human choriogonadotropin (hCG) to diagnose pregnancy is a good example.

A biomarker can be any biological substance, a protein, genetic or metabolic marker, that can be measured as an indicator of disease. Diagnostic tests which rely on the measurement of a biomarker as an indication of a specific disease or condition have been important tools in the diagnostician's arsenal.

Biomarkers can also be used for prognosis and as a means of guiding treatment options, for example, where the ability to determine aggressiveness of a tumor, or responsiveness to a therapeutic agent is linked to a particular genetic expression pattern. Genetic biomarkers provide more specific information regarding the cells of a patient tumor sample and are generally viewed as more useful in determining treatment options for cancer patients than traditional methods such as tissue typing and morphology.

Following a spate of cases adjudicating patent-eligibility of various diagnostic methods, the subject came under Supreme Court scrutiny in *Mayo v. Prometheus*. In *Mayo*, the court found that the relationships between concentrations of certain drug metabolites in the blood following administration of the drug and the likelihood that a drug dosage will be ineffective (too low) or be toxic (too high) is nothing more than a law of nature and therefore, ineligible for patent protection.

More recently, in *Perkin Elmer v. Intema*, the Court of Appeals for the Federal Circuit reiterated the Supreme Court's rationale in *Mayo*, stating that the basis for distinguishing between claims that recite laws of nature, and no more, and claims to specific inventive applications of that natural law, is the existence of an "inventive concept." Finding the claims at issue in Intema to be lacking an "inventive concept" and therefore patent-ineligible, the court distinguished them from patent-eligible claims, stating that claims to specific "applications of patent-ineligible subject matter" do not risk the broad preemption of the basic tools of scientific and technological work.

One of the burning questions is whether the loss of patent protection on diagnostic methods will cause companies that develop these tests to forego research on promising biomarkers. Bringing diagnostic tests from bench to bedside, that is, from the first recognition that a biomarker signifies disease to a validated clinical test, requires a significant commitment of financial resources. At least initially, however, with no clear cut guidance from the courts, the more significant challenge may be determining what "inventive concept" is necessary to push a patent-ineligible diagnostic method claim over the line to patent eligibility.

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