Patent Subject Matter Eligibility of Diagnostic Method Claims

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Diagnostic tests are significant and essential steps in clinical decision making. Among such tests, those using biomarkers have developed greatly along with the success in the field of molecular biology. As such diagnostic tests become a crucial part of the health industry, more patent applications directed to diagnostic methods have been filed.

The U.S. Patent Office and U.S. courts routinely treated diagnostic methods using biomarkers as patent-eligible subject matter until 2012. However, in 2012, the U.S. Supreme Court decided that a method of optimizing therapeutic efficacy for treatment based on the relationship between the metabolite and the efficacy of the drug is patent ineligible. According to the Court's rationale, the relationship between the metabolite and the efficacy of the drug is a law of nature, and thus should be available for all to use without the encumbrance of a patent.

See Mayo Collaborative Services v. Prometheus Laboratories, Inc. 132 S. Ct. 1289 (2012). In reaching its decision, the Court set forth a framework for distinguishing patents that claim judicial exceptions, which are not eligible for patent protection, from those that claim patent-eligible applications of those concepts.

First, the Court determines whether the claims at issue are directed to a patent-ineligible concept, e.g. a law of nature. And then, if the answer is yes, the Court considers the elements of each claim both individually and as an ordered combination to determine whether additional elements transform the nature of the claim into a patent-eligible application. The Court has described the second step of the analysis as a search for an inventive concept, an element that the patent in practice amounts to “significantly more” than a patent upon the ineligible concept itself. In setting forth the above test, the Mayo decision completely turned the tables on patent eligibility of any form of medical diagnostic testing. This is because the inventive concept described in such patent applications lies in the discovery of the relationship between the recited biomarkers with a certain medical condition. Once such an inventive concept is carved out from the claim, the remaining part which relates to conventional technology would not be sufficient to transform the nature of the claim into a patent-eligible application. Therefore, the application of a biomarker in determining a medical condition is not patent eligible under Mayo unless the claims further recite a feature which is not related to a judicial exception, and is sufficient to transform the nature of the claim into a patent-eligible application.
In 2014 the U.S. Patent Office released the Interim Guidance on subject matter eligibility in line with the two-prong test provided in Mayo. However, this guidance lacks illustrative examples for diagnostic method claims that it provides for other types of nature-based claims, such as purified natural materials and nucleic acids. Therefore, clearer guideline as to what may be eligible and what may not be eligible for diagnostic method claims has been requested.

In June 2015, the U.S. Court of Appeals for the Federal Circuit decided the patent eligibility of another type of diagnostic method claim. See Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015). The invention at issue was based on the discovery of the presence of cell-free fetal DNA (“cfDNA”) in maternal plasma or serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste. In particular, the patent at issue claimed methods of using cfDNA comprising the steps of (i) amplifying a paternally inherited nucleic acid from the serum or plasma sample from a pregnant female, and (ii) detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample. In addition, it also claimed methods comprising additional steps of performing a prenatal diagnosis, using such a method for detecting cfDNA. Following Mayo, the Federal Circuit performed the two-prong test. First, the court determined that the existence of cfDNA in maternal blood is a natural phenomenon, which is one of judicial exceptions. Then, the court determined whether the claims contained an inventive concept that is sufficient to transform the claimed naturally occurring phenomenon into a patent eligible application. The court found that the remaining part of the claims such as using methods like PCR to amplify and detect cfDNA was well-understood, routine, and conventional activity at the time of the invention. Therefore, the court concluded that the claims at issue are not patent eligible. In December 2015, the Federal Circuit denied the petition for en banc rehearing, but this case may come before the Supreme Court for another review on the patent eligibility of diagnostic method type claims.

In view of the above, diagnostic method claims based on the correlation of a certain biomarker with a certain medical condition is not likely to be patent eligible at this juncture unless a patent applicant further limits the claims by reciting a feature to take the claim outside the judicial exception.

A possible strategy for claiming such diagnostic methods may be changing diagnostic method claims to therapeutic method claims by additionally reciting a step of administering a drug to a diagnosed patient after diagnosing steps. The Court in Mayo distinguished a typical patent on a new drug or a new way of using an existing drug over a diagnostic method. However, since such therapeutic method claims require an additional step compared with diagnostic method claims, it may be difficult for a patent holder to establish direct infringement and be faced with the additional hurdles of showing indirect infringement.

Another strategy may be claiming diagnostic methods requiring a reagent or a method which is not conventionally known. For instance, a novel antibody, which is specifically designed to bind a claimed biomarker, may be considered significantly more than a judicial exception. In addition, a novel method for detecting and analyzing a claimed biomarker, which is not conventionally known, may add a feature significantly more than a judicial exception to diagnostic method claims. Although such additional features may narrow the scope of protection, if such features greatly increase accuracy or efficiency of diagnostic tests, it may be difficult for a practicing party to find an alternate effective way. In such circumstances, the claims would still have great value.

Moreover, claiming diagnostic methods using a man-made probe (e.g., fluorescent probes) may be a possible strategy as well. This is because such claims require detecting a man-made probe-biomarker complex, which is not naturally occurring.

However, none of the above necessarily provides sufficient protection for a broader scope of diagnostic method invention based on the correlation of a certain biomarker with a certain medical condition. Stakeholders and patent practitioners have voiced questions as to the correctness of the Supreme Court’s analysis in Mayo, and its impact on development and improvement in the area of diagnostic methods. With the Federal Circuit declining to rehear
Ariosa, the boundaries of the Mayo test remain hurdles for protecting diagnostic methods. However, patent protection is still available if the natural correlation can be elevated with an additional man-made improvement. More thoughtful consideration of how to present such inventions for examination at the Patent Office must be given, at least until the issue is addressed again by either a new decision from the Supreme Court or legislative action. And that must be why there are many people paying attention to whether Ariosa may be heard by the Supreme Court. The extended due date for a petition for a writ of certiorari is April 1, 2016.

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Hyunseok Park is an associate in the firm’s Biotechnology/Pharmaceutical Group. Mr. Park focuses his practice on patent prosecution, litigation, and client counseling, primarily in the chemical, pharmaceutical, and biotechnology areas. Prior to joining Sughrue, Mr. Park worked at a law firm in Seoul, Korea where he has been involved in a diverse intellectual property practice, encompassing world-wide patent prosecution, client counseling, post-grant patent challenges and patent litigation. He is a registered Korean Patent Attorney.