

Personalized Medicine Diagnostic Patents

Recent *Prometheus*, *Myriad*, and *Classen* Decisions Clarify Eligibility Requirements

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The U.S. Court of Appeals for the Federal Circuit has recently decided three important cases pertaining to patent-eligible subject matter for personalized medicine diagnostic tools, therapeutic treatments, and DNA sequences. Although still under further requests for appellate review, the decisions in *Prometheus Laboratories v. Mayo Collaborative Services* (“*Prometheus*”), *Associates for Molecular Pathology v. U.S. Patent and Trademark Office, et al.* (“*Myriad*”) and *Classen Immunotherapies v. Biogen Idec* (“*Classen*”) are largely consistent and provide much needed clarity in this area of patent law. These cases follow the U.S. Supreme Court’s 2010 decision on statutory patentable subject matter of method claims in *Bilski v. Kappos* (“*Bilski*”), which validated the use of the machine-or-transformation test as an important guide to patent eligibility in the life sciences.

In essence, it is clear from these cases that diagnostic method claims are patent-eligible to the extent they recite physically transformative steps and do not merely require mental comparisons or thought analyses. Furthermore, “isolated” DNA is also patent-eligible because it is a unique chemical entity that does not exist in nature.

Metabolite Diagnostic Claims in

The method claims at issue in *Prometheus* were directed to optimizing a patient’s dosage level of thiopurine drugs used to treat certain autoimmune diseases. These claims were directed to *administering* thiopurine to a patient who has an immune-mediated gastrointestinal disorder, and *determining* the level of thiopurine in the patient’s body, wherein the amount of thiopurine detected indicated whether the dosage should be increased or decreased. In December 2010, the Federal Circuit held again on remand that these therapeutic optimization claims were patentable subject matter meeting the transformation test, because they included an affirmatively recited administration step, and the resultant biochemical transformations were central to the purpose of the claimed method.

Indeed, the Federal Circuit did not make a patent-eligible distinction between methods of treatment and diagnosis *per se*. With respect to the steps of *administering* a drug to a patient and *determining* the level of the drug in the patient’s body, the Federal Circuit found that these steps were each significant parts of the claimed treatment regime. Thus, a medical treatment that results in a chemical or physical transformation of substances is patent-eligible. Further, a diagnosis that involves transformative purifications and analytical tests to determine the level of metabolites in a sample is also patent-eligible. The Supreme Court granted a *certiorari* review of *Prometheus* in June 2011.

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Genetic Diagnostic and Screening Claims in

In a vindicating July 2011 win for the biotechnology industry, the Federal Circuit in *Myriad* reversed the lower court and held that “isolated” DNA, including genes (e.g., *BRCA*₁ and *BRCA*₂ genes) and sequence-specific nucleic acid probes for detecting breast and ovarian cancer, were patent-eligible subject matter, since these isolated molecules were “markedly different” new chemical entities that did not exist in nature.

Moreover, two types of method claims were at issue in *Myriad*: diagnostic claims directed to *comparing* and *analyzing* DNA sequences for genetic diagnosis, and screening claims for identifying potential anti-cancer therapeutics. The Federal Circuit in *Myriad* again applied the transformative test and unanimously ruled that Myriad’s diagnostic claims of merely *comparing* and *analyzing* two DNA sequences were patent-ineligible, because they were directed to an abstract mental process that did not include any transformative step. A different finding might have resulted if the claims had included patent qualifying steps such as isolating, extracting, sequencing, or otherwise transformative processing of tissue samples.

In contrast, Myriad’s screening claims for potential anti-cancer therapeutics were found to be valid, because they included active transformative steps, such as *growing* and *determining*, that were central to the purpose of the claimed process and involved more than an abstract mental step of looking at and comparing two numbers. This screening claim was found to present functional and palpable applications in the field of biotechnology and to qualify as patentable subject matter.

Diagnostic and Immunization Claims in

Two types of method claims were at issue in *Classen*: claims directed to *immunizing* a mammalian subject on a schedule that presented the lowest risk of chronic immune-mediated disorders, and claims directed to *evaluating* immunization schedules that minimize the risk of an autoimmune disorder. Not so surprisingly, in August 2011, the court in *Classen* held on remand that the method claims reciting the physical step of *immunizing* a mammalian subject were patent-eligible, even though other evaluating parts of the claims may have included a mental step. The majority reasoned that similar to treatment claims, the *immunizing* step was directed to a specific, tangible application, and thus, transformative under *Prometheus*, and the presence of an additional mental step was not fatal. In contrast, method claims for determining an immunization schedule by gathering, reviewing, and comparing known immunization results found in the scientific literature, without a physical immunization step, were merely data gathering directed to an intangible mental process, and thus, were patent-ineligible.

The *Classen* decision at this point is still quite consistent with the *Prometheus* and *Myriad* decisions, providing that, to be patent-eligible under the transformative test, a method claim directed to a diagnostic tool or therapeutic treatment or immunization must include an active physical modification step that is central to the purpose of the claimed method.

Conclusion

Patent law protection excludes that which is naturally occurring, a law of nature, or an abstract mental process. The Federal Circuit decisions in *Prometheus*, *Myriad*, and *Classen* for patenting diagnostic, therapeutic and prophylactic methods balance legal precedent and public policy, essentially finding that claim wording which includes a chemical transformation of material is sufficient to confer patent eligibility. Of course, in addition to qualifying as patentable subject matter, the claims must also be novel and non-obvious, and the application must meet the written description requirements. Importantly, the method

claims should also be written to include steps that can all be performed by a single entity in order to be enforceable against an infringer.

Patent applicants will benefit by ensuring that claims to diagnostic and related personalized medicine methods and tools incorporate active transformational steps, such as extracting, isolating, amplifying, or sequencing, rather than merely making observational comparisons. While appellate review of the cases will follow, these decisions are generally consistent with the expectations of those in the biotechnology industry and support the continued commercial development of useful diagnostic tools and personalized medicine based on patent protection.

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If you have any questions about this article, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

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