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Applying Prometheus To Myriad: Possible Outcomes

Law360, New York (May 21, 2012, 1:23 PM ET) -- On March 26, 2012, the U.S. Supreme Court issued a much anticipated GVR (grant [certiorari], vacate and remand) order in the Association for Molecular Pathology v. the United States Patent Office (a.k.a. ACLU v. Myriad), remanding the case to the Federal Circuit for reevaluation in light of the Supreme Courts' recent decision in Mayo Medical Laboratories v. Prometheus Laboratories 566 U.S. ____ (US 2012). The Prometheus decision has been extensively discussed in the media but its possible impact on the Federal Circuit decision in Myriad has received much less attention.

Both cases deal with the patent-eligibility of certain diagnostic methods under 35 U.S.C. § 101. 35 U.S.C. § 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter … may obtain a patent therefor, subject to the [other conditions for patentability under the Patent Act]." Although this language is broadly cast, judicial exceptions to patent-eligible subject matter pertaining to laws of nature, natural phenomenon and abstract ideas have become very significant in light of Supreme Court decisions and particularly the decision in Prometheus.

The claims in Prometheus were directed to optimizing therapeutic efficacy for treatment of a disorder by administering a specified pro-drug to a subject having the disorder and then determining the level of active form of the drug which arises as a metabolic byproduct in the patient. The claim also included a "wherein" clause specifying a relation between the measured level of active drug and the need to either increase or decrease the dose of the administered pro-drug.

In evaluating the claims under Section 101, the Prometheus court first identified the wherein clause relationship as a law of nature and then asked whether the remainder of the claim adds sufficiently to this law of nature to render the claim patent-eligible. After evaluating all the steps, both individually and in the ordered combination specified by the claim, the court concluded that Section 101 was not satisfied because the claim merely informed a relevant audience (physicians) about the specified law of nature with the additional steps consisting of well-understood, routine, conventional activity already engaged in by the scientific community.

The court based its decision on earlier cases, namely Diamond v. Diehr, 450 U. S. 175, 185 (1981) and Parker v. Flook, 437 U.S. 584 (1978). In Diehr, a claim with a well-known mathematical algorithm was patent-eligible because the claim was directed to a method of curing rubber wherein the algorithm was only one part of the method, while in Flook, the claim was patent-ineligible because the only specified use of the algorithm, to calculate an alarm limit, was not considered inventive without the algorithm.

The Prometheus court also following earlier precedent stated that any additional steps beyond those representing laws of nature, natural phenomenon and abstract ideas must be significant because “post-solution activity that is purely conventional or obvious … cannot transform an unpatentable principle into a patentable process." In short, the Prometheus court conflated the inquiry of patent eligibility with an analysis of the novelty and possibly nonobviousness and applied this to the additional claim features.

Novelty under 35 U.S.C. § 102 and nonobviousness under section 103 were traditionally separate inquires from that of Section 101. In reaching its decision, the Prometheus court clarified that, although the Federal Circuit's preferred "machine-or-transformation" test to evaluate Section 101 patent-eligibility may provide a useful clue to determining patentability, the impact of any transformation should be considered for it's significance to the claim and that the test cannot trump the law of nature exclusion.

In Myriad, the patentee identified the human BRCA1 and BRAC2 breast cancer genes and identified mutations in these genes which dispose individuals to breast cancer. There are two claim types at issue in Myriad: isolated BRCA DNA claims and method claims. The method claims are further subdivided into (1) methods of evaluating BRCA gene sequence for mutations and (2) methods of screening therapeutic cancer drugs. The mutation screening claims, for example, are directed to detecting a germline alteration in a BRCA gene in a human by analyzing the sequence of a BRCA gene from a human sample and determining if any of a number of specified sequence mutations are present.

The Federal Circuit found these method claims limited to noneligible abstract mental processes because they did nothing more than compare or analyze two nucleotide sequences. The court denied Myriad's request to evaluate patent-eligible subject matter after reading processing steps from the specification into the mutation testing claims. In contrast, the court upheld patent-eligibility for the drug screening claims which tested candidate drugs on two cell populations, one of which had been made to express the BRCA gene by insertion of the gene into the cells, and compared the growth rates of the two cell populations following treatment with the drugs.

The Myriad court reasoned that the step of growing the cells in the presence of the drug and the step of measuring the growth rate of the cells were transformative and manipulative steps, respectively, both central to the purpose of the claimed method. The court further explained that the drug screening claims were not essentially claiming a scientific principle and were quite limited in scope — being tied to specific genetically transformed host cells, being limited to growth rate measurement, and involving only certain candidate drugs.

The Myriad court evaluated the isolated BRCA DNA claims for patent-eligible subject matter in view of a long-standing judicial exception to patenting natural products. The court explained that "isolated" DNA, which is obtained from the chromosomal DNA by the breaking of covalent bonds in the DNA to release a gene from the genomic DNA, was different from purified DNA which has the DNA enriched relative to what is contained in the chromosome but where the chromosomal DNA remains intact. The Myriad court held isolated BRCA genes to be non-natural products with “markedly different or distinctive characteristics” following a related test by the Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303 (1980).

The Myriad court rejected the idea that sharing of the nucleotide sequence between isolated BRCA genes chromosomal BRCA genes should control the utility analysis because sequence similarity is a physiological use or benefit irrelevant to patent-eligibility. Finally, the Myriad court was sympathetic to the view that any challenge to the issuance of thousands of DNA patents by the U.S. Patent and Trademark Office over nearly a 30-year period should come from Congress rather than the courts to avoid disrupting "settled expectations."

The order from the Supreme Court in Prometheus remanding Myriad to the Federal Circuit for reconsideration was typical of Supreme Court GVR orders; providing no guidance on how to apply the decision in Prometheus to the facts in Myriad. Some possible outcomes are offered for each claim type.

1) Method of Screening DNA for BRCA Mutations

We believe that the Federal Circuit, on remand, is unlikely to reverse its conclusion of patent-ineligibility for these method claims. The approach in Prometheus to identify in the claims at issue any laws of nature, natural phenomenon and abstract ideas and then to look at the remaining steps for novelty and contribution to an overall invention is likely to result in the same conclusion in Myriad that it's mutation screening claims are essentially limited to noneligible abstract mental processes (sequence comparison).

2) Method of Drug Screening

We believe that the Federal Circuit likely will sustain its prior conclusion of patent-eligibility for these method claims but possibly on altered grounds. The court's earlier emphasis on identifying transformative and manipulative steps in the claim and considering whether they are central to the method is not consonant with the principle in Prometheus to identify in the claims any laws of nature, natural phenomenon and abstract ideas and then to look at the remaining steps for novelty and contribution to an overall invention.

The novelty of drug screening using transformed cells expressing the mutated BRCA genes is unquestionably novel. The court could find patent-eligibility for the drug screening claims solely on the use of a novel composition, BRCA expressing recombinant cells, which would be fully consistent with the Supreme Court's decision in Chakrabarty, which held as patent-eligible, claims to a genetically engineered bacterium capable of breaking down crude oil.

3) Isolated BRCA DNA

The effect of Prometheus on the patent-eligibility of the remanded isolated DNA claims is more difficult to predict. Many have suggested that the Federal Circuit is free to disregard Prometheus with respect to these claims because Prometheus evaluated only method claims. We believe this to be the most likely outcome because it is not readily apparent how to translate the principles in Prometheus to claims encompassing natural products having “markedly different characteristics” or a “distinctive name character [and] use,” as set forth in Chakrabarty. Furthermore, the Federal Circuit is likely to affirm eligibility of the DNA claims so as not to upset "settled expectations" in view of the long-standing practice of granting isolated DNA claims by the USPTO.

However, should the Federal Circuit feel compelled to apply the principle in Prometheus to consider novelty of the nonexempt subject matter, such analysis might have a different outcome. For example, isolated DNA in general is not novel, with many genes being isolated from human DNA more than 20 years ago. Similarly, using the natural products test in Chakrabarty, one can view isolated DNA in general as not having “markedly different characteristics” or a “distinctive name character [and] use” relative to any other isolated DNA.

From each perspective, the only novel elements in the Myriad claims are the nucleotide sequences of the BRCA genes. This logic leads to the BRCA nucleotide sequence as the sole basis for the invention, which sequence is no different from the BRCA nucleotide sequence in the chromosome. Should the Federal Circuit seriously consider such analysis, it may reverse itself and find isolated BRCA DNA to lack patent-eligibility.

In sum, we believe that the most likely outcome is that the Federal Circuit will affirm its prior decision that the isolated BRCA DNA claims are patent-eligible based on its having “markedly different characteristics” from chromosomal DNA and a reluctance to upset settled expectations in the field.

However, we believe that there is a possibility that the Federal Circuit will reverse itself and hold these claims as patent-ineligible. Such a decision would likely rely heavily on Prometheus and characterize the novel aspect of the claims as being limited to the nucleotide sequence, which is a natural phenomenon and existed before its discovery. The requirement that the BRCA gene be isolated would be viewed as merely a routine formulation of a DNA molecule well known in the art. Thus, the Supreme Court's decision in Prometheus increases the invalidity risk for the isolated BRCA DNA claims of Myriad and other patents having similar claims.

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