

Myriad Illuminates High Court's Approach To Section 101

Law360, New York (July 08, 2013, 12:21 PM ET) -- On June 13, 2013, the [U.S. Supreme Court](#) handed down its long-awaited decision in *Association for Molecular Pathology v. Myriad Genetics Inc.*, in which it found claims to isolated DNA not patent eligible under 35 U.S.C. § 101. The Myriad opinion is interesting not only in its own right, but also for how it illuminates the Supreme Court's recent approach to cases involving Section 101, an issue with a long and complex history reflecting a variety of legal tests and approaches.

An examination of Myriad together with the Supreme Court's recent opinions in *Bilski v. Kappos* and *Mayo Collaborative Services v. Prometheus Laboratories Inc.* shows that the court has applied a common analytical framework: first focusing on whether the claim substantially embodies an abstract idea, natural phenomenon or law of nature; and second, if it does, determining whether enough has been added to the claim to confer patent eligibility under Section 101.

As written, Section 101 states that any process, machine, manufacture or composition of matter is patent-eligible. Given the breadth of that statement, the Supreme Court long ago crafted three exceptions to patent eligibility — abstract ideas, natural phenomena and laws of nature — which it found to be basic building blocks that should be freely available to all. The Supreme Court's three recent Section 101 decisions — *Bilski*, *Prometheus* and *Myriad* — each addressed a different one of these exceptions. But each did so using a similar analytical approach.

Myriad — Isolated DNA as a “Natural Phenomenon”

Myriad involved the “natural phenomenon” or “product of nature” exception. The natural phenomenon here was DNA found in human genes. Myriad, the patent owner, argued that claims to DNA isolated from the body but having the identical sequence to DNA found in the body satisfied Section 101, because the isolated DNA was a molecule not found in nature. The Supreme Court rejected that argument, finding the isolated DNA not patent eligible.

In rejecting Myriad's argument, the court first determined that the isolated DNA claims involved a product of nature, because “Myriad did not create or alter any of the genetic information encoded” in the DNA and “[t]he location and order of the nucleotides existed in nature before Myriad found them.”[1] Next, it looked at what Myriad added to this “product of nature.” It found that the act of “separating that gene from its surrounding genetic material is not an act of invention.”[2] Additionally, the claims were not “saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule,” because the claims focused on the genetic information encoded in the gene, not the chemical structure of the composition.[3]

The Supreme Court in *Myriad* distinguished the isolated DNA claims from claims to complementary DNA (cDNA), which it found were patent eligible. cDNA is created in the laboratory and lacks the nonprotein coding portions (introns) found in naturally occurring genes. Because cDNA “is not naturally occurring,” the court found that it “is not a ‘product of nature’ and is patent eligible under § 101.”[4]

Mayo v. Prometheus — “Laws of Nature”

The court’s opinion a year earlier in *Mayo v. Prometheus* involved a “law of nature,” but followed the same basic approach to patent eligibility that the court followed for the “product of nature” exception in *Myriad*. In *Prometheus*, the inventors discovered that certain concentrations of a particular metabolite in a patient’s blood could be used to determine whether the dosage of a drug should be increased or decreased. The claims at issue were method claims that included a step of administering a drug, a step of determining the level of the metabolite in the drug, and then two “wherein” clauses stating that particular concentrations of the metabolite “indicate[] a need to” increase or decrease the amount of the drug administered to the patient.[5]

The court first determined that the claims “set forth laws of nature — namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a [] drug will prove ineffective or cause harm.”[6] Given that a law of nature was implicated, it then described the relevant inquiry as “whether the claims do significantly more than simply describe these natural relations” or, “[t]o put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?”[7] It found that the patent claims did not add enough, because the “additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community.”[8] Thus, the claims did not meet the Section 101 threshold.

Bilski — “Abstract Ideas”

The *Bilski* case — the earliest in this trio of opinions — involved the “abstract idea” exception. *Bilski* involved method claims directed to a method of protecting, or “hedging,” against the risk of price changes. The court found that hedging was an age-old “fundamental economic practice,” that was no more than an “unpatentable abstract idea.”[9] It explained that allowing hedging to be patented would “pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”[10] In reaching this opinion, the court likened the claims at issue to the mathematical algorithms found to be unpatentable in the court’s earlier opinions in *Gottschalk v. Benson* and *Parker v. Flook*. [11]

The court next considered whether the claims added enough to the abstract idea to satisfy Section 101. Although some of the claims included specific examples of hedging in commodities and energy markets, the Court found that those limitations did not add enough to the abstract idea to render the claims patent-eligible. Relying again on its earlier *Flook* decision, the court emphasized that merely adding “field of use” limitations or “token postsolution components” do not add enough to an abstract idea to meet the Section 101 threshold.[12]

Common Themes and Future Questions

The *Myriad*, *Prometheus* and *Bilski* opinions show the Supreme Court’s desire to adhere to a common analytical framework for determining patent eligibility regardless of the type of exception involved (natural phenomena, laws of nature, or abstract ideas) and regardless of the

area of technology or science implicated. This approach involves (1) determining whether the claim falls into one of the Section 101 exceptions (abstract idea, natural phenomenon, law of nature); and (2) if it does, determining whether enough has been added to satisfy Section 101.

Even though they use a common analytical framework, the court's decisions still leave much to be resolved. This is especially true with respect to the question of exactly how much must be added to a natural product, law of nature, or abstract idea in order to confer patent eligibility under Section 101. In *Myriad* (with respect to isolated DNA), *Prometheus*, and *Bilski*, what was added could be characterized as limited. It is clear from these cases that the addition cannot simply be effort (as effort was put forth in isolating the DNA in *Myriad*, coming up with the hedging method in *Bilski*, and identifying the natural law at issue in *Prometheus*). Nor can it be simply routine (using a computer as a calculator, isolating genetic materials) or a field of use limitation (limited to particular commodities markets or to an audience of treating physicians). Beyond that, the Supreme Court has largely left the question open.

As practitioners adapt to these decisions, we will likely see more claims that include elements and limitations beyond those in *Myriad*, *Prometheus*, and *Bilski*, which may be harder to dismiss as insufficient. For example, one could implement an "abstract idea" in a computer system including detailed hardware or software limitations, add further treatment steps to a method of treatment that implements a law of nature, or create a DNA molecule that includes more than simply the sequence of the isolated gene (although perhaps less than in the case of cDNA). It is left to future cases to consider these questions and further refine the boundaries of patent eligibility under Section 101.

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[1] -- S. Ct. --, *Association for Molecular Pathology v. Myriad Genetics Inc.*, at *8 (June 13, 2013).

[2] *Myriad* at *8.

[3] *Myriad* at *9.

[4] *Myriad* at *10.

[5] 132 S. Ct. 1289, 1295 (2012).

[6] 132 S. Ct. at 1296.

[7] 132 S. Ct. at 1297.

[8] 132 S. Ct. at 1298.

[9] 130 S. Ct. 3218, 3231 (2010) (quoting *In re Bilski*, 545 F.3d 943, 1013 (Fed. Cir. 2008)).

[10] 130 S. Ct. at 3231.

[11] 130 S. Ct. at 3231 (discussing *Gottschalk v. Benson*, 409 U.S. 63 (1972) and *Parker v. Flook*, 437 U.S. 584 (1978)).

[12] 130 S. Ct. at 3231.

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