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The authors suggest that a recent court ruling that isolated gene sequences are not patentable subject matter could have implications for nanotechnology, nutraceuticals, and plant breeding.

The Attack on Patentable Subject Matter: *ACLU v. Myriad Genetics* as a Harbinger of Things to Come



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Patents claiming isolated gene sequences have long been issued by the Patent and Trademark Office, meeting statutory subject matter requirements under 35 U.S.C. § 101. The conventional wisdom is that “isolated” gene sequences are considered by examiners and courts alike as having been “touched by the hand of man,” and therefore are not products of nature.

After all, a gene sequence having a certain number of base pairs that is isolated as cDNA by extensive experi-

mental protocols is structurally different from the sequence as present within the chromosome insofar at least as the terminal bases of the isolated gene sequence are not linked to other bases and the isolated gene sequence itself is not subject to the chemical environment of the chromosome within the cell.

However, *ACLU v. Myriad Genetics* (*Association of Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09 Civ. 4515, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010) (79 PTCJ 661, 4/2/10)) attacked isolated genes as being products of nature or natural phenomena because they are not “markedly different” from the naturally occurring gene sequence. While the facts of *Myriad* are limited to genes, the implications, with the support of *Bilski v. Kappos*, 129 S.Ct. 2735, 95 USPQ2d 1001 (U.S. June 28, 2010) (80 PTCJ 285, 7/2/10), could create a domino effect limiting patentable process and product claims in many fields, including nanotechnology, nutraceuticals, and plant breeding.

Section 101 states that patentable subject matter includes “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” The Supreme Court has stated that the only limits on patentable subject matter

are “laws of nature, physical phenomena, and abstract ideas.” *Bilski*, quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193 (1980) (484 PTCJ A-1, 6/19/80).

However, *Myriad* held that particular claims to isolated DNA molecules were “unpatentable products of nature” because they were not “markedly different” from products found in nature. In *Myriad*, Judge Robert W. Sweet of the U.S. District Court for the Southern District of New York began his analysis by harkening back to *Chakrabarty*, in which the Supreme Court held that genetically engineered bacteria constituted patentable subject matter under Section 101.

In *Chakrabarty*, the Supreme Court noted that “the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.” *Chakrabarty*, 447 U.S. at 310. The Supreme Court did not and need not have relied upon the observation that the bacterium possessed “markedly different characteristics” in order to find patentable subject matter. Instead, the Supreme Court found that the genetically altered bacterium was “not nature’s handiwork,” which is all that is required by Section 101 to be patentable subject matter.

‘Markedly Different’ Standard Invoked. But Sweet in *Myriad* seized upon this dictum and required a new element to demonstrate statutory subject matter, namely properties “markedly different” from a product found in nature. Sweet concluded that *Myriad Genetics’* isolated DNA sequences were unpatentable since they were not “markedly different” from products found in nature because the “primary biological function” of DNA is to encode genetic information, and this remains unchanged when genes are isolated.

This line of reasoning is filtering into further court decisions. Judge Timothy B. Dyk of the U.S. Court of Appeals for the Federal Circuit, in the recent decision of *Intervet Inc. v. Merial Ltd.*, No. 2009-1568 (Fed. Cir. Aug. 4, 2010) (80 PTCJ 502, 8/13/10), holds the view, albeit by way of a dissenting opinion, that “it appears that in order for a product of nature to satisfy section 101, it must be qualitatively different from the product occurring in nature, with ‘markedly different characteristics from any found in nature.’” Dyk even goes so far as to refer to the Supreme Court’s “markedly different” dictum as a “test.”

Myriad went further in its assault on patentable subject matter in its discussion of process claims. Judge Sweet applied the “machine-or-transformation” test to invalidate claims directed towards *Myriad Genetics’* prognostic methods of detecting germline mutations in BRCA1 or BRCA2. *Myriad* distinguished diagnostic test claims upheld in *Prometheus Laboratories Inc. v. Mayo Collaborative Services*, 581 F.3d 1336, 92 USPQ2d 1075 (Fed. Cir. 2009) (78 PTCJ 635, 9/25/09), against *Myriad Genetics’* prognostic methods. The *Prometheus* claims were transformative because the act of “determining metabolite levels was itself construed to include the extraction and measurement of metabolite concentrations.” *Association for Molecular Pathology*, slip op. at 140-41. In contrast, *Myriad’s* prognostic methods, in-

cluding “comparing” and “analyzing” gene sequences, were simply “mental steps.” The necessary transformative steps involving isolating a nucleotide or determining its sequence were, at best, only “data-gathering.” *Id* at 145. Thus, the claims failed the machine-or-transformation test and were patent-ineligible abstract ideas.

Following *Myriad*, the machine-or-transformation test was endorsed by the Supreme Court. Although the Court recognized that the machine-or-transformation test was not the only test for patentable subject matter, *Bilski* endorsed the machine-or-transformation test as “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.” The Court further refined the machine-or-transformation test: merely limiting the abstract idea to a particular field or technology does not create a patentable claim. Furthermore, to pass the machine-or-transformation test, the machine or transformation must not be “insignificant post-solution” or “extra-solution” activity.

The PTO has latched onto this endorsement, stating in its “Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*” that “the machine-or-transformation test remains an investigative tool and is a useful starting point for determining whether a claimed invention is a patent-eligible process.” The multi-factor test for patentable subject matter elucidated in the Interim Guidance relies heavily on the machine-or-transformation test. 75 Fed. Reg. 43,922 (80 PTCJ 416, 7/30/10). Thus, process claims that fail the machine-or-transformation test are in danger of being rejected as ineligible subject matter. As foreshadowed in *Myriad*, this is a considerable concern for those trying to patent diagnostic or prognostic testing procedures.

Domino Effect for Other Technologies? *Myriad* highlights the potential impact of constricting patentable subject matter and may create a domino effect across industries. As process and product claims are subjected to heightened standards by both courts and patent examiners alike, more method claims will be labeled “abstract ideas” and more products will be deemed to be “found in nature.”

Three technology areas come to mind: (1) nanotechnology, where patentable subject matter is often based on the nanometer scale nature of devices; (2) nutraceuticals, where patentable subject matter is often based on combinations of natural foods; and (3) plant breeding, where patentable subject matter is often based on introducing one desirable trait into another by cross fertilization.

The outcome of *Classen Immunotherapies Inc. v. Biogen IDEC* (involving process claims directed to the selection of a vaccine regime involving comparing two regimens and identifying the regime less likely to cause chronic autoimmune disorder), vacated and remanded by the Supreme Court in light of *Bilski*, may reveal some of the ramifications of *Myriad* and *Bilski*. No. 08-1509 (U.S., judgment vacated June 29, 2010).

Given that the Federal Circuit already has one judge applying the reasoning of *Myriad*, it is far from certain that the Federal Circuit will reverse the decision in *Myriad*.