



Bio *Bilski*: The SDNY's *ACLU v. Myriad Genetics* Decision

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A month ago, Judge Robert Sweet of the Southern District of New York caused a sensation in the patent world, and made headlines outside it, when he invalidated fifteen claims in seven patents relating to the *BRCA 1* and *BRCA 2* breast cancer genes. These patents, issued between 1995 and 1998, are owned by the University of Utah Research Foundation and Myriad Genetics, a diagnostic company that had participated in the research to isolate and sequence the genes and now sells breast cancer screening tests based on them. The claims at issue fall into two categories, generally covering either [1] “isolated DNA” or DNA sequences (in contrast to naturally occurring DNA), or [2] methods of “analyzing” or “comparing” the DNA sequences to detect mutations associated with an increased risk of breast cancer.

The Southern District invalidated all of the claims on summary judgment, finding them to be non-patentable subject matter under 35 U.S.C. § 101. A theme running throughout the 152-page opinion is that Myriad’s patents are attempts to claim exclusive rights over unpatentable “products of nature.”

I. THE CONTEXT

The *ACLU v. Myriad Genetics* decision¹ is the latest chapter in a litigation campaign against “gene patents” led by the American Civil Liberties Union and the Public Patent Foundation. This particular lawsuit was filed about a year ago, in May 2009, amid broad rhetoric that patents like Myriad’s unfairly allow claims over DNA in the human body (“about 20 percent of our genes are patented”), thwart genetic research, and limit patients’ ability to receive inexpensive genetic tests (“scientific research and genetic testing has been delayed, limited or even shut down due to concerns about gene patents”).²

But rhetoric does not tell the whole story. None of Myriad’s patents claim rights over natural forms of DNA as they exist in the human body; rather, the patents cover DNA sequences that have been isolated or purified via sophisticated biotechnological processes. The PTO has allowed such patent claims for two decades. And, even at the level of public policy rather than legal doctrine, many acknowledge that “gene patents” like Myriad’s promote private investment both in basic genetic research and in commercialization efforts to bring useful products based on that research to market.³

¹ The opinion, officially captioned *Ass’n for Molecular Pathology et al. v. USPTO et al.*, Civil Action No. 09-cv-4515 (SDNY), has not yet been published in a case law reporter. But it is available in original form on the web, including at <<http://www.patentlyo.com/files/myriad-opinion.pdf>> (last visited Apr. 15, 2011). Citations to the decision throughout this paper are to the original opinion (“Op.”).

² The quotes are taken from the Public Patent Foundation’s webpage about the litigation, <<http://www.pubpat.org/brca.htm>> (last visited Apr. 15, 2010).

³ For one such discussion, take a look at the current *Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, prepared by a committee of the National Institute of Health’s Office of Science Policy, pages 20-23 and 26-28 in particular. The draft, approved in February, is available at <http://oba.od.nih.gov/SACGHS/sacghs_home.html> (last visited Apr. 18, 2010).

To many in the patent world, the issue of whether “gene patents” qualify as patentable subject matter seems like a resurrection of the debates from the late 1970s and early 1980s about whether “life” itself, back then in the form of genetically engineered bacteria, can be patented. Judge Giles Rich, then with the Court of Customs and Patent Appeals, probably gave the best answer, seeing no distinction for § 101 purposes between assemblages of chemical molecules considered to be “dead” and those treated as “living”.⁴

Chemical compounds, to take an example, presumed “dead” though very active in various environments, have unquestionably always been regarded as both “manufactures” and “compositions of matter,” yet we have never heard that their possible number is other than infinite. When we examine “living” cells, it appears that they too are chemical compounds assembled in infinite complexity with an added facility for replication. From the standpoint of construing the patent statutes, we do not see, and the PTO has not shown us, *any sound reason* for making the distinction it seeks to make here between the living and the dead. Its arguments are mere lawyers’ techniques to support an a priori conclusion.

The point of this paper, however, is not to dwell on the broader policy and scientific issues implicated by the *Myriad Genetics* decision, which, in any event, would be difficult to resolve to anyone’s satisfaction here. (The Southern District purported not to be deciding the policy debate either.⁵). Instead, we will focus squarely on the court’s § 101 logic, first examining its substance, and then taking a look at the many longer-term questions the court’s analysis raises.

II. THE DECISION’S RELATIONSHIP TO *BILSKI*

The *Myriad Genetics* lawsuit was filed about six months after the Federal Circuit handed down its en banc decision in *Bilski*.⁶ In *Bilski*, the Federal Circuit deliberated over the proper doctrinal test for determining whether a method claim qualifies as patentable subject matter under the “process” prong of § 101.⁷ For this prong (and only this prong), the court settled on the “machine or transformation” test, after canvassing a series of old Supreme Court decisions in which this test could be found.⁸ That heavy reliance on Supreme Court precedent harkens back to the *KSR* obviousness decision, in which the Supreme Court relied on a quartet of its former decisions to reverse the Federal Circuit’s supposedly “rigid” teaching-suggestion-motivation test for obviousness.⁹

Bilski casts a long shadow over the Southern District’s *Myriad Genetics* opinion. The Southern District grouped the 15 patent claims at issue into two categories, [1] composition claims directed to “isolated DNA” or DNA sequences, and [2] method claims generally directed to “analyzing” or “comparing” DNA sequences to find mutations associated with an increased risk of breast cancer. The court’s § 101 analysis, and its application of *Bilski*, differed somewhat for each of the two categories, but in both instances, the Southern District invalidated the patent claims either by applying *Bilski*’s “machine

⁴ *In re Bergy*, 596 F.2d 952, 985 (CCPA 1979).

⁵ Op. at 79.

⁶ *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

⁷ Section 101 sets out four basic categories of patentable subject matter: [1] a “process,” [2] a “machine,” [3] a “manufacture,” and [4] a “composition of matter.” *Bilski*, 545 F.3d at 951.

⁸ *Id.* at 954.

⁹ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

or transformation” test directly (in the case of the method claims) or by borrowing *Bilski*'s overall methodological approach of using vintage Supreme Court cases to fashion a governing standard (in the case of the composition claims).

III. THE METHOD CLAIMS

For the method claims, the Southern District's application of *Bilski* was relatively straightforward. *Bilski* announced the “machine or transformation” standard as the one governing “processes” under § 101, and the Southern District applied the “transformation” part of the test to Myriad's method claims, the “machine” aspect being inapplicable. In particular, the Southern District looked to the Federal Circuit's additional post-*Bilski* discussion in the 2009 *Prometheus Labs* decision as to what counts as a “transformation” in the context of a life sciences method claim.¹⁰

Under *Bilski* and *Prometheus Labs*, a “transformation” does not allow for § 101 patentability if it represents a preparatory “data-gathering step” that is not the “central” focus of the claimed method.¹¹ For Myriad's patents, the bulk of the method claims at issue covered methods of “analyzing” or “comparing” DNA sequences. This analysis is performed on isolated or purified DNA, which clearly requires the DNA to be altered from its naturally occurring form. But the Southern District simply labeled this isolation and purification of DNA a “data-gathering step” that had to occur before the “essence” of the claimed methods – the analysis of sequences – could take place. As such, the claimed methods could not qualify for patentability under §101, according to the court.¹²

It is hard to tease out broader implications from the Southern District's method claims logic. If anything, the court's analysis illustrates the abstract and often unsatisfying nature of the “machine or transformation” standard: A test that turns on a binary decision about whether a change is a “data-gathering step” or not can easily lend itself to conclusory decision-making. If the Supreme Court renounces the “machine or transformation” test in its forthcoming *Bilski* decision, this part of the Southern District's opinion should not stand. Otherwise, it likely is up to the Federal Circuit to assess whether the application of the “transformation” test to Myriad's method claims was proper on the facts and consistent with the *Prometheus* decision, and whether the “transformation” test itself needs further clarification.

IV. THE COMPOSITION CLAIMS

For the “isolated DNA” composition claims, the Southern District struck out in new doctrinal directions. Here, the court did not apply *Bilski*'s “machine or transformation” test, which is limited to § 101 processes only, but it did borrow a page out of *Bilski*'s methodological playbook. The court fashioned a test for the subject-matter patentability of isolated DNA sequences by focusing on a series of old Supreme Court decisions.

¹⁰ Op. at 138-139, citing *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009). *Prometheus* involved claims directed to a method of calibrating the therapeutic dosage of a particular drug involving the steps of administering the drug and monitoring the resulting levels of the drug.

¹¹ *Prometheus*, 581 F.3d at 1343.

¹² Op. at 145-147.

A. “Markedly Different”

According to the Southern District’s new test, to be patentable under § 101, isolated DNA must be “markedly different” from naturally occurring DNA.¹³ The Southern District took the “markedly different” phraseology from the Supreme Court’s landmark *Diamond v. Chakrabarty* decision upholding the patentability of genetically engineered bacteria.¹⁴ But whereas *Bilski*’s “machine or transformation” standard seems to have been actually developed in the Supreme Court cases on which *Bilski* relied, the “markedly different” phraseology appears in only one sentence in *Chakrabarty*, apparently as a quick way of distinguishing the engineered bacteria in *Chakrabarty* from a collection of natural bacteria at issue in an earlier Supreme Court decision, *Funk Brothers*:¹⁵

Here, by contrast [to *Funk Brothers*], the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.¹⁶

The Southern District’s standard, of course, begs the questions of [1] what counts as a “markedly different” feature or characteristic?, and [2] how is this “marked difference” to be determined? The other vintage cases on which the Southern District relied are not illuminating.¹⁷ For instance, one 1930s-era Supreme Court opinion says only that the claim must be to a “new or distinct form, quality or property”¹⁸ – not a particularly helpful or concrete test.

B. “Fundamental Quality”

To further complicate matters, the Southern District added a gloss on its test by focusing the inquiry as to whether “marked differences” exist only on the “fundamental qualities” or “essential characteristics” of the isolated and natural DNA. Unlike “markedly different,” a phrase that is at least used in *Chakrabarty*, the notion of “fundamental qualities” does not appear in any of the cases the Southern District used to craft its § 101 test.

Nonetheless, the court applied the idea of “fundamental qualities” to invalidate *Myriad*’s isolated DNA composition claims in almost syllogistic fashion. Per the court’s analysis, summarized at the outset of the decision, [1] naturally occurring DNA’s “fundamental quality” is to function as “the physical embodiment of biological information”; [2] isolated DNA has this same “fundamental quality”; [3] ergo, naturally occurring DNA and isolated DNA are not “markedly different.”¹⁹ The Southern District’s logic was no more nuanced than that.

¹³ Op. at 107.

¹⁴ 447 U.S. 303 (1980).

¹⁵ *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

¹⁶ *Chakrabarty*, 447 U.S. at 310.

¹⁷ These include *The Wood Paper Patent*, 90 U.S. 566 (1874), *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884), and *General Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928).

¹⁸ *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931).

¹⁹ Op. at 3-4; see also *id.* at 126-27.

V. LONGER-TERM QUESTIONS

At a broader level, the Southern District's § 101 reasoning, particularly with regard to the isolated DNA composition claims raises more questions than it answers, chief among them:

1. Will the “markedly different” formulation survive as the standard for determining the patentability of isolated DNA? Relatedly, will this standard be applied more broadly to biological molecules and chemicals other than DNA, like monoclonal antibodies? The Southern District tried, in a footnote, to suggest that its decision was based on, and limited by, “the unique properties of DNA,”²⁰ but there is little in the court's broad legal analysis that could not be extended to other “compositions of matter” or “manufactures.”

2. What effect will the Supreme Court's forthcoming *Bilski* decision have on the Southern District's opinion?

3. What will happen next, in the Federal Circuit and (maybe) the Supreme Court? An appeal of the decision to the Federal Circuit is virtually guaranteed. And there is little doubt that the Federal Circuit will closely examine the Southern District's “markedly different” standard, as well as the cases that purport to support it. Many patent lawyers predict a reversal.

Whether the case will then proceed to the Supreme Court is much harder to predict. It would not be a surprise were the Court reluctant to grant certiorari on another § 101 patentable subject matter issue so soon after delivering its *Bilski* decision, which should arrive by the end of the Court's 2009 term in June.

²⁰

Op. at 123 n. 51.