WILMERHALE

District Court Invalidates Composition and Method Claims Relating to BRCA1/2 Human Cancer Genes as Unpatentable Subject Matter

2010-03-31

On March 29, 2010, Judge Robert W. Sweet of the United States District Court for the Southern District of New York issued a summary judgment opinion invalidating (i) composition of matter claims directed to the BRCA1 and BRCA2 human genes implicated in breast and ovarian cancer and (ii) methods of detecting mutations in those genes that are linked to incidence of cancer. *See* *Ass'n for Molecular Pathology v. U.S.P.T.O.*, S.D.N.Y. No. 09-CV-4514, Docket No. 255. The central question on summary judgment as stated by the court was: "Are isolated human genes and the comparison of their sequences patentable?" (Slip op. at 2.)

One composition claim that the court considered to be representative was:

> An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

(*Id*. at 80.)

The court held that such composition claims "directed to 'isolated DNA' containing sequences found in nature, are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101." (*Id.* at 4.)

In evaluating the composition claims, the court said, "Supreme Court precedent has established that products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product." (*Id.* at 107.) The court further noted:

> [T]he clear line of Supreme Court precedent and accompanying lower court authorities, stretching from *American Wood-Paper* through to *Chakrabarty*, establishes that purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess "markedly different characteristics" in order to satisfy the requirements of § 101.

(*Id*. at 121.)

In ultimately rejecting the composition claims, the court reasoned, "In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by [Defendant Myriad Genetics] between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA 'markedly different.'" (*Id.* at 125.) The court then concluded, "The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature." (*Id*.)

The court distinguished the composition claims from those in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), which involved claims to a "genetically engineered" and "man-made" bacterial strain. Instead, it analogized to *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), noting, "like the aggregation of bacteria in *Funk Brothers*, the isolation of the BRCA1 and BRCA2 DNA, while requiring technical skill and considerable labor, was simply the application of techniques well-known to those skilled in the art." (*Id*. at 109, 134-35.)

A method claim the court considered representative was:

> A method for detecting a germline alteration in a BRCA1 gene [selected from a referenced list] in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample . . . .

(*Id*. at 83.)

In evaluating the method claims at issue, the court applied the "machine or transformation" test as articulated in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*), *cert. granted*, 129 S. Ct. 2735 (2009), noting that a "transformation must be central to the purpose of the claimed process." (*Id*. at 136.) The court held, "because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter under § 101." (*Id*. at 4.)

Myriad argued that just as the act of "determining" metabolite levels in *Prometheus Labs. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009), was held to be a transformation satisfying the *Bilski* standard, so too should the act of "analyzing" or "comparing" gene sequences satisfy that standard. (*Id.* at 140.) The court, however, rejected Myriad's claims and distinguished *Prometheus* on the ground that determining metabolite levels in that case "was found to be transformative because the act of 'determining metabolite levels' was itself construed to include the extraction and measurement of metabolite concentrations." (*Id*. at 140-41.) "In contrast," the court noted, "the language of the method claims-in-suit and the plain and ordinary meanings of the terms 'analyzing' or 'comparing' establish that the method claims-in-suit are directed only to the abstract mental processes of 'comparing' or 'analyzing' gene sequences." (*Id*. at 141.) The court went on to state, "Even if the challenged method claims were read to include the transformations associated with

isolating and sequencing human DNA, these transformations would constitute no more than 'data-gathering step[s]' that are not 'central to the purpose of the claimed process.'" (*Id*. at 141 (quoting *Bilski*).)

Notably, the court's rejection of the composition claims directly countermands the well-established policy articulated by the United States Patent and Trademark Office with respect to patentability of genes and genetic molecules. (*See id*. at 80 n.25; Utility Examination Guidelines, 66 Fed. Reg. 1,093 (Jan. 5, 2001).)

Myriad has publicly indicated that it intends to appeal the district court's summary judgment decision to the United States Court of Appeals for the Federal Circuit. The case, which is likely to be considered *en banc* – and quite possibly on *certiorari* to the Supreme Court thereafter – could have substantial and far-reaching consequences in the biotechnology and pharmaceutical industries. The immediate implications, and the results of following appellate decisions, will be closely monitored in these industries.

Authors

James B. Lampert

RETIRED PARTNER

james.lampert@comcast.net

+1 617 526 6000

Colleen Superko

RETIRED PARTNER

+1 617 526 6000