Gene Patenting: Federal Circuit Upholds Patents to Isolated DNA

On Friday, the Federal Circuit issued its highly anticipated decision in *Association for Molecular Pathology, et al. v. Myriad Genetics*. The Federal Circuit held that isolated DNA sequences (both genomic DNA and cDNA) are patentable subject matter, while Myriad's claims for "comparing" or "analyzing" DNA sequences to identify mutations in patients' genes only required abstract mental steps and were ineligible for patent protection. The decision rejects the position of the Obama administration, which had filed an amicus brief arguing that isolated genomic DNA should not be patentable, and conforms with the settled expectations of the biotechnology industry and long-standing practice of the Patent Office to issue patents to isolated DNAs.

The case involved Myriad's claims to isolated *BRCA1* and *BRCA2* genes, two genes involved in human breast cancer, and method claims directed to "comparing" or "analyzing" a patient's *BRCA1/2* gene sequences with "normal" *BRCA1/2* gene sequences to identify the presence of mutations known to correlate with an increased risk of breast cancer. The district court found both types of claims unpatentable under 35 U.S.C. § 101. According to the district court, isolated human genes possess the same information as genes in their native state and are not patentable subject matter because they are not "markedly different" from what exists in nature. The district court further found the method claims unpatentable because they claimed only abstract mental steps.

On appeal, the Federal Circuit reversed the district court as to the claims to isolated DNA. Writing for the majority, Judge Lourie held that the relevant question was whether the isolated DNA was "markedly different" or "distinctive" from naturally occurring DNA. Judge Lourie observed that the isolation of DNA required cleaving covalent bonds connecting the isolated DNA to the remaining DNA in the cell. Because these covalent bonds represented "the defining boundary between one molecule and another," their cleavage to obtain isolated DNA resulted in molecules "markedly different – hav[ing] a distinctive chemical identity and nature – from molecules that exist in nature." The fact that the isolated DNA might have the same nucleotide sequence as naturally occurring DNA was irrelevant to the question of patentability: DNA "when it is bonded to other genetic material[] is worlds apart from possessing an isolated DNA molecule that is in hand and usable."

Judge Moore, in a concurring opinion, agreed with Judge Lourie that cDNA – DNA in which the naturally occurring intron sequences had been removed – possessed unique chemical characteristics that rendered it "markedly different" from naturally occurring DNA for purposes of § 101. But Judge Moore departed from the majority opinion in her analysis of isolated genomic DNA, *i.e.*, DNA containing naturally occurring nucleotide sequences. In Judge Moore's view, the chemical changes resulting from isolating DNA – the breaking of covalent bonds – did not, by themselves, establish that the isolated DNA was "markedly different" from its naturally occurring counterpart. Instead, Judge Moore relied on the additional utility provided by isolated genomic DNA compared to naturally occurring DNA. Judge Moore also placed significant emphasis on the biotechnology industry's reliance on the Patent Office's long-standing policy of granting patents to isolated DNA in upholding the patentability of isolated genomic DNA.

Judge Bryson dissented from the majority with respect to isolated genomic DNA. Judge Bryson noted that "the genetic coding sequence that is the subject of each of the BRCA gene claims remains the same whether the gene is in the body or isolated," concluding that "[t]he structural differences between the claimed 'isolated' genes and the corresponding portion of the native genes are irrelevant to the claim limitations, to the functioning of the genes, and to their utility in their isolated form." As a result, Judge Bryson disagreed with the majority as to the patentability of isolated genomic DNA, stating that "extraction of a product in a manner that retains the character and function of the product as found in nature does not result in the creation of a human invention." But Judge Bryson agreed with the majority in one important respect: isolated cDNA, as a laboratory creation, incorporated sufficient human intervention and new utility to be considered patentable subject matter under § 101.

While divided on the question of the patentability of isolated genomic DNA, the panel was unanimous in affirming the lower court's determination that Myriad's method claims directed to "comparing" or "analyzing" DNA sequences covered unpatentable abstract mental processes. In doing so, the court distinguished Myriad's method claims from similar method claims recently held valid in *Prometheus v. Mayo*, a case now before the Supreme Court. In *Prometheus*, the challenged method claims were directed to "determining" levels of a drug metabolite in a patient's blood. The Federal Circuit concluded that "determining" the levels of metabolites in a patient's blood was not a step accomplished by inspection of the samples alone, but instead required transformative steps (such as processing the patient's blood) that satisfied the "machine or transformation test" for subject matter patentability. In contrast, the Federal Circuit concluded that Myriad's method claims encompassed nothing more than the mental process of comparing two DNA sequences – a process which "can be accomplished by mere inspection [of the sequences] alone."

Friday's decision is unlikely to be the last word in a case that presents issues of significant legal and social dimensions. En banc review and/or review by the Surpeme Court are likely. In the meantime, a few things are clear. First, the Federal Circuit, the Obama administration and the Patent Office are all in agreement that claims to isolated cDNAs are patentable. Such claims offer important protection to the biotechnology industry. Second, claims to isolated genomic DNA, although found to be patentable subject matter in *Myriad*, are on somewhat less sure-footing given the position of the Obama administration and Judge Bryson's dissent. Third, diagnostic method claims involving mental steps should explicitly encompass some type of physically transformative step in order to avoid running afoul of § 101. ◆

If you would like more information about this alert, please contact one of the following attorneys or call your regular Patterson contact.

William F. Cavanaugh	**212.336.2793**	**wfcavanaugh@pbwt.com**
Gregory L. Diskant	**212.336.2710**	**gldiskant@pbwt.com**
Jeffrey I.D. Lewis	**212.336.2549**	**jidlewis@pbwt.com**
Irena Royzman	**212.336.2081**	**iroyzman@pbwt.com**
Steven A. Zalesin	**212.336.2110**	**sazalesin@pbwt.com**
Poopak (Paki) Banky	**212.336.2115**	**pbanky@pbwt.com**
Melissa Mandrgoc	**212.336.2379**	**mmandrgoc@pbwt.com**
Herman H. Yue	**212.336.2873**	**hyue@pbwt.com**