ANDRUS SCEALES STARKE & SAWALL

Intellectual Property Newsletter

Summer 2010 Volume 3, Issue 1

Andrus Expands Biotech Practice, Establishes Madison Office

Andrus, Sceales, Starke & Sawall, LLP, has added three experienced biotech attorneys and a new Madison office to better serve its expanding biotech practice.

On March 1st, Rebecca Scarr, Ph.D., joined Andrus' Milwaukee office. Rebecca specializes in patent prosecution and client counseling in the areas of antibodies, protein therapeutics, methods of treatment, medical diagnostics, nucleic acids, and research tools. Prior to moving to the Midwest, Rebecca spent eight years in the Palo Alto office of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP.

Members of the BioTech team, *from left*: Tammy VanHeyningen, Jill Fahrlander, Scott McBride, Rebecca Scarr.

On April 26th, Jill Fahrlander, Ph.D., and Tambryn (Tammy) VanHeyningen, Ph.D., joined Andrus and have established a new Madison office for the firm. Jill brings over 13 years of experience in patent prosecution and client counseling in the areas of engineered proteins, genetically modified organisms, research tools, diagnostics, vaccines, methods of treatment, biofuels, bioremediation, and bioprocess engineering, and joins Andrus from the Madison office of Michael, Best & Friedrich, LLP, where she was a partner. Tammy also joins Andrus from the Madison office of Michael, Best & Friedrich, LLP, where she focused on patent prosecution and client counseling in the areas of vaccines, antibodies, protein therapeutics, medical diagnostics, research tools, genetically engineered organisms, treatment methods, and food science.

EastPark One office building, home to Andrus' new Madison office.

Andrus is thrilled to have Rebecca, Jill, and Tammy join the firm in view of their expertise in the field of biotechnology. The new attorneys join M. Scott McBride, Ph.D., a partner in Andrus' Milwaukee office. With the addition of Rebecca, Jill, and Tammy, Andrus has established a top tier biotech practice. We are very excited about what we can offer our existing and new clients in this area.

Myriad Genetics Appeals the District Court Decision Finding Claims to Isolated DNA to be Unpatentable

By Tambryn K. VanHeyningen

In June, Myriad Genetics and the University of Utah Research Foundation filed a Notice of Appeal in *Association for Molecular Pathology and ACLU v. Myriad Genetics and the University of Utah Research Foundation.* Thus, the recent decision of the U.S. District Court for the Southern District of New York finding claims to isolated DNA sequences coding for human genes unpatentable as non-statutory subject matter will be reviewed by the U.S. Court of Appeals for the Federal Circuit and perhaps ultimately by the U.S. Supreme Court. If the ruling is upheld on appeal, many issued patents covering isolated DNA sequences may be jeopardized.

The claims at issue cover isolated "naturally-occurring" sequences for the BRCA1 and BRCA2 genes and mutations in the sequences. Certain mutations in these sequences correlate with an increased risk for breast or ovarian cancer. The court found that "in light of

(Continued on page 2)

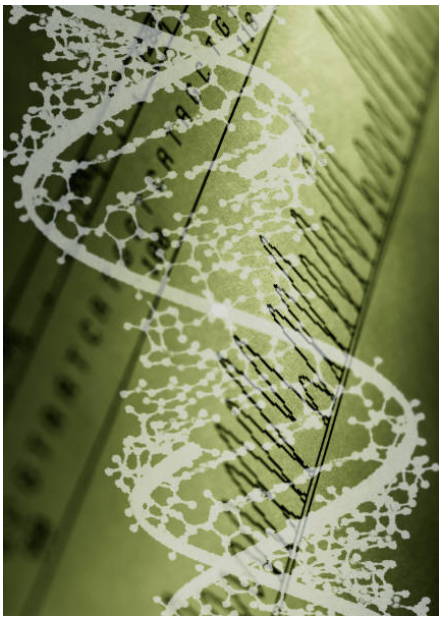
Myriad Genetics Appeals District Court Decision

(Continued from page 1)

DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by [the defendants] between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA 'markedly different.'" Slip opinion at 125. The court found that human genes are not statutory subject matter, but instead are merely the "physical embodiment of genetic information" and thus not patentable based on a line of case law interpreting 35 U.S.C. 101. The ruling conflicts with established U.S. Patent Office practice allowing patenting of isolated DNA sequences, and reliance on this ruling by the Patent Office would result in a much more restrictive treatment of these types of claims than that of other countries.

Additionally, the district court held that diagnostic method claims covering methods of screening cells by comparing DNA sequences isolated from an individual to specific sequences associated with development of cancer are also not patentable as non-statutory subject matter. When reviewing the patentability of these claims the Federal Circuit will need to consider the Supreme Court's recent decision in *In re Bilski*.

Citing *In re Bilski* (Fed Cir 2008) and *Prometheus v. Mayo* (Fed Cir 2009), the district court held that the diagnostic method claims requiring only "analyzing" and/or "comparing" DNA sequences were not valid because they were not tied to a specific machine and did not cause a transformation of matter. The U.S. Supreme Court recently affirmed the *In re Bilski* decision holding that claims directed to abstract ideas are not patentable. However, the Court emphasized that the "machine or transformation test" delineated by the Federal Circuit is not the exclusive test of patentability. In fact, the day after issuing their *In re Bilski* decision, the Supreme Court granted *certiorari* in *Prometheus v. Mayo*, which turns on the question of which types of diagnostic methods claims constitute patentable subject matter. The Supreme Court vacated the judgment of the Federal Circuit and remanded *Prometheus v. Mayo* to the Federal Circuit for reconsideration. The Supreme Court has signaled that the analysis of patentable subject matter does not end with the determination that the claims are not tied to a particular machine or do not cause a transformation of matter. Thus, the Federal Circuit's analysis of Myriad's claims will not be limited to the "machine or transformation test" as the district court's analysis was.



The decision of the district court in *Myriad* is unlikely to affect the validity of issued patents claiming isolated DNA sequences prior to review by the U.S. Court of Appeals for the Federal Circuit. Nonetheless, the case merits monitoring, and we will continue to update you with developments.

Exclusively IP Since 1939

100 East Wisconsin Avenue
Suite 1100
Milwaukee, Wisconsin 53202

ANDRUS SCEALES STARKE & SAWALL

Tel: 414-271-7590
Fax: 414-271-5770
Website: www.andruslaw.com