Federal Circuit Applies *Alice* to Biotechnology in Striking Down Myriad Method of Screening Claims, Leaves Door Open for Narrower Method Claims

On December 17, 2014, a three judge panel of the Federal Circuit issued a ruling that may significantly narrow the scope of patent eligible subject matter with respect to method claims in the biotechnology field. The unanimous decision, authored by Judge Dyk, held that claims to isolated short primers derived from genomic DNA and certain diagnostic method claims utilizing those primers recited patent ineligible subject matter. Following the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics*, which held that Myriad's patent claims directed to the BRCA1 and BRCA2 genes were directed towards natural products and accordingly were not eligible for patent protection, Myriad filed suit on different BRCA1 and BRCA2 patents against Ambry Genetics. In the decision issued by the Federal Circuit yesterday, captioned *University of Utah Research Foundation et al. v. Ambry Genetics Corp*, the appellate court applied the Supreme Court's reasoning in *Myriad* and in *Alice Corp v. CLS Bank Int'l* to hold that claims directed towards primers derived from naturally-occurring DNA and methods of diagnosing an alteration in the BRCA1 gene using those primers are ineligible for patent protection.

The patents at issue involved two separate sets of claims. The first set comprised a number of composition of matter claims directed towards short, synthetic, single-stranded DNA molecules known as primers. Such primers serve as a starting point for DNA synthesis. The primers were derived from genomic DNA. Also at issue was a pair of method claims involving the comparison of a portion of a patient's genome at a particular location (specifically the BRCA1 gene) to the sequence most typically at that location in the human genome (known as the "wild-type" sequence). The method claims were not limited to identifying specific mutations or to diagnosing a predisposition to specific diseases or even specific cancers.

In holding that the composition of matter claims were patent ineligible, the Court relied on the *Myriad* decision, stating that DNA "can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature," and thus cannot be based on naturally-occurring nucleotide sequences. The Court rejected the patentee's argument that the primers were patentable because they were synthetically replicated, as were the cDNAs upheld as patentable in *Myriad*. The Court distinguished the claims at issue from the *Myriad* cDNA claims, noting that the structures of the claimed cDNAs were altered to exclude introns, those portions of naturally occurring DNA that do not code for amino acids. Because isolated DNA is "routinely synthetically created," the Court held that the proper inquiry when assessing patentability is whether the DNA has a structure that can be "found" in nature.

The Court also rejected the patentee's argument that the primers were patentable because single-stranded DNA molecules are not found in the human body as directly contravened by *Myriad*. Quoting the *Myriad* decision, the Court held that separating DNA from its surrounding genetic material "is not an act of invention," and thus not amenable to patentability even if the molecule in question is not found in nature as a single isolated unit. The Court was also not convinced by Myriad's argument that its primers had a different function than natural DNA.

Turning to the method claims, the Court did not decide if they were patent ineligible under the "law of nature" reasoning of the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories*, which also involved diagnostic claims. Instead, the Court held that the claims failed as reciting "abstract ideas." In reaching its decision, the Court applied the two-step analysis used by the Supreme Court in *Alice Corp v. CLS Bank Int'l*. First, the Court held that the comparison of a sequence of a patient's genome to a particular reference sequence was nothing more than "the abstract mental steps necessary to compare two nucleotide

sequences," and thus directed toward patent ineligible subject matter. The Court expressed particular concerns that allowing a patent on a comparison between a gene sequence taken from a human subject and a reference sequence would allow "basic building blocks of scientific research to be monopolized," and that the resulting monopoly could seriously impede future research relating to the BRCA genes.

Next, the Court considered whether the claim elements in addition to the comparison step, either in isolation or in combination with the comparison step, contained a sufficient "inventive concept" to render the claims patent eligible. Here the Court relied on the district court's unchallenged finding that the subsequent elements "set forth well-understood, routine and conventional activity engaged in by scientists at the time of Myriad's patent applications," and that "any scientist engaged in obtaining the sequence of a gene in a patient sample would rely on these techniques." Myriad argued that the method claims at issue were sufficiently similar to a method claim that Judge Bryson had suggested was patentable in a separate opinion in the Federal Circuit's original decision in the *Myriad* case. That claim also involved a method of comparing a patient's BRCA1 gene to a reference sequence, but it limited the application of the method to detecting specific mutations in the patient's genes that are known to predispose the patient to specific forms of cancer. The Supreme Court in its *Myriad* decision had also referred to that claim and Judge Bryson's opinion, but had not ruled on its patent eligibility.

The Court was not convinced by Myriad's argument. Rather, it held that the claims at issue here were "qualitatively different" than those that Judge Bryson and the Supreme Court had addressed. Significantly, the Court did not take up the question of whether the limitation of the claims to detecting specific mutations that predispose a subject to specific cancers was sufficient to establish that the claims were directed to patent eligible subject matter. Furthermore, the Court found that the lack of such limitations in the rejected claims rendered them "significantly broader and more abstract." As such, the Federal Circuit may have read the enablement standards of 35 U.S.C. § 112 into its § 101 analysis. However, the Court may have left the door open for method claims directed towards diagnosing genetic predisposition to specific diseases, provided that those claims are also limited to the detection of particular mutations.

The effects of this decision remain to be seen. Method claims directed towards diagnosis of predisposition to specific diseases may still be viable if sufficiently limited in scope, but the extent of the necessary limitations remain unclear. This ruling also suggests that the "significantly more" analysis outlined in the December 16, 2014 Interim Guidance of the U.S. Patent and Trademark Office may need to be reconsidered to take into account the breadth of the claim at issue.

A copy of the Federal Circuit's *University of Utah Research Foundation v. Ambry Genetics Corporation* decision is available here. To discuss further the potential impact of *Ambry Genetics* or the Court's other decisions related to patent eligible subject matter, please contact your usual Ropes & Gray attorney or one of the Ropes & Gray attorneys listed below.

Dalila Argaez Wendlandt
James F. Haley, Jr.
Douglas Hallward-Driemeier