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## Patent attorneys ponder Myriad ruling

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As the U.S. Court of Appeals for the Federal Circuit considered the *Myriad Genetics* case, patent attorneys like Heather R. Kissling were most interested in how the court would rule on the patent eligibility of isolated DNA.

In March 2010, the U.S. District Court for the Southern District of New York held that BRCA1 and BRCA2 genes, which help predict a woman's risk of breast and ovarian cancer, were not patentable. A similar decision by the Federal Circuit would have forced significant change in the biotechnology industry and the way its companies settle property rights.

"For at least a decade, if not longer, the patent office has been allowing claims directed to isolated deoxyribonucleic acids," said Kissling, a partner at Marshall, Gerstein & Borun LLP. "A decision the other way would have turned those issued patents on their head."

On July 29, the Federal Circuit instead overturned the district court's decision, ruling that the composition of matter claims that cover isolated DNA of the two genes were patent-eligible.

Kissling, who focuses her practice on biotech patent prosecution, works to give her clients as much protection as possible when drafting patent applications. She said taking away the ability to use isolated DNA claims would also take away a level of protection that clients have historically relied upon in patents.

Paul M. Rivard, a shareholder at Banner & Witcoff Ltd., who practices in the firm's Washington, D.C., office, prepares and prosecutes patent applications for clients in the chemical and pharmaceutical industries. Many of his clients became interested in *Myriad Genetics* and how the case would affect existing practices at the U.S. Patent and Trademark Office, he said.

"I think it really is welcome news, because this has been the practice before the patent office for a number of years," Rivard said. "Isolating a DNA segment is arriving at something different than [what] exists in nature."

According to past interpretation of the U.S. Patent Act, inventions are not patent-eligible if they involve laws of nature, physical

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phenomena or abstract ideas.

Rivard pointed out that while *Myriad Genetics* reaffirmed existing practices, its fractured 2-1 decision opened the door for the Federal Circuit or Supreme Court to re-examine the idea of patenting isolated DNA.

"In one sense, it's a complex issue, but it's also indicative of this issue not being completely resolved yet, either through this case or a different case," he said.

Nabeela Rasheed, a patent attorney and partner at McAndrews, Held & Malloy Ltd., prosecutes patents for the firm's biotech and pharmaceutical clients.

Like Rivard, she agreed that the Federal Circuit applied existing case law in *Myriad Genetics*, but also that biotechnology companies and their lawyers need to see how courts decide cases like *Prometheus Laboratories Inc. v. Mayo Collaborative Services*.

In December 2010, the Federal Circuit ruled that methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and nongastrointestinal autoimmune diseases were patent-eligible. The Supreme Court is now considering the case.

"I think as of right now, we need to wait and see what's going to happen with *Prometheus*," Rasheed said. "However, this is an important decision, because we are at an age where personalized medicine is becoming ever important.

"The combination of a diagnosis with a specific tailored therapeutic for that diagnosis is going to become ever more important in personalized medicine. This decision, which went the right way, speaks to the very heart of whether or not those 'theragnostics' are going to be patentable."

While the Federal Circuit ruled that the composition of matter claims in *Myriad Genetics* were patent-eligible, the court also ruled that five of the six method claims in the case were patent-ineligible.

The people who are entrenched in the biotech industry look at the issue of isolated DNA, but the ruling on method claims in the case affects a wider audience, Kissling said.

"People outside the biotech industry might look at what the Federal Circuit says about method claims in view of the *Bilski* decision," she said. "For example, the *Myriad* case had a step of analyzing a sequence and the Federal Circuit held that a claim that has a step of only analyzing does not fall within subject matter eligibility — it's merely a mental process."

In June 2010, the Supreme Court ruled in *Bilski v. Kappos* that processes must be tied to a machine or transform an article into a different state or thing in order to be patent-eligible. The decision regarding method claims in *Myriad* upheld that precedent, Kissling said.

"This is another example of how the Federal Circuit is looking at cases post-*Bilski*," she said. "It doesn't necessarily change my practice, and it doesn't necessarily change the type of inventions that my clients will file on, it just provided additional guidance on how a patent practitioner should craft claims."

From Rasheed's perspective, the *Myriad Genetics* case also turned into a public policy issue since it involves a test for breast cancer as well as just one company that sells the test.

While Rasheed views the issue of one company benefiting from the suffering of the public as important, she argues that it must be considered by Congress and not the courts.

"This court objectively applied the law to determine whether or not an isolated DNA molecule is patent eligible," she said. "If you take away the emotive parts and the public policy parts, yes, it is.

"Now if you lay public policy around it, the question of should it be patent-eligible is a question that Congress has to decide. The Supreme Court has repeatedly said it is not for courts to read into the patent laws."

The case is *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 2010-1406.