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Patents

CAFC Again Rules for Patent Eligibility Of Claims on DNA; Reaction Mostly Positive

A Federal Circuit panel Aug. 16 virtually duplicated its previous reversal of a district court's ruling and found patent claims related to two genes associated with breast cancer to be patent-eligible (*Association for Molecular Pathology v. U.S. Patent and Trademark Office,* Fed. Cir., No. 2010-1406, *reversed in part* 8/16/12).

The U.S. Court of Appeals for the Federal Circuit, reviewing the case again on remand from the Supreme Court after the high court's surprise ruling rejecting method claim patent eligibility in *Mayo Collaborative Services v. Prometheus Laboratories Inc.,* 132 S. Ct. 1289 (2012) (6 LSLR 668, 6/15/12), rejected plaintiffs/appellants' argument that *Mayo* should undermine the patents' eligibility.

As it had in its July 29, 2011, decision, the Federal Circuit 2-1 reversed the ruling of the U.S. District Court for the Southern District of New York that Myriad Genetics' composition claims to ''isolated'' DNA molecules and cDNA related to the BRCA1 and BRCA2 genes cover patent-ineligible products of nature under 35 U.S.C. § 101 because each of the claimed molecules represents a non-naturally occurring composition of matter.

The court also reversed the district court's ruling that Myriad's method claim for screening potential cancer therapeutics through changes in cell growth rates of transformed cells is directed to a patent-ineligible scientific principle. And the court once again affirmed the district court's decision that Myriad's method claims directed to ''comparing'' or ''analyzing'' DNA sequences are patent-ineligible because they include no transformative steps and cover only patent-ineligible abstract, mental steps.

William G. Gaede of McDermott Will & Emery LLP, Menlo Park, Calif., told BNA in a phone interview that, to the extent that the Federal Circuit kept the status quo regarding the patentability of composition claims, the life sciences industry should breathe easier. But he said that the challengers to the patents are likely to file a writ of certiorari to the Supreme Court and that there is a reasonable chance the court will grant it.

Same Judges, Similar Opinions. The case arose from a 2009 declaratory judgment challenge against patents (5,747,282; 5,837,492; 5,693,473; 5,709,999; 5,170,001, 5,753,441; and 6,033,857) for which Myriad is the exclusive licensee (3 LSLR 512, 5/22/09). The American Civil Liberties Union and the Public Patent Foundation filed the lawsuit on behalf of the Association of Molecular Pathology and other medical associations, individuals involved in medical research, breast cancer counselors, and women diagnosed with or seeking diagnosis for cancer. They argued that claims on isolated DNA, cDNA, and methods related to the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer were ineligible for patenting under Section 101.

In its first decision, the Federal Circuit agreed that only one of the method claims—Claim 20 of the '282 patent—and all the claims to cDNA are patent-eligible, but the court was divided as to claims to isolated DNA (5 LSLR 803, 8/12/11).

Lourie Says *Chakrabarty* Set Framework. The three appeals court judges who had been on the original panel reheard the case. Judge Alan D. Lourie again wrote the majority opinion, stating, ''Isolated DNA is not just purified DNA. Purification makes pure what was the same material, but was combined, or contaminated, with other materials. Although isolated DNA is removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body.''

Lourie rejected arguments that the result in *Mayo* should undermine Myriad's composition claims' patent eligibility. ''While *Mayo* and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles, the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers* set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules,'' he wrote, referring to *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), and *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

The court also found that the *Mayo* ruling did not affect its original analysis of the eligibility of cDNA patent claims or the general ineligibility of Myriad's method claims, and it affirmed its ruling that the plaintiffs had standing for the litigation.

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Moore Focuses on Utility. Judge Kimberly A. Moore, in a concurring opinion, agreed with the majority's ruling of patent eligibility, but her focus regarding isolated DNA claims was on their utility rather than their composition.

''As an initial matter,'' she said, ''the *Prometheus* discussion of laws of nature (process claims) clearly ought to apply equally to manifestations of nature (composition claims).'' Nevertheless, she agreed with Lourie that the applicable precedents regarding composition claims remained intact after *Mayo v. Prometheus*.

''*Prometheus* did not . . . overturn *Funk Brothers* or *Chakrabarty*; cases clearly more analogous to the one before us,'' she said. Moore applied ''the framework'' of those two cases ''in conjunction with the direction of *Prometheus*'' to the isolated DNA claims at issue here, and she concluded that they are patent-eligible.

And as she had done in her original opinion, Moore cited the utility of the claimed isolated DNA as a determining factor under Section 101, and she used that utility to distinguish this case from *Mayo v. Prometheus*.

''Unlike *Prometheus*, the claims to short isolated strands of DNA are not directed to the relationship between the mutation and cancer, but rather to a new tool that can be used to determine if that relationship exists,'' she said. ''The short isolated DNA sequences have markedly different properties which are directly responsible for their new and significant utility.''

As to the patent eligibility of the longer DNA strands, the plaintiffs in their remand arguments to the Federal Circuit seemed hopeful that Moore would reconsider the concern from her original opinion that a ruling against patent eligibility for those claims would disturb the ''settled expectations'' of the patent community. Moore remained steadfast in her concern for those expectations. ''I believe we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved,'' she said.

Dissent Draws Support From *Mayo*. William C. Bryson concurred with the majority as to the patentability of the cDNA claims and the method claims and dissented from the holding that Myriad's BRCA gene claims and its claims to gene fragments are patent-eligible.

''In my view, those claims are not directed to patentable subject matter, and the court's decision, if sustained, will likely have broad consequences, such as preempting methods for whole-genome sequencing, even though Myriad's contribution to the field is not remotely consonant with such effects,'' Bryson wrote.

Bryson used the *Mayo* opinion to buttress his view that the isolated DNA claims are ineligible. ''The majority suggests that I have 'focus[ed] not on the differences between isolated and native DNAs, but on one similarity: their informational content,' '' he wrote. ''In light of *Mayo*, that approach seems appropriate.''

He found *Mayo* relevant to the question of whether the isolated DNA claims are effectively drawn to the ''informational content''—the nucleotide sequences—rather than to the DNA's chemical composition. As he had argued previously, he said that the isolated DNA claims should not be patent-eligible because ''[t]he nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes.''

Bryson then pointed to the high court's concern in *Mayo* about ''how much future innovation is foreclosed relative to the contribution of the inventor'' and its warning of the ''danger'' that overly broad patent claims might ''foreclose[] more future invention than the underlying discovery could reasonably justify.''

Policy Arguments Irrelevant. Lourie, however, discounted Bryson's concerns—essentially that the preemption doctrine applied to these claims—and the plaintiff's reliance on policy concerns as overstating the scope of the patent claims and their real-world effects:

> [I]t is important to state what this appeal is not about. It is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion. Nor is it about whether the University of Utah, the owner of the instant patents, or Myriad, the exclusive licensee, has acted improperly in its licensing or enforcement policies with respect to the patents. The question is also not whether is it desirable for one company to hold a patent or license covering a test that may save people's lives, or for other companies to be excluded from the market encompassed by such a patent—that is the basic right provided by a patent, i.e., to exclude others from practicing the patented subject matter. It is also not whether the claims at issue are novel or nonobvious or too broad. Those questions are not before us. It is solely whether the claims to isolated BRCA DNA, to methods for comparing DNA sequences, and to a process for screening potential cancer therapeutics meet the threshold test for patent-eligible subject matter under 35 U.S.C. § 101 in light of various Supreme Court holdings, particularly including *Mayo*. The issue is patent eligibility, not patentability.

Extending the discussion of what this case is not about, Lourie wrote that patents on lifesaving material and processes, involving large amounts of risky investment, would seem to be precisely the types of subject matter that should be subject to the incentives of exclusive rights. ''But disapproving of patents on medical methods and novel biological molecules are policy questions best left to Congress, and other general questions relating to patentability and use of patents are issues not before us,'' Lourie concluded.

Parties' Reactions Are Predictable. Christopher A. Hansen, a staff attorney with the ACLU Speech, Privacy and Technology Project who had argued for the patents' ineligibility before the Supreme Court and the Federal Circuit, said in a statement, ''It is extremely disappointing that despite the Supreme Court's ruling, the appeals court has failed to fully reconsider the facts of this case.''

''This is a devastating decision for a woman's health,'' said Sandra Park, staff attorney with the ACLU Women's Rights Project. ''Patients facing life-changing medical decisions deserve the best quality care and re-

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search available. They should not be blocked from getting that care because a company owns the exclusive right to access their genes.''

Peter Meldrum, president and chief executive officer of Myriad Genetics, said the company was very pleased. ''Importantly, the court agreed with Myriad that isolated DNA is a new chemical matter with important utilities which can only exist as the product of human ingenuity.'' Gregory A. Castanias of Jones Day, Washington, represented Myriad.

The Biotechnology Industry Organization issued a statement that the ruling confirmed long-standing law and that the patents issued under that law ''have long provided critical incentives for expensive and time-consuming research that takes place at U.S. universities and biotech companies every day.''

Method Patent Analysis May Be Most Significant. Gaede told BNA that it was clear on the issue of isolated DNA sequences that *Mayo* did not play a role in the court's analysis and that Lourie did not change his analysis from his previous written opinion.

''While it was a forgone conclusion after *Mayo* that the court would again find that all but one of Myriad's method claims were not patent-eligible, I think the boundaries concerning genetic correlation claims are unclear. We know that Mayo's method claims were not directed to patent-eligible subject matter because they contributed nothing 'inventive' to the law of nature at the heart of the claimed invention and that Myriad's claim 20 of the '282 patent is patent-eligible.'' Claim 20 is directed to the scientific method of finding a cancer treatment that involves growing a host cell that has been genetically modified to include a BRCA1 gene and then testing to see whether any compound particularly inhibits the growth of those cells.

''Between the two of them, there's still a lot of uncertainty about, for instance, multiple genetic correlations,'' Gaede said. ''The issue of the method claims may be more significant for the life sciences industry for the long-term because they pertain to the big movement going forward, which is personalized medicine and diagnostics. It's hard to patent DNA sequences now because of all the prior art—remember that Myriad's patents were filed in the 1980s.''

Rochelle K. Seide of RKS Consulting, Boca Raton, Fla., told BNA Aug. 20 there would have been a significant detrimental effect on the biopharma industry if the court had ruled that isolated DNA molecules were patent-ineligible given how, in the 30 years since *Chakrabarty*, the ability to patent DNA molecules has, directly or indirectly, provided new treatments and diagnostics for a vast number of diseases.

''The court wisely noted that it is the role of Congress to determine whether a whole class of inventions should be deemed patent-ineligible by revising the Patent Act accordingly. However, the last time such an issue was before Congress—concerning the patentability of medical procedures following *Pallin v. Singer*, D. Vt., No. 5:93-202, 5/1/95, 36 U.S.P.Q. 2d 1050 (1995), it declined to do so.''

Seide noted that, regarding Claim 20 of the '282 patent, the fact that the court found the claimed method for screening for potential cancer therapeutics to be patent-eligible may have little value for Myriad. ''The method may be readily practiced outside the United States to identify a potential therapeutic,'' she said. ''Importation of that information into the United States would not be barred, pursuant to the decision in *Bayer AG v. Housey Pharms. Inc.*, 340 F.3d 1367 (2003), which had a similar type of claim.''

Deborah L. Lu of Vedder Price LLP, New York, told BNA Aug. 17 that one thing that stood out was the Federal Circuit clarifying what the appeal was not about and that it was ruling on issues of patent-eligibility, not patentability.

''The court also made it quite clear that any question of policy or health care was not within their purview. Even though I do not think it was necessary for the court to make this statement, I do think it addressed any detractors head on, especially those who proclaimed the decision to be disastrous for health care,'' Lu said. ''By making the comment that they were ruling on issues of patent eligibility and not patentability, I also think that the Federal Circuit is taking a neutral stance with respect to the implications to the life sciences industry.''

BY JOHN T. AQUINO AND TONY DUTRA

The decision is at http://op.bna.com/hl.nsf/r?Open=jaqo-8x8p8a.