Bloomberg BNA

Life Sciences Law & Industry Report™

Patents

Familiar Lines Drawn for Isolated DNA Patent Challenge in Second Appellate Review Briefs

Briefing through June 15 in the U.S. Court of Appeals for the Federal Circuit's second review of the case challenging patenting of isolated DNA provided few surprises (*Association for Molecular Pathology v. U.S. Patent and Trademark Office*, Fed. Cir., No. 2010-1406, *briefs filed* 6/15/12).

The case is on remand from the U.S. Supreme Court for reconsideration in light of the high court's unanimous decision against method claim eligibility in *Mayo v. Prometheus*.

Those who previously favored granting patents on isolated DNA now argued that *Mayo*'s method claim focus has little or nothing to say about Myriad Genetics Inc.'s composition of matter claims. Those previously in opposition claimed that *Mayo* changed the way all patent claims should be assessed under 35 U.S.C. § 101, not just method claims.

The Challenge in *Myriad*. The *Myriad* case arose from a 2009 declaratory judgment challenge against patents for which Myriad is the exclusive licensee (3 LSLR 512, 5/22/09).

The patents (5,747,282; 5,837,492; 5,693,473; 5,709,999; 5,170,001, 5,753,441; and 6,033,857) claim isolated DNA, cDNA, and methods related to the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer.

The ACLU 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 the claims were ineligible for patenting under Section 101.

Three Federal Circuit panel judges agreed that only one of the method claims—Claim 20 of the '282 patent—and all claims to cDNA are patent eligible, but they were divided as to claims to isolated DNA. 653 F.3d 1329 (Fed. Cir. 2011) (5 LSLR 803, 8/12/11).

A week after its surprising unanimous decision rejecting method claim patent eligibility in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 132 S. Ct. 1289 (2012) (6 LSLR 284, 3/23/12), however, the Supreme Court granted the ACLU's petition for writ of certiorari, vacated the Federal Circuit's opinion, and remanded the case for reconsideration (6 LSLR 402, 4/6/12).

Judge Alan D. Lourie had written the Federal Circuit's *Mayo* opinion. He also wrote the majority opinion in *Myriad*.

Federal Circuit Limits Briefing. After *Mayo* was decided, multiple stakeholders commented on the likely impact of that decision on the *Myriad* case.

In general, their comments focused on whether there should be overlap in the assessment of the judicially-created exceptions to patent eligibility—laws of nature, natural phenomena, and abstract ideas—and how they relate to different statutory categories of patent eligibility—machine, manufacture, composition of matter, and processes, which include methods.

In an April 30 order on the *Myriad* remand, the Federal Circuit requested supplemental briefs only from the parties, covering two areas: What is the applicability of the Supreme Court's decision in *Mayo* to Myriad's isolated DNA claims and to method claim 20 of the '282 patent?

The order invited friends of the court to submit briefs on those questions as well (6 LSLR 480, 5/4/12). The court expressly invited the United States to file an amicus brief.

In addition to the parties and the United States, 12 amicus briefs listing 34 distinct stakeholders were filed through the June 15 deadline.

A separate challenge by Myriad attempting to stop the case in its tracks for lack of standing failed (6 LSLR 635, 6/15/12).

Oral arguments are scheduled July 20.

ACLU Cites 'Law/Product of Nature' Exception. "We're grateful for a second chance to make the case that a company cannot claim to invent something as natural as human DNA," Christopher A. Hansen, staff attorney with the ACLU Speech, Privacy and Technology Project, said in a press release just after submitting the challenger's supplemental brief.

The challengers to date have argued that the Myriad isolated DNA claims are not patent eligible in that they attempt to capture a "product of nature," which does not map to the exact wording of any of the three exceptions. The ACLU's current brief took advantage of that ambiguity by referring to a "law/product of nature" exception as a single concept, thus claiming a broad sweep in the *Mayo* ruling.

"*Mayo* reemphasized and gave new vigor to three principles for determining whether a law/product of nature has been 'transformed' into something patentable," according to the brief:

- A claim that preempts an unpatentable law/product of nature is not patent eligible even if a trans-

 ISSN 1935-7257

formation is involved. In the instant case, the ACLU contended, ''It is clear that patents on 'isolated' DNA that claim laws and products of nature impermissibly foreclose future scientific work and innovation.''

■ The court must define the ''inventive concept'' of every claim and if that is an exception to patent eligibility, determine whether the claim ''adds enough'' to impart eligibility. The brief characterized the creation of isolated DNA as involving ''trivial chemical transformations'' that fail this test.

■ Even if industry has relied on patent eligibility of particular claim types, ''the role of the courts is to decide whether claims fall within the law/product of nature doctrine.''

The brief specifically called out Lourie and the concurring opinion of Judge Kimberly A. Moore for overemphasizing the relevance of settled expectations in DNA patent grants by the Patent and Trademark Office. Lourie said in the majority opinion: ''If the law is to be changed, and DNA inventions excluded from the broad scope of § 101 contrary to the settled expectation of the inventing community, the decision must come not from the courts, but from Congress.''

The ACLU reversed that view. ''According to the Supreme Court [in *Mayo*],'' the ACLU brief said, ''the burden on Congress, if it disagrees, is not to broaden the law/product of nature doctrine to prevent patentability of genes, but to narrow it to allow patentability of genes.''

Myriad Relies on Novel, Useful Structure. Myriad's brief, submitted by Gregory A. Castanias of Jones Day, Washington, countered with arguments that *Mayo* should apply to method claims only, that even the general principles of *Mayo* do not change the Federal Circuit's prior analysis, and that public policy favors granting patents even beyond the settled expectations.

''*Mayo* never addressed, and did not alter, the composition-of-matter test previously applied in this case, the 'distinctive name, character and use' test of *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980),'' according to the brief. ''Process (or method) claims fundamentally differ from the other three types of patent-eligible claims.''

Myriad claimed that the *Mayo* court only referenced *Chakrabarty* ''at the highest level of generality.'' The general principle described in *Mayo*, the brief said quoting from the opinion, is ''whether the claims do significantly more than simply describe the[] natural relations'' used in the claims.

To be patent eligible, composition claims require ''a novel and useful *structure*,'' Myriad said, again quoting *Mayo*. The patent owner recited its history in identifying the BRCA1/2 genes and contended that ''Myriad invented a new structure and discovered a new analyte entirely. Moreover, those new structures gain functions not possessed by the native BRCA genes.''

Finally, the brief referenced ''the PTO's longstanding practice'' of granting patents on isolated DNA claims, but more in the context of ''established general legal rules'' than as settled expectations.

''*Mayo* instructs the Court to reject plaintiffs' invitation to depart from these established general legal rules to create a new protective rule that seems to suit the needs of one field (i.e., BRCA testing) but which will surely produce unforeseen results in another (i.e., the rest of the biotechnology world and beyond),'' Myriad concluded.

U.S. Against Isolated DNA Patents. As was true the first time the Federal Circuit queued up this case for review, the United States government submitted a brief against patenting isolated DNA—again apparently without buy-in from the PTO.

The government was given time to present its ideas at oral arguments in 2011. Neal Kumar Katyal, acting solicitor general at the time, proposed a ''magic microscope'' test, denying patent eligibility if one could zero in on a gene and determine if one was looking at the same thing that one could see in the isolated DNA. The test was explicitly rejected by the court, especially in Moore's concurring opinion.

Acting Assistant Attorney General Stuart F. Delery of the Department of Justice's Appellate Staff, Civil Division, did not repeat those words in the brief submitted June 15. However, he maintained the DOJ's prior distinction between patent eligible cDNA and ineligible isolated DNA.

''Patent protection is not available to those who simply discover existing aspects of nature, even if the discovery requires arduous work, represents keen scientific insight, and is of great value to society,'' Delery said. ''*Mayo* underscores this fundamental limitation on patent protection.''

The brief asserted that the three views of the earlier Federal Circuit panel decision all relied on *Chakrabarty*, ''but disagreed about how to apply that standard to DNA isolated from nature.'' Addressing the majority and concurrence's focus on the ''markedly different chemical characteristics'' of isolated DNA, the DOJ said, ''those characteristics are simply a consequence of separating DNA from its native environment.''

''In light of *Mayo*, this Court . . . should also ask whether the [chemical] differences . . . are sufficient to leave the public free to study and exploit the native BRCA1 and BRCA2 genes. The answer to that question is no.''

Briefs Against DNA Patenting. Amici in favor of the patent challengers—all of whom filed briefs the first time around—were as follows:

■ AARP, Canavan Foundation, Claire Altman Heine Foundation, Facing Our Risk of Cancer Empowered, March of Dimes Foundation, National Association for Pseudoxanthoma Elasticum, Ovarian Cancer National Alliance, filed by John L. Hendricks of Hitchcock Evert, Dallas;

■ the American Medical Association, American Society of Human Genetics, American College of Obstetricians and Gynecologists, American Osteopathic Association, American College of Legal Medicine, American College of Embryology, and the Medical Society of the State of New York, by Lori B. Andrews of the IIT Chicago-Kent College of Law, Chicago;

■ Eileen M. Kane of the Penn State Dickinson School of Law, University Park, Pa.;

■ Knowledge Ecology International and Universities Allied for Essential Medicines, by Krista L. Cox of KEI; and

■ National Women's Health Network, Reproductive Health Technologies Project, Forward Together, the Center for Genetics and Society, the Pro-Choice Alliance for Responsible Research, Alliance for Human

   ISSN 1935-7257

Biotechnology, G. Michael Roybal, and Anne L. Peters, by Debra L. Greenfield, professor at the UCLA Institute for Society & Genetics, Los Angeles.

Briefs in Favor of DNA Patenting. Only a brief filed by the Intellectual Property Owners Association explicitly favored Myriad's position. The brief, by Paul H. Berghoff of McDonnell Boehnen Hulbert & Berghoff, Chicago, relied extensively on *Chakrabarty* and argued that Mayo did not overrule *Chakrabarty*.

However, those briefs claiming to support neither party all supported Section 101 patent eligibility for isolated DNA claims:

- the American Intellectual Property Law Association brief, by Robert D. Litowitz of Finnegan, Henderson, Farabow, Garrett & Dunner, Washington;
- a brief on behalf of Gilead Sciences Inc., Confluence Life Sciences Inc., and Euclises Pharmaceuticals Inc., by J. Timothy Keane of Harness, Dickey & Pierce, St. Louis;
- a brief filed by Christopher M. Holman, professor of law at the University of Missouri-Kansas City;
- the brief of Eli Lilly and Co., submitted by Robert A. Armitage, general counsel;
- the New York Intellectual Law Property Association's brief, by Ronald M. Daignault of Robins, Kaplan, Miller & Ciresi, New York; and
- a brief for Protein Sciences Corp., filed by Thomas J. Kowalski of Vedder Price, Chicago.

But What Exactly Is Claimed? Holman took the parties and courts to task for failing to reach agreement as yet on exactly what the claims cover and how they can be enforced.

''There has been no specific allegation that any particularly technology infringes any of the challenged claims, and in fact my research indicates that no US court has ever addressed the question of whether an isolated DNA claim would be infringed by any form of DNA sequencing or diagnostic testing,'' Holman said. ''As a consequence, the claims have yet to be adequately construed, and their purported preemptive effect remains entirely speculative.''

Holman provided an extensive lesson on the activities involved in creating isolated DNA molecules. Based on his description of the end product, he concluded that some participants in the case have been arguing about ''unfounded assumptions regarding the utility of isolated genomic DNA'' and ''unfounded assumptions as to the impact of isolated DNA patents on genetic testing and whole genome sequencing.''

''Properly construed, the challenged claims are limited to synthetic DNA molecules that are structurally and functionally distinguishable from their native counterparts,'' he said.

Method Claim Still at Issue? The method claim at issue was clearly of secondary interest to the parties. The ACLU devoted just a bit over a page—out of 20—to the topic, and Myriad's primary argument was that the Federal Circuit should not even consider it, since it was not implicated in ACLU's cert petition.

The United States' brief took no position on the issue.

Some of the amicus briefs, on the other hand, focused on the method claim, seizing the opportunity to provide more guidance in light of the Supreme Court's lack of specificity in the *Mayo* opinion as to the terms ''inventive concept'' and ''adding enough.''

Protein Sciences, in a separate motion to participate in oral arguments, asked for time to present, among other arguments, its ''novel concept that DNA has a 'chemical-information duality,' '' such that patent eligibility of a process claim depends on whether the claim involves the chemical or information aspect. The ACLU opposed the motion, however, saying that Protein's position is neither novel nor neutral.

The Eli Lilly brief argued for a bright line rule, to ''reject patent eligibility whenever one or more 'mental steps' are set out in a multi-step process claim.'' According to Lilly, Section 112(f) unequivocally requires that each step in a process claim relate to an ''act,'' which would allow exclusion under Section 101 if any step, after construction, ''includes embodiments that can be carried out mentally.'' Lilly thus defined a ''poison step'' rule.

That rule likely would mean that the claim at issue in the instant case is not patent eligible, Lilly said, though it asked the court to construe the claim first.

BY TONY DUTRA

The ACLU brief is available at http://pub.bna.com/ptcj/101406ACLUJun15.pdf.

The Myriad brief is at http://pub.bna.com/ptcj/101406MyriadJun15.pdf.

The United States brief is at http://pub.bna.com/ptcj/101406AmicusUSJun15.pdf.