July 6, 2012

Federal Circuit to Consider Bounds of Patent Eligible Subject Matter in Light of *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*

On June 15, the parties and several *amicus curiae* filed briefs with the Court of Appeals for the Federal Circuit in *Ass'n for Molecular Pathology* v. *U.S. Patent and Trademark Office.* The case is the first time that the Federal Circuit will apply the Supreme Court's recently decision in *Mayo Collaborative Services* v. *Prometheus Laboratories. Inc*. and may thus shed light on how courts will handle future patent claims that implicate natural laws or products, particularly those in healthcare-related fields.

Ass'n for Molecular Pathology concerns whether patent claims covering isolated DNA and a method to screen cancer therapeutics through changes in cell growth rates are directed to patent eligible subject matter. Although the Federal Circuit initially found these patents to be valid, the Supreme Court vacated the decision in March and remanded the case for further consideration in light of its decision in *Mayo*. As reported in our previous release, in *Mayo,* the Supreme Court reversed a Federal Circuit decision which had held that patents claiming multi-step processes for determining the right dosage of a drug were directed to patent eligible subject matter. The Supreme Court concluded that the claimed processes did not contain sufficient additional features such that "the patent in practice amount[ed] to significantly more than a patent upon the natural law itself."[1]

Background. 35 U.S.C. § 101 provides that an individual may obtain a patent on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, subject to the conditions and requirements of this title." The Supreme Court has long held that "laws of nature, physical phenomena, and abstract ideas" are not patent eligible. The difference between a mere law of nature and patent eligible subject matter, however, is not always clear-cut.

The patents at issue in *Ass'n for Molecular Pathology* concern two genes: BRCA1 and BRCA2. Mutations in these genes correlate with a predisposition to breast and ovarian cancers. The United States Patent and Trademark Office (PTO) issued patents to Myriad Genetics and the University of Utah Research Foundation ("defendants") for (1) isolated DNA containing all or portions of the BRCA1 and BRCA2 gene sequence, (2) methods for "comparing" or "analyzing" BRCA1 and BRCA2 gene sequences to identify the presence of mutations that correlate with a predisposition to breast or ovarian cancer, and (3) a method for screening potential cancer therapeutics via changes in cell growth rates. The Association for Molecular Pathology and others ("plaintiffs") brought suit seeking, among other things, a declaration that these claims were not drawn to patent eligible subject matter.

[1] For additional information on *Mayo*, see our client alert dated March 21.

Prior Proceedings. *S.D.N.Y.* The United States District Court for the Southern District of New York granted summary judgment for the plaintiffs on the patent-related causes of action.[2] The court concluded that the defendants' isolated DNA claims were invalid because they concerned a "product of nature" that is not "markedly different" from native DNA, *i.e.* DNA in the human body. The court also found that the defendants' methods claims were invalid because they did not include sufficiently "transformative" acts under the "machine or transformation" test of patent eligible subject matter.

Federal Circuit. In July 2011, the Court of Appeals for the Federal Circuit reversed with respect to the isolated DNA claims and the method claim for screening potential cancer therapeutics via changes in cell growth rates.[3] Writing for the majority, Judge Lourie reasoned that isolated DNA has a markedly different chemical structure than native DNA and is therefore patent eligible subject matter. The majority also found that the method for screening potential cancer therapeutics was patent eligible subject matter because it included "transformative steps" under the "machine or transformation" test, namely growing host cells in the presence or absence of a potential cancer therapeutic and determining the cells' growth rates. Judge Bryson concurred in part and dissented in part, concluding that BRCA genes and gene fragments, as compared to cDNA (a different type of isolated DNA), are not patent eligible subject matter. He reasoned that BRCA genes only accumulate incidental changes when extracted and therefore are not "materially different" from native genes. Plaintiffs appealed.

Supreme Court. The Supreme Court vacated the decision and remanded the case for further consideration in light of its *Mayo* decision. The Federal Circuit requested supplemental briefing from the parties – and invited *amicus* briefing – on the applicability of *Mayo* to the two patent claims that that it found to be directed to patent eligible subject matter: the isolated DNA claims and the method claim for screening potential cancer therapeutics via changes in cell growth rates.

Merits Briefs. Plaintiffs argue that isolated DNA molecules are not sufficiently different from native DNA to be patent eligible. They contend that, under *Mayo*, the isolation of DNA is simply a "routine, conventional preparatory step" that discloses a natural law: the claimed correlation between disease and genetic mutations in BRCA gene. They further maintain that the *Mayo* Court minimized the importance of deferring to the PTO, and that it instead took into account the negative effect of the patents at issue on innovation and the quality of medical care. Plaintiffs argue that Prometheus's isolated DNA patents similarly inhibit research on the BRCA genes, including the development of new and more effective treatment methods. With regard to the method claim, plaintiffs contend that it is functionally identical to the method claim in *Mayo*, in that it merely sets forth a law of nature – the effect of a drug – and related "well-understood, routine, conventional activity."

Defendants argue that *Mayo* should have no effect on the Federal Circuit's prior decision. They contend that *Mayo* is inapplicable to the isolated DNA claims because *Mayo* only addressed methods claims. Defendants also argue that even if *Mayo* applied to the isolated DNA claims, the Federal Circuit's decision was correct, because isolated DNA molecules have

---

[2] In a separate portion of the opinion, the district court also dismissed plaintiff's constitutional claims.

[3] In a separate portion of the opinion, the Federal Circuit also ruled that only the competitor who intended to resume clinical diagnostic testing of the DNA sequences in question had standing to sue.

a "distinctive name, character, and use," and are sufficiently different from what is found in nature to be patent eligible. Further, defendants urge deference to the PTO's long-held view that DNA is patent eligible subject matter. With regard to the method claim, defendants contend that while it was not in the original petition for *certiorari*, on the merits, the claim involves significantly more than a "well-understood, routine, conventional activity" because it starts with a product of human ingenuity: a transformed cell containing an altered BRCA1 gene.

Amicus Curiae. Stakeholders filed nine *amicus curiae* briefs with the court. Several medical, health, and social justice organizations filed briefs in support of the plaintiffs. They argue that the patent claims at issue (a) do not pertain to subject matter that is markedly different from laws or products of nature that exist apart from the isolation and replication process, and (b) preempt the use of patents in the field of genetic testing and identification and are already impeding innovation and improvements in the quality and availability of medical treatment for breast and ovarian cancers, a major factor in the *Mayo* Court's decision.

The New York Intellectual Property Law Association (NYIPLA) and the Protein Sciences Corporation each filed briefs in support of neither party. Protein Sciences argues that (a) *Mayo* is not relevant to the patent eligibility of isolated DNA (which is patent eligible subject matter because it is sufficiently different from native DNA), and (b) the method claim is directed to patent eligible subject matter because it utilizes cells that are not naturally occurring. The NYIPLA similarly argues that (a) *Mayo* did not alter existing law on this issue, (b) isolated DNA is patent eligible because it is a product of human invention, regardless of its resemblance to native DNA, (c) the method claim is likely patent eligible because it includes the use of transformed cells, and (d) the patent-eligibility of both claims is consistent with longstanding practices of the PTO, and it would be unwise to upset these expectations.

Among the other *amici* was a brief filed by a Eli Lilly and Company that argues for a bright line rule that rejects patent eligibility whenever one or more "mental steps" are set out in a multi-step process claim, and a brief filed by law professor Christopher M. Holman of the University of Missouri-Kansas City that discusses why isolated DNA is different than native DNA based on its chemical and physical structure and how concerns about the patents preempting other work in gene sequencing are overblown.

Conclusion. Oral argument in the case is scheduled for July 20. Given the uncertainty in this area of patent law, and the variety of stakeholders who have indicated interest in the outcome of the case, the Federal Circuit's decision in *Ass'n for Molecular Pathology* could have a significant impact on patent claims in healthcare-related industries.

* * * *

This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

David J. Ball Jr.
202-223-7352
dball@paulweiss.com

Craig Benson
202-223-7343
cbenson@paulweiss.com

Kenneth A. Gallo
202-223-7356
kgallo@paulweiss.com

Nicholas P. Groombridge
212-373-3212
ngroombridge@paulweiss.com

John E. Nathan
212-373-3156
jnathan@paulweiss.com

Catherine Nyarady
212-373-3532
cnyarady@paulweiss.com

Eric Alan Stone
212-373-3326
estone@paulweiss.com

Summer Associate Jason Anton contributed to this client alert.

About our practice.

Patent

The Paul, Weiss Patent Litigation Group offers the skills of a boutique patent litigation firm in the context of one of the finest litigation departments in the world. In the courtroom, we are adept in the delicate task of presenting sophisticated technical and scientific material in plain language to facilitate informed judgment by judge, jury, or arbiter. We also pride ourselves on the strategic insight we provide our clients — and we can help clients protect their most important assets, especially in regards to high-stakes litigations and enterprise-threatening suits.

Our lawyers possess degrees in many disciplines, including computer science, biophysical studies, chemistry, and electrical and mechanical engineering.

We have litigated patent cases and disputes before juries and judges in U.S. District Courts across the country, as well as in bench trials, Federal Circuit appeals, International Trade Commission proceedings and U.S. Patent and Trademark Office interferences.

Healthcare

The Paul, Weiss Healthcare Litigation Group offers a deep understanding of the relevant healthcare issues of the day, and combines it with the power of one of the finest litigation departments in the world. Our ability to cut through complexity and anticipate issues before they arise in negotiation is a true differentiator for our firm.

We represent some of the largest companies in the pharmaceutical and medical device industries, handling some of their most complicated and critical matters. Our work includes trials and complex mediations, civil and criminal cases, government fraud investigations, antitrust enforcement actions both domestically and internationally, mass tort class actions and grand juries. We appear in federal and state courts around the country, at the DOJ, SEC and FTC, before Congress and in state Attorney General offices across the United States.

NEW YORK
1285 Avenue of the Americas
New York, NY 10019-6064
+1-212-373-3000

BEIJING
Unit 3601, Fortune Plaza Office
Tower A
No. 7 Dong Sanhuan Zhonglu
Chao Yang District, Beijing 100020
People's Republic of China
+86-10-5828-6300

HONG KONG
12th Fl., Hong Kong Club Building
3A Chater Road
Central Hong Kong
+852-2846-0300

LONDON
Alder Castle, 10 Noble Street
London EC2V 7JU
United Kingdom
+44-20-7367-1600

TOKYO
Fukoku Seimei Building, 2nd Floor
2-2, Uchisaiwaicho 2-chome
Chiyoda-ku, Tokyo 100-0011
Japan
+81-3-3597-8101

TORONTO
Toronto-Dominion Centre
77 King Street West, Suite 3100
P.O. Box 226
Toronto, ON M5K 1J3
Canada
+1-416-504-0520

WASHINGTON, D.C.
2001 K Street NW
Washington, DC 20006-1047
+1-202-223-7300

WILMINGTON
500 Delaware Avenue, Suite 200
Post Office Box 32
Wilmington, DE 19899-0032
+1-302-655-4410