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Supreme Court Hears Oral Argument in Case Concerning Patent Eligible Subject Matter

The Supreme Court heard oral arguments yesterday in a patent case involving diagnostic testing, *Mayo Collaborative Services v. Prometheus Laboratories*. This case marks the second pharmaceutical patent related case the Court heard this week, *Caraco v. Novo Nordisk* having been argued on Monday.

The background. This case is another installment in a series of recent cases attempting to define what exactly is patent eligible subject matter under 35 U.S.C. § 101. That statute states 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, natural phenomena, and abstract ideas” are not patent eligible. But practical applications of those subjects can be patented. Federal courts, including the Supreme Court, have recently attempted to clarify just where to draw that line.

The patents at issue in the case, exclusively licensed to pharmaceutical and diagnostic manufacturer Prometheus, relate to multi-step processes for improving the treatment of autoimmune disorders (like Crohn’s disease) using a drug consisting of synthetic thiopurine compounds. Research revealed a correlation between a safe and effective dosage of the drug and the level of certain metabolites in the bloodstream of a patient after such a drug had been administered. The patents at issue therefore claim a method of (1) administering the drug, and then (2) determining the level of metabolites in the bloodstream, where (3) that determination will indicate that the amount of the drug will either need to be increased or decreased for safe and effective usage.

Proceedings below. Mayo had purchased Prometheus’s PROPredictRx metabolite tests for five years before deciding to use and sell a test of its own. Prometheus then sued Mayo, claiming Mayo’s test infringed its patents. In response, Mayo argued that Prometheus’s patents were invalid because they claimed subject matter that was not patent eligible. The district court agreed and entered summary judgment in favor of Mayo. The court found that the patents improperly claimed natural phenomena—the correlations between the administered drugs and the metabolites in the bloodstream. The “administering” and “determining” steps were, in the court’s view, merely data-gathering steps which could not convert an otherwise “unpatentable principle” into a “patentable process.” It held that the patents were invalid.

The United States Court of Appeals for the Federal Circuit reversed, applying that court’s then-definitive “machine-or-transformation” test for patent eligible subject matter. Under that test, a claimed process is patent eligible if it (1) is tied to a particular machine, or (2) transforms a particular object. But while *certiorari* was pending, the Supreme Court handed down another § 101 case, *Bilski v. Kappos*, which explained that although the “machine-or-

transformation” test was “useful,” it was not the sole test for determining patent eligibility. The Court thereafter granted *certiorari* in the *Prometheus* case, vacated the Federal Circuit’s decision, and remanded for further consideration, in view of *Bilski*.

On remand, the Federal Circuit again concluded that Prometheus’s claims were patent eligible. First, the court held that the claims did not wholly preempt natural phenomena, reasoning that although the correlations between the metabolite levels and the drug’s efficacy were a matter of natural principles, the patents claimed a particular method of applying those correlations. Second, the court returned to the machine-or-transformation test. It concluded that the treatment-specific steps of administering the drug and then determining the level of metabolites in the blood caused actual transformations within the body, thus passing the machine-or-transformation test.

Mayo again appealed to the Supreme Court.

Merits briefs. The overarching theme of Mayo’s brief is that Prometheus’s patents fail to claim a real-world application of natural phenomena and are therefore invalid. Mayo argues that the claims are not brought back within the field of patentable subject matter by adding the “administering” and “determining” steps, which it characterizes as mere data-gathering. Mayo further argues that these steps were well-known in the field, lacking the novelty it contends is necessary for patent eligibility. Ultimately, Mayo views the claims as covering a mental observation that preempts natural phenomena.

Mayo also raises several policy-based arguments. It argues that patents like the ones at issue here harm competition and research in the medical field and that patent protection is unnecessary for diagnostic medical research, where costs are low and scientists are intrinsically motivated to reach results. It also argues that treatment-specific patents like the ones at issue here interfere with a doctor’s ability to treat patients.

Prometheus, on the other hand, contends that the Federal Circuit got the analysis right. Prometheus frames the inquiry as two-pronged, and argues that it satisfies both: subject matter is patent eligible if it (1) claims not an abstract principle, but a concrete application of a principle, and (2) does not effectively preempt basic scientific knowledge. Prometheus’s claimed process here passes both tests, it argues, because its claims describe a process of applying natural phenomena and are sufficiently narrow as to not preempt an entire field of science.

Prometheus disagrees also with Mayo’s argument that novelty and non-obviousness are appropriate considerations in considering patent eligible subject matter. Prometheus argues that these requirements stem from separate statutory provisions (35 U.S.C. §§ 102 and 103), and must therefore be analyzed separately. Finally, Prometheus argues that a ruling in Mayo’s favor would hinder medical research and development.

Amicus curiae. Interested parties weighed in on all sides – including some who sided with *neither* of the named parties.

Those supporting Mayo included such diverse groups as the Cato Institute, the ACLU, AARP, and the American College of Medical Genetics. Parties filing briefs in support of Prometheus

included Myriad Genetics (who is also involved in a § 101 case), SAP, and the Pharmaceutical Research and Manufacturers of America.

The United States weighed in but supported neither party, concluding that the claims here are patent-eligible – but not likely patent-worthy. The government views the patents as (1) within the bounds of § 101 patent eligibility, but (2) likely invalid on the basis that the steps were either previously known, § 102, or that they would have been obvious to someone skilled in the field, § 103. We note that the Solicitor General's views generally command respect from the Court, but may carry even greater weight in patent cases, where, because the Federal Circuit has exclusive intermediate appellate jurisdiction, there is no opportunity for a "circuit split."

The argument. Counsel for Mayo began by arguing that the patents here are so broad as to foreclose an entire field of treatment methods. Justices Kennedy and Scalia then pushed counsel to identify what type of specificity would be necessary to make the claimed processes patent eligible. Justice Breyer approached the question from the other direction, seeking counsel's views on what could be added to the claims to make them applications of natural phenomena, as opposed to the phenomena themselves. Counsel responded that what is necessary is something more than just additional conventional steps.

The Solicitor General argued next, opening with the government's contention that Mayo's argument focused primarily on a question of novelty, which is not proper under a § 101 analysis, and should be examined in a separate analysis under §§ 102 and 103. The Solicitor emphasized that while the patents at issue here may seem simple, the Court should not rule in such a way as to prevent all processes involving natural phenomena.

Prometheus's counsel argued that the patents were narrower than Mayo represented. Responding to a question from Justice Breyer, counsel stated that there is a continuum, with cases involving abstract ideas like the business method at issue in *Bilski* on the one end (ruled not to be patent eligible), and the concrete application of principles on the other (which are). He argued that Prometheus's patents fell on the patent eligible side. In response to a question from Justice Kagan as to whether Prometheus's patents actually covered any treatment protocol, as opposed to mere general observations of facts, counsel asserted that the patents claim a process of taking data and making it useful. He stated that this was patent eligible, citing examples of such other patents ending with a "mental step that produces information" (including patents on identification of biomarkers and methods for identifying locations and sizes of earthquakes on the San Andreas fault).

As noted by Mayo's counsel, one issue underlying the dispute over this patent eligibility framework is the fact that § 101 presents a threshold legal question, in contrast to the more fact-intensive (and thus costly) determinations for novelty and obviousness. Both the Solicitor General and counsel for Prometheus argued that the doctrines of novelty and obviousness are complex and well developed, and should not be interjected into the initial question of subject matter eligibility.

Notably, the "machine-or-transformation" test which garnered so much attention in *Bilski* went unmentioned.

Conclusion. The Supreme Court has the opportunity to issue a broad ruling on the scope of patent eligible subject matter. But the arguments highlighted the challenge of drawing a line as to when exactly something transforms from a law of nature to a patentable process. It may be fair to assume that the Court will take an approach similar to the one it did in *Bilski* – issuing a narrow decision, rather than resetting § 101 law.

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

Robert A. Atkins

212-373-3183

ratkins@paulweiss.com

James Brochin

212-373-3582

jbrochin@paulweiss.com

Jacqueline P. Rubin

212-373-3056

jrubin@paulweiss.com

David J. Ball Jr.

202-223-7352

dball@paulweiss.com

Kenneth A. Gallo

202-223-7356

kgallo@paulweiss.com

Theodore V. Wells Jr.

212-373-3089

twells@paulweiss.com

Craig A. Benson

202-223-7343

cbenson@paulweiss.com

Nicholas Groombridge

212-373-3212

ngroombridge@paulweiss.com

Beth A. Wilkinson

202-223-7340

bwilkinson@paulweiss.com

Daniel R. McCallum contributed to this client alert.

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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
+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