No. 10-1150

IN the Supreme Court of the United States

MAYO COLLABORATIVE SERVICES
(D/B/A MAYO MEDICAL LABORATORIES)
AND MAYO CLINIC ROCHESTER,
Petitioners,

v.

PROMETHEUS LABORATORIES, INC.,
Respondent.

On Writ of Certiorari
To The United States Court of Appeals
For the Federal Circuit

BRIEF OF *AMICI CURIAE* AARP AND PUBLIC PATENT FOUNDATION IN SUPPORT OF PETITIONERS

DANIEL B. RAVICHER
Counsel of Record
PUBLIC PATENT FOUNDATION
BENJAMIN N. CARDOZO
SCHOOL OF LAW
55 Fifth Avenue
New York, NY 10003
(212) 796-0570
ravicher@pubpat.org

STACY CANAN
AARP FOUNDATION
LITIGATION
MICHAEL SCHUSTER
AARP
601 E Street, NW
Washington, DC 20049
(202) 434-2060
scanan@aarp.org

Counsel for Amici Curiae

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INTEREST OF *AMICI CURIAE*[1]

Amicus AARP is a nonpartisan, nonprofit membership organization dedicated to addressing the needs and interests of people age 50 or older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable and quality health care is particularly important to the older population because of its higher rates of chronic and serious health conditions. Patents that claim medical correlations prohibit diagnosis and treatment, and discourage communication of medical information between a patient and physician. AARP works at the state and national levels for laws and policies that ensure greater freedom and competition in the healthcare marketplace. AARP supports this petition because allowing patents on pure medical correlations raises costs of and denies access to critical health services.

Amicus Public Patent Foundation ("PUBPAT") at Benjamin N. Cardozo School of Law is a not-for-profit legal services organization that represents the public interest in the patent system, and most particularly the public interest in protecting against the harms caused by undeserved patents and unsound patent policy. PUBPAT provides the

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[1] The parties have consented to the filing of this brief. In accordance with Supreme Court Rule 37.6, AARP and the Public Patent Foundation state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amici*, their members and counsel has made a monetary contribution to the preparation or submission of this brief.

general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education. PUBPAT has argued for sound patent policy before this Court, the Court of Appeals for the Federal Circuit, various district courts, the United States House of Representatives, the United States Patent and Trademark Office (USPTO), the United Nations, the European Union Parliament, and other judicial, governmental and political bodies. PUBPAT has also requested that the USPTO reexamine specifically identified undeserved patents causing significant harm to the public. The USPTO has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform. PUBPAT supports petitioner because of PUBPAT's interest in ensuring that laws of nature like medical correlations are not patented.

SUMMARY OF ARGUMENT

Amici Curiae AARP and the Public Patent Foundation submit this brief in support of petitioners and reversal of the judgment of the United States Court of Appeals for the Federal Circuit because that judgment stems from the application of an approach to patentable subject matter that is inconsistent with this Court's precedent and with both health and patent policy. Allowing patents on pure medical correlations (i.e. that an overly high or low level of some chemical in the body correlates to an unhealthy condition) threatens doctors with claims of patent infringement should they discuss mere laws of nature with their patients, burdens the public with excessive health

care costs, and dulls incentives for real innovation in medical care.

The patenting of medical correlations – which are nothing more than expressions of laws of nature – has led to severe restraint on the provision of medical care and a greatly increased cost and reduced availability of vital medical services, damaging the public health of the nation. Federal Circuit decisions upholding medical correlation patents fail to abide by this Court's prohibition on the patenting of laws of nature. As a result, there are now countless patents on medical correlations, including the patent in this case and patents on correlating genetic mutations with a person's increased risk for a particular disease. The Federal Circuit has latched on to trivial steps beyond mental processes, such as the "administering" step in this case, to uphold patents that effectively preempt all uses of laws of nature. This is not a substantive analysis, but rather the application of a formulaic rule that saves any patent claim drafted with some "transformative" step – no matter how trivial. This directly conflicts with this Court's precedent that prohibits both the actual and effective patenting of laws of nature.

ARGUMENT

I. Medical Correlations Are Laws Of Nature And Thus Unpatentable.

The patenting of medical correlations, which are mere expressions of laws of nature, has led to severe restraint on the provision of medical care and a greatly increased cost and reduced availability of vital medical services, damaging the public health of

the nation. As just one example, medical correlation patents have been used to prevent patients contemplating surgery to remove their breast and ovaries from getting independent verification that they have genetic mutations corresponding to an increased predisposition for diseases affecting those body parts. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 2009 U.S. Dist. LEXIS 101809, *16-17 (S.D.N.Y. 2009) ("*AMP*") (owner of patents on medical correlations prevented patients from receiving medical services from physicians). But nature creates medical correlations, such as that between genetic mutations and predisposition for disease, not man. Thus, any patent that effectively preempts use of a medical correlation is invalid subject matter even if the patented correlation was only recently discovered by man. *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978).

Rather than examine the effect of patents relating to medical correlations to determine whether they preempt all effective uses of the underlying law of nature, the Federal Circuit has instead relied on a formulaic rule to erroneously uphold medical correlation patents. As it did in this case, so long as there is some trivial "transformation of matter" included in the patent claim, the Federal Circuit holds that all concerns about patenting laws of nature disappear. It does no further analysis to see whether a law of nature is nonetheless being effectively preempted by the patent.

As a result, there are now countless patents on medical correlations, including the patent in this case and patents on correlating genetic mutations with an increased predisposition for a particular

disease. *See*., *e.g.*, *AMP* (involving patents claiming the correlation between mutated BRCA genes and an increased propensity for developing breast cancer). According to the Federal Circuit, one can get a patent on correlating fair skin with an increased risk of sunburn, being a woman with an increased risk of becoming pregnant, and being elderly with an increased risk of suffering from Alzheimer's disease so long as some trivial step involving a transformation of matter is added.

In an attempt to abide by this Court's guidance in *Bilski v. Kappos,* 130 S. Ct. 3218 (2010), the Federal Circuit held in the *AMP* gene patent case that the challenged correlation claims there, which contained "only abstract mental processes," were ineligible subject matter. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 2011 U.S. App. LEXIS 15649, at *67 (Fed. Cir. July 29, 2011) ("We conclude that Myriad's claims to 'comparing' or 'analyzing' two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes"). However, in doing so, it continued to apply its strict rule that is easily circumvented by adding any trivial non-mental step to a patent claim. *Id*. Thus, while the Federal Circuit reached the correct result in *AMP*, finding the correlation claims involving "only abstract mental processes" were invalid, it did so by continuing to follow the same improper test that it applied in this case, which condones medical correlation patents that have the effect of preempting all uses of an underlying law of nature, even if they are not purely abstract.

By completely failing to protect laws of nature from patents that effectively proscribe all use

thereof, the Federal Circuit's rule is contrary to this Court's long established precedent that prohibits the patenting of laws of nature. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citations omitted). This Court has repeatedly held that laws of nature cannot meet the threshold for qualifying as "inventions patentable" under 35 U.S.C. § 101 because "[s]uch discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Id.* quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). "[T]he reason for the exclusion is that sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection." *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126-27 (2006) (J. Breyer, dissenting).

This Court has also repeatedly rejected formulaic rules on issues in patent law, particularly what constitutes patentable subject matter. *Bilski* (rejecting the Federal Circuit's "machine or transformation" test for patent eligibility). Despite this, the Federal Circuit below again retreated to implement a formulaic rule-based analysis, finding as patentable subject matter anything that involves a transformation of matter, regardless of whether that transformation is central to the patented invention or whether the claim effectively preempts all uses of the underlying law of nature.

The "administering" step at issue in this case is of trivial importance, as there is no requirement in the claims of the patent in this suit that the amount of drug being administered cause any chemical change in the patient to whom the drug is being

administered. 2 J.A. 16 (U.S. Pat. No. 6,355,623, cl. 1).

This is in stark contrast to most pharmaceutical patents that require a "therapeutically effective amount" of a drug be administered. Here, the "administering" step may result in no change whatsoever to the patient's condition, but the Federal Circuit nonetheless latched on to it to uphold the patent as not being on a law of nature. This was not a substantive analysis, but rather the application of a formulaic rule that any transformation of matter – no matter how trivial – is sufficient to make a claim patent eligible, regardless of whether the claim still preempts all pragmatic uses of a law of nature.

Had the Federal Circuit correctly applied the pragmatic preemption analysis mandated by this Court, it would unquestionably have found that the claim has the practical effect of preempting all uses of the law of nature that underlies the claim, namely that between the presence of certain metabolite levels and the presence of a drug. That medical correlation is not an invention of the patentee. It is the result of nature's handiwork. But the existence of the patent forecloses all effective use by others of the law of nature. Thus, it is unpatenable under this Court's precedent.

CONCLUSION

For the foregoing reasons, the decision of the Court of Appeals should be reversed.

September 9, 2011

Respectfully submitted,

Daniel B. Ravicher
Counsel of Record
Public Patent Foundation
Benjamin N. Cardozo School Of Law
55 Fifth Avenue
New York, NY 10003
(212) 796-0570
ravicher@pubpat.org

Stacy Canan
AARP Foundation Litigation
Michael Schuster
AARP
601 E Street, NW
Washington, DC 20049
(202) 434-2060
scanan@aarp.org

Counsel for Amici Curiae